Effect of Shockwave on Postnatal Coccydynia: A Randomized Controlled Clinical Trial

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Abstract

Background: One of the major problems affecting postpartum women is coccydynia, which makes it difficult for them to carry out everyday tasks, and even leads to an inability to work.

Objective: To ascertain how shockwave therapy affects postpartum women's coccydynia.

Material and Methods: Forty-six postnatal females who had coccydynia for at least six weeks following delivery (N = 46), aged between 25 and 35 years, were recruited from Al-Agoza Police Hospital, Giza, Egypt. The females were split randomly into a study group (A) (n = 23) and a control group (B) (n = 23). The study group participants were treated by shockwave therapy (SWT) (1 session weekly for 4 weeks), medical treatment in the form of Ibuprofen (400 mg) twice daily for 4 weeks, and behavioral therapy advice. The control group participants received the same medical treatment plus behavioral therapy advice only. Pain intensity, pain pressure threshold (PPT), functional disability, and lumbar mobility were measured for the two groups by using the visual analogue scale (VAS), pressure algometer, Oswestry disability index (ODI), and modified-modified Schober Test (MMST), respectively, before and after 4 weeks of the treatment program.

Results: Following treatment, both groups (A and B) showed a statistically significant reduction in VAS and ODI, as well as a significant increase in PPT and MMST in flexion and extension as compared to baseline. Comparing between groups revealed a statistically significant reduction in VAS ($p = 0.001$), ODI ($p = 0.006$), and a significant increase in PPT ($p = 0.001$) and MMST in flexion ($p = 0.001$) and extension ($p = 0.005$) in favor of group A.

Conclusion: These findings suggest shockwave therapy as an efficient, conservative therapeutic approach for treating coccydynia in postnatal women.

Keywords: Shockwave therapy, coccydynia, postnatal period.

INTRODUCTION

The coccyx, which has four or five segments, is the end section of the spine. It is connected to the terminal sympathetic plexus, the fifth sacral, and the coccygeal nerve roots **(Lota et al., 2023).** The coccyx is small, but it serves lots of essential functions. Besides being the attachment point of various muscles, tendons, and ligaments, it forms one leg of the tripod—

alongside the ischial tuberosities that support the individual's weight when they are seated **(Garg and Ahuja, 2021).**

Coccydynia is represented by pain in the coccyx and/or coccygeal joints **(Lota et al., 2023).** With no complaints of significant low back pain (LBP) or radiating pain, the most typical manifestation of coccydynia is discomfort in and around the coccyx. The pain is usually confined to the sacrococcygeal joint and can be defined as a "pulling" or "cutting" sense. Individuals often report experiencing tenderness upon palpating their coccyx **(White et al., 2022).**

To relieve pressure on the coccyx, patients with coccydynia typically adopt a guarded sitting posture **(Meer et al., 2022).** Cycling, prolonged sitting in one position or repeatedly, and standing up from a sitting position typically worsen pain **(Arif et al., 2022)**. Additionally, patients may report pain during bowel movements or a frequent need to void **(Embaby et al., 2017).** Coughing pain or exacerbated pain in women before and during their menstruations are possible additional complaints **(Vishnu et al., 2022).**

There are three possible causes of coccydynia: traumatic, nontraumatic, and idiopathic. Fractures, displacements, unsteadiness, a distal coccygeal spur, improper pelvic flexion or extension, pelvic floor disorders, obturator internus or gluteus maximus muscle disorders, and psychological disturbances can all cause coccygeal pain **(White et al., 2022).** Childbirth may contribute to the higher prevalence of coccydynia in women, as it affects them five times more frequently than in men **(Lota et al., 2023).**

After giving birth, 86.5% of women experienced coccydynia **(Shah et al., 2023).** This condition makes it difficult for women to carry out their everyday tasks, which negatively affects their quality of life (QoL). Sufferers and their families experience the behavioral, social, and physical impacts of pain. In addition to causing urogynecological, rectal, and sexual dysfunction, it can also impact interpersonal relationships, the psychological domain, and even the capability to work (**Lee et al., 2023; Arif et al., 2022**).

