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Effect of the Pavlik harness used in the treatment of developmental dysplasia of the hip on unaided sitting and independent walking age

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Abstract

Background: Pavlik harness is the most widely used orthosis in the treatment of developmental dysplasia of the hip. The aim of this study was to evaluate the effect of the Pavlik harness on the development of "unaided sitting" and "independent walking" in infants with developmental dysplasia of the hip.

Methods: This prospective study, conducted from 2017 to 2020, included infants undergoing Pavlik harness therapy. Inclusion criteria comprised gestational age >37 weeks, treatment initiation before 6 months of age, and no prior treatment for developmental dysplasia of the hip. We assessed treatment initiation age, treatment duration, and the age of achieving unaided sitting and independent walking.

Results: In the patient group, unaided sitting commenced at a mean age of 6.8 ± 1.6 (range: 4–11) months, while independent walking began at a mean age of 12.7 ± 1.8 (range: 9–18) months. By 15 months, 92% of the patients achieved independent walking. In the control group, unaided sitting occurred at a mean age of 6.1 ± 1.1 (range: 4–8) months, and independent walking at 11.8 ± 1.6 (range: 9–18) months. A significant positive correlation was observed between the duration of Pavlik harness usage and the age of unaided sitting ($p < 0.001$) and independent walking ($p < 0.001$).

Conclusion: Our study indicates that Pavlik harness treatment for developmental dysplasia of the hip is generally safe and does not lead to clinically significant delays in unaided sitting and independent walking. However, some minor delays may occur due to extended orthosis use.

Level of evidence: level III—prospective cohort study.

Keywords: Developmental dysplasia of the hip, Pavlik harness, unaided sitting, independent walking, infants

Introduction

Developmental dysplasia of the hip (DDH) is one of the most common developmental deformities of the musculoskeletal system and consists of a series of disorders, such as dysplasia, subluxation, and dislocation between the femoral head and the acetabulum.[1] The standard initial treatment method of DDH is orthosis to keep the hip joints in flexion and abduction.[2,3] One of the most widely used orthosis is the Pavlik harness due to its ease of use and excellent results.[2,3] The Pavlik harness is a dynamic orthosis that prevents the joint from being completely immobilized while keeping both hips in flexion and abduction.[4] This allows for the femoral head to remain reduced within

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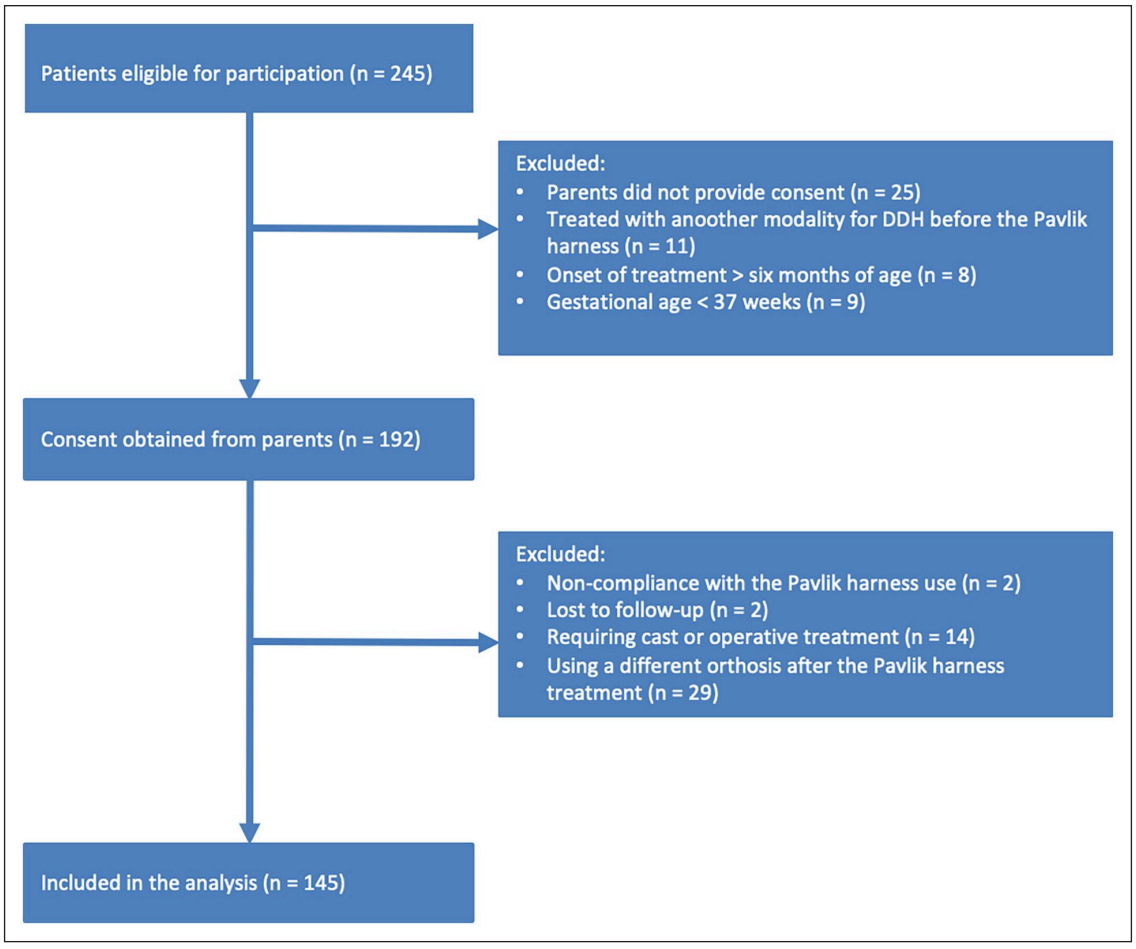

Figure 1. Patient inclusion and exclusion criteria.

the acetabulum and both the femoral head and the acetabulum to develop normally.[5–7] Despite these advantages of the Pavlik harness, many parents express concerns about whether this treatment method will affect their child's motor development, especially their ability to walk independently because it inhibits hip extension and adduction at the beginning of treatment. Although the Pavlik harness is the most used orthosis in infants in the rapid developmental stage, we did not find any studies investigating its effect on locomotor development in the current literature. The Pavlik harness may have a negative effect on the development of "unaided sitting" and "independent walking" skills in infants with DDH. The purpose of this prospective study was to evaluate the effect of the Pavlik harness on the development of unaided sitting and independent walking in infants with DDH.

Patients and methods

Study population

The study was initiated after receiving the approval of the Ethical Review Board and conducted in accordance with the principles of the Declaration of Helsinki. The study was conducted with infants receiving Pavlik harness therapy between July 2017 and April 2020. The inclusion criteria were a gestational age of more than 37 weeks, an age of less than 6 months at the initiation of treatment, not having received any other treatment for DDH, and not having any locomotor problems other than DDH, which could affect motor development. The exclusion criteria were requiring cast or operative treatment and use of a different orthosis after the Pavlik harness treatment (Figure 1). The control group consisted of 100 infants who were referred to the pediatric orthopedic department for routine developmental follow-ups and did not have any locomotor or neurological disorder that could affect walking. Although it may not be the case in most countries, in our country, every child undergoes a national screening that includes a hip ultrasound examination.

Patient management and follow-up

A pediatric orthopedic surgeon conducted a comprehensive orthopedic neonatal examination on all children. Physiological findings were defined as having normal Ortolani