The treatment options for coccydynia that are currently available include conservative options like rest and wedge-shaped coccygeal cushions; medication, such as nonsteroidal anti-inflammatory drugs (NSAIDs) **(Andersen GØ et al., 2022)**; physiotherapy, such as interferential current (IFC) **(Fuentes et al., 2010)**, shortwave diathermy (SWD) **[Wu et al., 2009],** kinesiotaping **[Abdel-Aal et al., 2020]**, stretching of the piriformis and iliopsoas muscles **(Mohanty & Pattnaik, 2017; Vishnu et al., 2022)**, and pelvic floor exercises **(Ahadi et al., 2020);** and interventional methods including radiofrequency destruction of coccygeal disks, corticosteroid or intradiscal injections, and coccygectomy **(Grgić, 2011; Andersen GØ et al., 2022)**.

Shockwave therapy (SWT) is a conservative approach that provides pain relief for a variety of musculoskeletal problems that is both effective and long-lasting, with no detectable adverse effects **(Lota et al., 2023).** Through cell membrane hyperpolarization, Ras protein activation, and the generation of oxygen radicals, the mechanical shockwave impact on the tissues is converted into a biological one that causes a local increase in growth factors like vascular endothelial growth factor-A and transforming growth factor-b **(Simplicio et al., 2020).** This results in neovascularization, new tissue growth, and rapid healing (**White et al., 2022**).

Need for the study

A woman's health cannot be compromised because she plays a crucial role in a family. Taking care of a child, cleaning the house, and breastfeeding add to a woman's burden when she becomes a mother. Coccydynia can cause chronic discomfort and significantly lower the

QoL for post-parturition females if it is not detected and treated early. Therefore, it is crucial to rule out coccydynia in all postnatal women (**Vishnu et al., 2022**).
A review of the literature revealed that only a few researchers have employed and demonstrated the effectiveness of shockwaves for coccydynia (**Marwan et al., 2014; Haghighat & Mashayekhi, 2016; Lota et al., 2023)**. However, **Movva et al. (2022)** conducted a retrospective study on a smaller sample size (n = 22) to focus on the effect of shockwaves on post-partum coccydynia, relying solely on the VAS as a subjective measure for pain level. So, this study was carried out as a prospective trial to investigate the effect of SWT on post-partum coccydynia, considering the pain pressure threshold, function ability, and lumber mobility as additional significant outcome measures.

METHODS

Study design

This prospective, randomized, controlled, single-blinded study was carried out at the outpatient clinic of Al-Agoza Police Hospital, Egypt, with the practical aspect lasting for 11 months between June 2022 and May 2023. Before the first evaluation and inclusion in the trial, every patient received an overall clarification of the study protocol, and then they signed a consent form. Cairo University's Faculty of Physical Therapy's Ethics Committee approved the research protocol in December 2021 (P.T.REC/012/003494). The Pan African Clinical Trial Registry database has the trial registered under the number PACTR202206727183355.

Study population

In this study, 46 postpartum women who delivered vaginally and experienced coccydynia for at least six weeks following delivery, diagnosed by the physician, were included. They were aged between 25 and 35 years, and their BMI was less than 35 kg/m2. They were multipara (1-3 deliveries). Women who had any of the following criteria were not allowed to take part in the study: they had to be pregnant, have a fractured or dislocated coccyx, be patients with psychiatric illness, have had recent surgery related to the pelvis or the colon, have peri-anal conditions, have localized tumors or infections in the sacrococcygeal region, have a cauda equina tumor, or have a history of chronic pain (fibromyalgia and polymyalgia rheumatica, for example).

Randomization and blinding:

The women were randomized using an online randomization program (http://www.randomizer.org/) to receive SWT plus medical treatment (Group A) (n = 23) or medical treatment alone (Group B) (n = 23): A researcher who did not have any clinical involvement in the study created systematically numbered index cards with random group allocations based on the generated random numbers to confirm distribution concealment. The index cards were tied before being put in sealed envelopes that were blind to all groups. The therapist delivering the procedures then opened every envelope and distributed the participants into groups based on the index card that was selected. The group assignments had been concealed from the participants. After randomization, there were no withdrawals of participants **(Figure 1).**