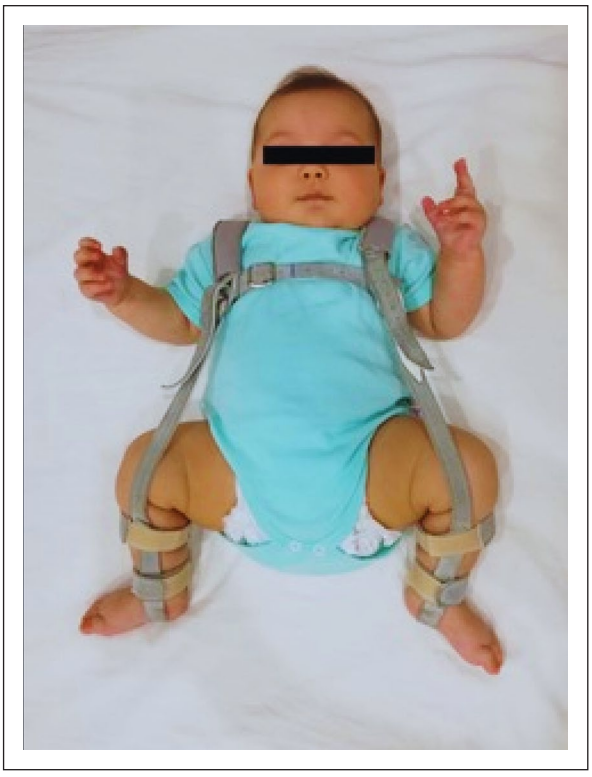

Figure 2. The Pavlik harness used for treatment.

and Barlow tests, full and symmetrical hip range of motion, and a negative Galeazzi test. Regardless of clinical examination findings, we conducted hip ultrasonography (USG) on both hips of all the children using the Graf method. In line with the DDH screening policy, which is routinely carried out using hip USG in Turkey, we conducted USG on all children. In all hip USGs, alpha and beta angles were digitally measured and categorized using the Graf system. Indications for treatment with the Pavlik harness included pathological clinical findings and sonographic pathologies according to the Graf classification system (Types 2b, 2c, D, and 3, 4), considering the child's age.

After undergoing USG, we fitted all the children with the Pavlik harness produced by the same manufacturer for full-time use (Figure 2). We conducted weekly follow-ups during the first 4 weeks to monitor compliance and check for any complications, such as femoral nerve palsy. Ultrasound examinations were performed weekly until stabilization in unstable hips and three weekly periods in stable hips. The treatment continued until an alpha angle of at least 60° was measured on USG examination in children younger than 6 months and until the acetabular index decreased below 30° on pelvic X-ray in those older than 6 months. Following the discontinuation of Pavlik harness treatment, we conducted follow-up examinations on the children every 3 months.

Data evaluation

The demographic and clinical characteristics of the patient were recorded on a specific form, including the following information: name, age, gender, medical record number, diagnosis, treatment start date, and duration. Following the discontinuation of the Pavlik harness, we conducted follow-up assessments at 3-month intervals. During each visit, we conducted interviews with the parents of children with DDH and the control group:

> The consent of our patients was obtained to participate in the scientific study, and it was emphasized that controls were not necessary; they are only for the study to determine when and whether the child had reached the milestones of unaided sitting and independent walking.

Unaided sitting was defined as the ability of the child to sit without any external support or assistance for at least 30 s, and independent walking as their capacity to walk at least 3 m on their own. The ages at which unaided sitting and independent walking started were recorded in months. Other collected data included the patient's age, gender, side of involvement, age at onset of treatment (in days), and duration of treatment (in months).

Statistics

The data were analyzed using IBM Statistics v. 19.5. Mean, standard deviation, lowest and highest frequency, and ratio values were used to describe the data. The comparison of the mean sitting and walking ages between the patient and control group was undertaken with the independent Student's t-test. The relationship between the age of starting the Pavlik harness treatment and the total duration of this treatment with the patient's sitting and walking ages was investigated with Pearson's correlation test. A p-value of less than 0.05 was considered statistically significant.

Results

From July 2017 to April 2020, a total of 245 infants with DDH were treated with the Pavlik harness at the pediatric orthopedic clinic. Out of these, 145 patients met the study criteria and were followed up for at least 2 years after receiving parental consent. The study group consisted of 127 female (87%) and 18 male (13%) patients, and their sonographic evaluation results according to the Graf classification are given in Table 1. The mean age of the patients at the start of treatment was 76.3 ± 31 days, and the mean duration of Pavlik harness use was 4.6 ± 2 months (Table 1). The onset of treatment in our study included babies older than 3 months of age. It is important to note that no cases with severe adductor contracture were documented.

Table 1. Demographic and clinical characteristics of the study group.