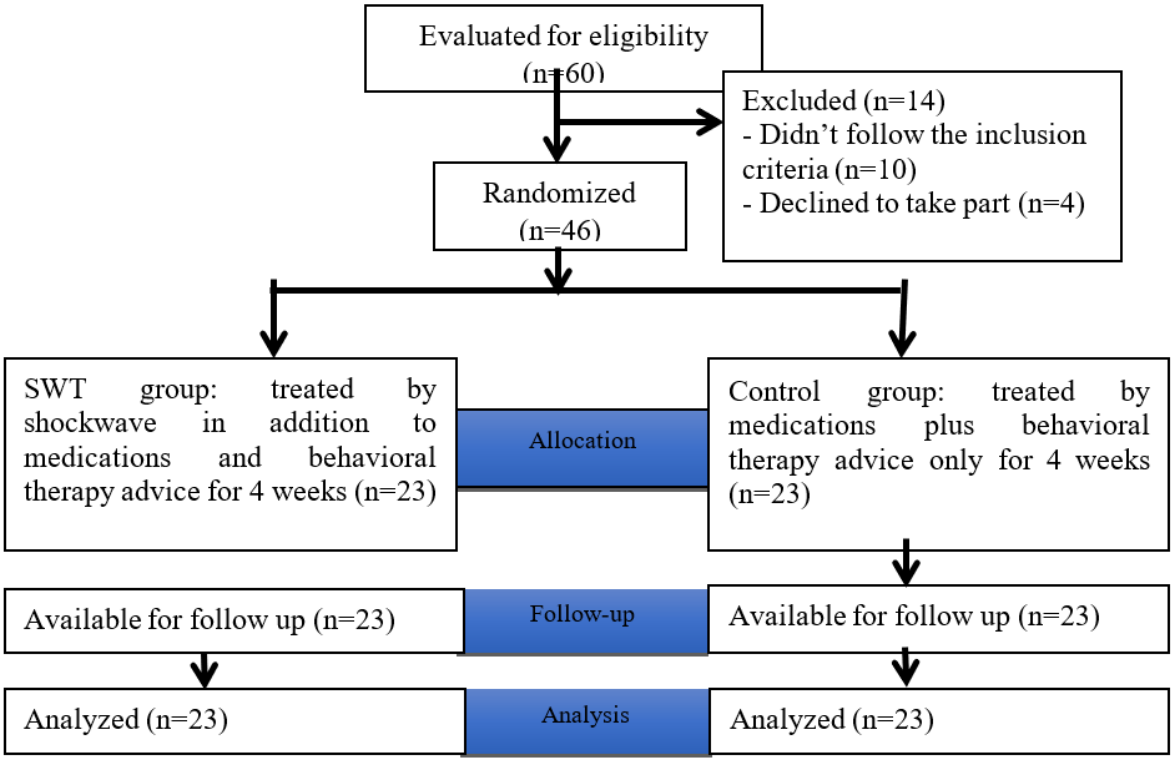

Fig. 1: Flow chart of the study.

Outcome measures:

Each woman in each group was evaluated before and following the treatment program through the VAS for assessing the pain intensity, the pressure algometer for assessing the PPT, the ODI for assessing functional disability, and the MMST for assessing lumber mobility.

The primary outcome measure:

Pain level:

a. Pain intensity

A 10-cm horizontal line representing the patient's pain degree, ranging from "no pain at all" to "worst pain imaginable," typically displays the VAS. The VAS is a suitable instrument for characterizing pain intensity owing to its ease, validity, and reliability. Each woman in each group was asked to indicate her level of pain by marking a point on a line between the extremes (**Klimek et al., 2017**).

b. Pressure pain threshold

The pressure algometer was used to measure PPT. The patient was told to lie prone with both forearms draped over the sides, and her clothing was taken off to expose the coccygeal region. The assessor identified the trigger points at the coccyx, as well as 3 cm laterally to the right and left. To ensure that the same points were evaluated throughout the procedure, the testing points were marked with a grease pencil. In order to increase the accuracy of PPT measurements during the post-treatment evaluation, the locations were also photographed after marking. The assessor placed the circular probe of the algometer perpendicular to the skin and applied pressure. When pressure or discomfort turned into a definite sense of pain during the PPT measurement, the participant was instructed to indicate "stop." At each location, four PPT measurements were taken in succession, with a 30-second break in between. After discarding the initial PPT measurement, the mean of the next three PPTs for

every area was determined. The average value of PPT for all triggering points for every patient was then computed and utilized for additional analysis **(Saleh et al., 2019).**

The secondary outcome measures include:

Functional disability:

Using the Arabic version of the Oswestry disability index (ODI), the degree of functional impairment brought on by the coccygeal discomfort was determined. Occupational health professionals utilize an easy, validated, and reliable questionnaire to assess functional disability and QoL impairments in individuals suffering from musculoskeletal illnesses, including lumbar and sacroiliac pain **(Ayoub et al. 2019).** The ODI is divided into ten sections that assess pain and aspects of daily life—personal care, lifting, walking, sitting, standing, sleeping, sexual activity, social interaction, and travel—that may be affected by LBP. A 0–5 scale was used to rate each part, with 5 denoting the highest degree of disability. The index was computed as a percentage by dividing the sum of the scores by the overall attainable scores. This result was then multiplied by 100. As a result, the denominator declined by 5 for every question that remained unanswered. When a patient checked more than one response to a given question, the sentence that received the highest score was regarded as an accurate indicator of disability. A 0–100% scale is used to report scores, with 100% denoting severe disability (**Saleh et al. 2019**).

Lumber mobility:

The modified- modified Schober test (MMST) revealed moderate validity and excellent reliability in the assessment of spinal range of motion (ROM) (**Tousignant et al., 2005**).

Lumbar Flexion ROM:

After standing behind the upright patient and identifying the posterior superior iliac spines, the investigator made an ink mark that ran horizontally from the midline of the lumbar spine to the PSISs. The investigator made another ink mark 15 centimeters above the first. The tape measure was positioned firmly against the participant's skin, between skin markings. After instructing the participant to flex the lumbar spine as much as she could, the investigator measured the new spacing between the superior and inferior skin marks. The range of lumbar flexion was estimated by analyzing the variation in the difference between markers. The test was repeated three times, and then the average value was regarded as the lumbar flexion ROM **(Ponte et al., 1984).**

Lumbar Extension ROM:

The procedure was the same as for evaluating lumber flexion, but instead of having the participant lean backward into complete extension, the investigator measured the new spacing as a straight line between the superior and inferior skin marks. The change in the disparity between markers indicated the range of lumbar extension. The test was repeated three times, and then the average value was regarded as the lumbar extension ROM **(Ponte et al., 1984).**

Treatment interventions:

Medication

Every woman in both groups (A and B) received treatment with Ibuprofen (400 mg) twice daily for four weeks **(Bachar et al., 2024).**

Shockwave therapy

Over four weeks, the SWT addressed each lady in the study group once a week. Each session included 2000 shock wave shots with a pressure of 3–4 bars and a frequency of 5 Hz applied over the coccygeal area **(Lin et al., 2015).**

The patient was positioned in the lateral position throughout the sessions, with both hips and knees bent as far as possible to provide optimal exposure to the sacrococcygeal region. Following this, the probe was positioned perpendicularly in contact with the coccyx in the sagittal plane within the intergluteal cleft **(Aydın et al., 2020).**

Advice

In order to relieve strain on the coccyx, it was recommended to all the women in both groups to sit on a well-padded seat with a gel cushion. To further reduce constipation, utilize stool softeners while increasing the amount of fiber and fluids in their diet **(White et al., 2022).**

Sample Size Calculation:

Using data from **Lin et al.'s (2015)** VAS, the sample size calculation was carried out utilizing G*POWER statistical software (version 3.1.9.2; Universitat Kiel, Germany). The results revealed that 23 is the minimum required sample size for each group. $\alpha = 0.05$, power = 80%, effect size = 0.86, and allocation ratio N2/N1 = 1 were employed in the calculations.

Data analysis and statistical design:

Age and BMI were compared across groups utilizing an unpaired t-test. The data was tested for normal distribution using the Shapiro-Wilk test. To evaluate the homogeneity between groups, Levene's test for homogeneity of variances was utilized. A mixed MANOVA was utilized to investigate how the intervention affected the VAS, ODI, PPT, and MMST. Post-hoc tests utilizing the Bonferroni correction were employed for subsequent multiple comparisons. All statistical tests were conducted with a significance level of $p < 0.05$. The statistical package for social studies, version 25 for Windows, was utilized for all statistical analysis (IBM SPSS, Chicago, IL, USA).

Results:

Participants' characteristics:

Table 1 illustrates the participant characteristics of both groups. Age and BMI did not significantly differ across the groups ($p > 0.05$).