Gender	
Male	18
Female	127
Graf types[a]	
Type 2b	96
Type 2c	33
Type D	2
Type 3	14
Age at onset of treatment (days, M ± SD)	76.3 ± 31
Duration of treatment (months, M ± SD)	4.6 ± 2

M: mean; SD: standard deviation.
[a]According to the Graf classification, higher grades were recorded in bilateral cases.

Table 2. Comparison of unaided sitting and independent walking ages between the Pavlik harness group and control group.

	Pavlik harness group (n = 145)	Control group (n = 100)	p
Unaided sitting age (months)			
Male	6.9 ± 1.6	6.1 ± 1.1	<0.001
Female	6.7 ± 1.8	5.7 ± 1	0.004
Total	6.8 ± 1.6	5.9 ± 1	<0.001
Independent walking age (months)			
Male	12.9 ± 1.8	11.8 ± 1.7	0.002
Female	12.6 ± 1.2	11.8 ± 1.7	0.022
Total	12.7 ± 1.8	11.8 ± 1.6	<0.001

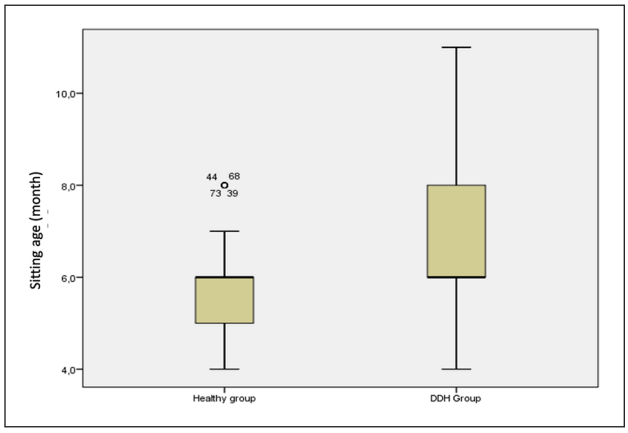

Figure 3. Comparison of unaided sitting ages between the Pavlik harness and control groups.

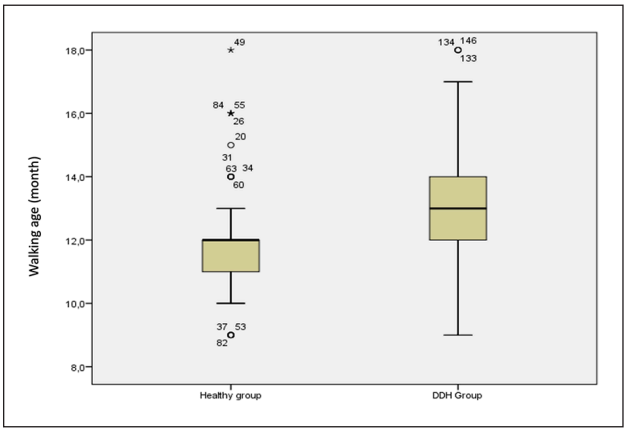

Figure 4. Comparison of independent walking ages between the Pavlik harness and control groups.

During the follow-up period, there were no instances of femoral head avascular necrosis or femoral nerve palsy in any of the patients.

The patients in the study group achieved unaided sitting at a mean age of 6.8 ± 1.6 months, which was later than the control group's mean age of 5.9 ± 1 months. This difference was statistically significant ($p < 0.001$) (Table 2) (Figure 3). Gender did not have a significant impact on the age of unaided sitting in either group (Table 2).

The patients in the study group started walking at an average age of 12.7 ± 1.8 months, which was 4 weeks later than the control group's average age of 11.8 ± 1.6 months ($p < 0.001$) (Table 2) (Figure 4). However, by 15 months of age, 92% (134/145) of the patients treated with the Pavlik harness were walking independently. While girls in the study group started walking 2 weeks earlier than boys, this difference was not statistically significant ($p = 0.144$).

Table 3. Correlations of the onset and duration of treatment with unaided sitting and independent walking ages.

	Unaided sitting age	Independent walking age
Age at onset of treatment		
Pearson's correlation	0.976	0.802
Significance (two-tailed)	−0.02	−0.02
Duration of treatment		
Pearson correlation	0.427	0.23
Significance (two-tailed)	<0.001*	0.005

*Correlation is significant at the 0.01 level (two-tailed).

The age at which Pavlik harness treatment was initiated did not affect the age of unaided sitting or independent walking (Table 3). The duration of Pavlik harness use was positively correlated with the ages of unaided sitting and independent walking (Table 3).

Discussion

Our study revealed that children treated with the Pavlik harness for DDH experienced a delay in achieving unaided sitting and independent walking, typically around 4 weeks when compared to healthy controls. It is important to note that this delay may not have clinical significance, as the majority or most of these children were still able to attain walking milestones within the normal range for their age. Furthermore, our findings demonstrated that 92% of the children treated with the Pavlik harness achieved independent walking by the age of 15 months.

Parents typically expect their babies to walk independently by the age of 1 year. A study by the World Health Organization (WHO) on 816 healthy children found that the mean walking age was 12.1 ± 1.8 months, which is consistent with parental expectations.[8] The use of orthoses, such as Pavlik harness, in early infancy for various reasons can potentially impact healthy musculoskeletal development.[6,9–12] Our results indicate that non-operative treatment of DDH with the Pavlik harness did not significantly affect the infant's ability to sit unaided or walk independently. Although the Pavlik harness restricts hip adduction and extension, it does not affect lower extremity muscle activities as it allows for active hip movements, as demonstrated by Siddicky et al.[10] Zgoda et al.[13] evaluated the locomotor development of 100 DDH patients treated with the Koszla abduction brace. They compared these patients to a control group of healthy children and reported a delay in the patient group's walking age by 3 weeks, but concluded that the Koszla abduction brace was a safe and effective method that did not cause significant delays in the child's locomotor development.[13] Masquijo et al.[14] similarly reported in their study that orthoses used in DDH treatment had no significant impact on walking. Our results support these findings. Although unaided sitting and independent walking were delayed by up to 4 weeks in children using the Pavlik harness, we consider this finding clinically negligible. Our results provide robust evidence that can help address parental concerns about their children receiving Pavlik harness treatment.

Our study has some limitations. We only examined the effect of the Pavlik harness on the development of unaided sitting and independent walking, but other factors, such as lifestyle, obesity, genetic factors, and parents' influence, also play a crucial role in locomotor development.[15-17] Furthermore, the impact of DDH on locomotor development remains unclear. However, our findings suggest that delayed sitting and walking are more dependent on the duration of orthosis wear rather than DDH. Moreover, the majority of the children in our study had Graf IIB-D hips, with only a small percentage having Graf III hips. It is worth noting that the Graf III group may require extended Pavlik harness treatment, and this might result in slightly delayed motor milestones. Finally, our study's reliance on parental reports of the child's first steps is a limitation. While studies have shown that parental memory of developmental milestones is reliable, we acknowledge that this approach has limitations.[18] Nonetheless, our numerous follow-up intervals, which allowed for almost concurrent physician observation, increase the accuracy of our results.

Conclusion

Our study indicates that Pavlik harness treatment for DDH is generally safe and does not lead to clinically significant delays in unaided sitting and independent walking. However, some minor delays may occur due to extended orthosis use. Further research is needed to better understand the complex interplay between other factors such as lifestyle, obesity, genetic factors, and parents' influence their impact on motor development in infants with DDH.

Author contributions

All authors contributed to the study conception and design. A.S., A.E., E.A., A.I.B., and O.N.O. performed material preparation, data collection, and analysis. H.U. wrote the first draft of the article, and all authors commented on previous versions of the article. All authors read and approved the final article.

Declaration of conflicting interests

The author(s) declared no potential conflicts of interest with respect to the research, authorship, and/or publication of this article.

Ethical approval

This article does not contain any studies with human participants or animals performed by any of the authors. The design and protocol of this study were approved by the Health Science University Baltalimani Bone Diseases Education and Research Hospital Institutional Review Board (ID: 81/575).

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Informed consent

Informed consent was obtained from all individual participants included in the study.

Supplemental material

Supplemental material for this article is available online.

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