Table 1. Comparison of participant characteristics across both groups:

	Group A	Group B			
	Mean ±SD	Mean ±SD	MD	t- value	p-value
Age (years)	30.95 ± 3.18	30.04 ± 2.82	0.91	1.03	0.31
BMI (kg/m²)	31.27 ± 1.71	31.4 ± 1.52	-0.13	-0.25	0.8

SD, Standard deviation; p value, Probability value

Effect of treatment on VAS, ODI, PPT, and MMST:

A significant interaction effect between treatment and time was revealed using mixed MANOVA (F = 22.16, p = 0.001). Treatment had a significant main impact (F = 3.32, p = 0.01). A significant main effect time was observed (F = 139.85, p < 0.001).

Within-group comparison

VAS and ODI were significantly reduced in both groups after therapy as compared to before therapy values (p > 0.001). Group A experienced a decrease in VAS and ODI of 41.53 and 13.77%, whereas Group B experienced a reduction of 20.35 and 8.25%, respectively. PPT and MMST flexion and extension were significantly higher in both groups after therapy than they were before (p > 0.001). Group A's PPT and MMST flexion and extension percentage increases were 44.50, 62.70, and 94.55%, respectively, while Group B's percentage increases were 19.76, 17.18, and 34.66%, respectively (Tables 2–3).

Between-group comparison

Before therapy, there was no significant change between the groups (p > 0.05). After therapy, a comparison between the groups revealed that group A's VAS and ODI were significantly lower than group B's (p < 0.01). After therapy, group A's PPT and MMST flexion and extension were significantly higher than group B's (p < 0.01) (Tables 2–3).

Table 2. Mean VAS, ODI and PPT before and after treatment of both groups:

	Pre treatment	Post treatment			
	Mean ±SD	Mean ±SD	MD	% of change	p value
VAS (Score)					
Group A	7.73 ± 0.75	4.52 ± 1.16	3.21	41.53	0.001
Group B	7.91 ± 0.9	6.3 ± 1.18	1.61	20.35	0.001
MD	-0.18	-1.78			
	p = 0.48	***p = 0.001***			
PPT (Kg)					
Group A	6.45 ± 1.02	9.32 ± 1.05	-2.87	44.50	0.001
Group B	6.73 ± 0.85	8.06 ± 0.96	-1.33	19.76	0.001
MD	-0.28	1.26			
	p = 0.31	***p = 0.001***			
ODI (%)					
Group A	39.72 ± 2	34.25 ± 2.78	5.47	13.77	0.001
Group B	39.66 ± 2.25	36.39 ± 2.25	3.27	8.25	0.001
MD	0.06	-2.14			
	p = 0.92	***p = 0.006***			

SD, Standard deviation; MD, Mean difference; p value, Probability value

Table 3. Mean MMST flexion and extension before and after treatment of both groups:

MMST (cm)	Pre treatment	Post treatment	MD	% of change	p value
	Mean ±SD	Mean ±SD			
Flexion					
Group A	5.55 ± 1.59	9.03 ± 1.92	-3.48	62.70	0.001
Group B	6.11 ± 1.52	7.16 ± 1.64	-1.05	17.18	0.001
MD	-0.56	1.87			
	p = 0.23	***p = 0.001***			
Extension					
Group A	2.20 ± 0.80	4.28 ± 1.11	-2.08	94.55	0.001
Group B	2.51 ± 0.92	3.38 ± 0.96	-0.87	34.66	0.001
MD	-0.31	0.9			
	p = 0.22	***p = 0.005***			

SD, Standard deviation; MD, Mean difference; p value, Probability value

DISCUSSION

Coccydynia is represented by pain in the terminal spinal segment. Parturition is one of the several causes that might lead to it. Because women's coccyxes are more visible and exposed than men's, the illness affects women more frequently than males. Constipation exacerbates the pain associated with this medical condition, which may be alleviated by bowel movements. Moreover, hip extension exercises like stair climbing and quick transitions from sitting to standing increase coccydynia pain **(Vishnu et al., 2022).**

Extracorporeal SWT (ESWT) inhibits pain impulse transmission and lessens pain perception by inducing physical changes in small axons **(Malay et al., 2006).**

This study was intended to ascertain how SWT affects postnatal women's coccydynia.

The study's findings demonstrated that, in postpartum females, both medication and SWT were useful in reducing coccydynia, with the combined effect of SWT and medication being more beneficial than that of medication alone. The current results revealed significant enhancements in all outcome variables in the two groups, but in favor of group A, which was treated with shockwaves and medication.

These results can be linked to how ESWT suppresses nociceptors, hence blocking the gate-control system and lowering pain by inducing neovascularization and new tissue growth; it improves circulation and reduces muscular tension and tissue adhesions (**Santamato et al., 2019**).

The present results were in line with those of **Lota et al. (2023),** who explored the efficacy of radial ESWT in the management of coccydynia. The VAS pain score dropped to ≤3, and the study confirmed the safety and efficiency of radial ESWT in treating coccydynia.

These findings were corroborated by **Movva et al. (2022),** who assessed the effectiveness of ESWT in treating postpartum coccydynia and came to the conclusion that ESWT was a low-risk, cost-effective treatment option, particularly for lactating mothers, for whom anti-inflammatory analgesics are not a recommended option for pain management.

They stated that to get the desired results, at least four sessions were required.

The findings of **Ahadi et al. (2022)** provided support for the present findings. Their study included 34 coccydynia patients, who were split into two groups. Patients in the ESWT group had SWT three times per week. A steroid injection at the sacrococcygeal junction, or coccyx tip, was administered to the second treatment group. The VAS, Short-Form Health Survey, and Dallas Pain Questionnaire were used as outcome measures. After a 6-month follow-up, the study concluded that ESWT is a better long-lasting pain management intervention than steroids for patients with coccydynia.

Additionally, this study's findings were connected to those of **Aydın et al. (2020),** who studied the impact of ESWT on 34 patients with chronic coccydynia (29 females and 5 men). The 36-item short form (SF-36) quality of life scale survey and VAS were administered and recorded. With the exception of two, all SF-36 measures showed significant improvement, and pain was effectively managed.

Furthermore, the current findings confirmed those of **Nahas et al. (2018),** who investigated the impact of ESWT on reducing postnatal LBP. Their findings demonstrated that both groups experienced a reduction in VAS and an increase in plasma serotonin levels following the intervention, with the study group, which received ESWT and exercises, achieving better results than the control group, which received exercises only.

The present results agreed with **Marwan et al. (2017),** who examined the impact of ESWT on 23 patients with sacrococcygeal trauma, the majority of whom were female. They received three sessions of SWT targeted at the maximum area of coccygeal discomfort (one session weekly for three weeks). The ODI and the numerical pain rating scale (NPRS) were used to evaluate the results. After this therapy, the majority of patients experienced a certain degree of pain and disability relief.

Moreover, the study's findings were connected to those of **Moon et al. (2017),** who examined the efficacy of ESWT on sacroiliac joint pain and found that the study group exhibited better ODI and a lower NPRS than the control group.

Lin et al.'s (2015) study further supported the present results by examining the differences in outcomes between ESWT, combined SWD, and interferential current therapy at each treatment session. The self-reported satisfaction score, ODI, and VAS were utilized to evaluate the impact of the treatment. They found that, compared to other physical modalities, ESWT is more satisfying and effective in alleviating coccydynia-related pain and disability.

Furthermore, this study's outcomes supported those **of Marwan et al. (2014),** who found that three ESWT sessions were helpful in coccydynia pain relief, which did not recur after a year of follow-up

On the other hand, **Buchbinder et al. (2006)** found, based on a systematic evaluation of nine placebo-controlled trials, that there is evidence that ESWT has little to no benefit for lateral elbow pain in terms of pain and function items. This contradicts the current findings. The differences in the ESWT parameters employed, the type of intervention, and the research population criteria may account for the discrepancy between the results of our investigation and those of earlier research.

Strengths and limitations:

Throughout the study period, no negative consequences were observed in the current patient series. The non-invasive SWT technique, randomized design, and calculated sample size are the strengths of this study. In addition, the study used the pain pressure threshold as an objective assessment. However, it was conducted without patient follow-up. So, further research is required to determine how ESWT will affect postpartum coccydynia and its symptoms over the long term with patient follow-up.

Conclusion

ESWT has a positive effect on pain intensity, PPT, functional disability level, and mobility index in postpartum women complaining of coccydynia and should be suggested as a part of the treatment protocol for such cases.

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Author Contributions
All authors conducted the idea, research design, data gathering, statistical analysis, and data interpretation. They collaborated to write, revise, and approve the final manuscript before publication.

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