

ASSESSMENT OF PAVLIK HARNESS EFFECTIVENESS IN 3-6 MONTHS OLD PATIENTS WITH UNSTABLE HIPS

İNSTABİL KALÇAYA SAHİP, 3-6 AYLIK HASTALARIN TEDAVİSİNDE PAVLİK BANDAJI ETKİNLİĞİNİN DEĞERLENDİRİLMESİ

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ABSTRACT

Objective: To investigate the effectiveness of the Pavlik harness (PH) in the treatment of patients who were diagnosed with unstable hips aged between three and six months.

Material and Method: We retrospectively reviewed patients aged three to six months who were diagnosed with unstable hips and treated with the PH. The patients were treated using PH and were closely followed by a weekly clinical examination. The primary outcome was to assess the success rate of PH treatment in children with unstable hips (Graf Type IID, III, IV). A successful outcome as a result of PH treatment was defined as either obtaining a Type I hip based on Graf's method of hip ultrasonography or a concentric reduction based on hip radiography.

Results: Thirty-three patients' 34 hips were included in this study with a diagnosis of DDH based on hip sonography performed according to the Graf's method at the time of initial admission to our department. The mean age of the children in the beginning of the PH treatment was 17 weeks (range, 14–22); the mean follow-up was 48 months (range, 24–84). On admission, the mean alpha angle was 46 (range, 35–58). According to the Graf classification, DDH was determined as Type D in 18 hips (52%), Type IIIa in 5 hips, Type IIIB in 3 (24%) and Type IV in 8 (24%). Of these 34 hips, 28 (82%) were treated successfully using PH, with a mean application time of 11.24 weeks (range, 4–20). The success rate of PH treatment was determined as 82% (28/34 hips).

Conclusions: Favorable outcomes can be expected from PH

ÖZET

Amaç: Üç ila altı aylık stabil olmayan kalça teşhisi konulan hastaların tedavisinde pavlik bandajın (PB) etkinliğinin araştırılması.

Gereç ve Yöntem: Üç ila altı aylık stabil olmayan kalça teşhisi konulan ve pavlik bandajı ile tedavi edilen hastalar geriye dönük olarak incelendi. Hastaların stabil olmayan kalçaları PB kullanılarak tedavi edildi ve haftalık olarak klinik muayene ile yakından takip edildi. Birincil sonuç kriteri, stabil olmayan kalçaları olan çocuklarda PB tedavisinin başarı oranını değerlendirmektir (Graf'a göre tip IID, III, IV). Başarı kriterleri, Graf'ın kalça ultrasonografisi yöntemine göre tip I kalça veya kalça radyografisinde konsantrik reduksiyon elde edilmesi olarak tanımlandı.

Bulgular: Bölümümüze ilk başvuru sırasında Graf yöntemine göre ultrasonografik muayene ile tanı konan 33 hasta ve 34 kalça çalışmaya dahil edildi. Pavlik bandajı tedavisinin başlangıcında çocukların ortalama yaşı 17 hafta (aralık, 14–22); ortalama takip süresi 48 ay (aralık, 24–84) olarak saptandı. Başvuru anında ortalama alfa açısı 46 (aralık, 35–58) olarak ölçüldü. Graf sınıflandırmasına göre GKD, 18 kalça Tip D (%52), 5 kalçada Tip IIIa, 3 (%24) tip IIIB ve 8 (%24) tip IV olarak saptandı. Bu 34 kalçadan 28'i (%82), ortalama 11,24 hafta (aralık, 4–20) uygulama süresi ile PB kullanılarak başarıyla tedavi edildi. PH tedavisinin başarı oranı %82 (28/34 kalça) olarak belirlendi.

Sonuç: İnstabil kalçası olan (Graf Tip IID, III, IV) üç ila altı ay arasında tanı konulan hastalarda PB tedavisinden başarılı sonuçlar elde edilebilir.

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treatment in patients with unstable hips (Graf Type IID, III, IV) who are diagnosed between the age of three and six months.

Keywords: Developmental dysplasia of the hip; Pavlik harness; harness treatment; treatment success rate; late-diagnosed hip dysplasia

Anahtar Kelimeler: Gelişimsel kalça displazisi; Pavlik bandajı; bandaj tedavisi; tedavi başarı oranı; geç teşhis edilen gelişimsel kalça displazisi

INTRODUCTION

Today, after more than 50 years, the Pavlik harness (PH) treatment, which works physiologically based on the principle that 'the hip is an organ of movement and must be treated by movement', has been the method of choice to manage children with developmental dysplasia of the hip (DDH) (1, 2). The PH treatment remains the mostly preferred treatment modality, especially in patients younger than six months of age, because PH is the most thoroughly analyzed type of splint and reported to be safe and highly effective method as compared to any other type of splint in large series of patients (3-6). Nonetheless, there is disagreement in the literature about the optimal age to begin PH treatment. Most authors advocate that the harness can endow successful results as long as the treatment is initiated before the age of two to three months (4-8).

Conversely, some authors suggest that there is no correlation between age at the start of treatment and failure of PH treatment (9, 10). According to our review of the literature, there certainly needs to be more research to clarify the question about whether the PH is a safe and effective method of treatment for patients with unstable hips diagnosed after three months of age. However, PH treatment is not effective after six months of age (4, 9).

Therefore, the present study aimed to investigate the effectiveness of the PH in the treatment of a specific group of children who were diagnosed with unstable hips aged between three and six months.

MATERIAL AND METHOD

Study design

We retrospectively reviewed 87 patients (127 hips) who were treated with the PH after suffering from DDH with

a subluxated or dislocated hip from 2009 to 2016 in a single center (university hospital). According to the eligibility criteria as shown in Table 1, after 54 children (93 hips) were excluded, the remaining 33 children (34 hips) with an unstable hip (25 females and 8 males) who were diagnosed between the ages of three to six months and treated using PH were included in the present study. This retrospective study was approved by the Institutional Review Board; written and informed consent was obtained from the patients' parents.

After detailed clinical examination, all of these 33 patients underwent hip sonography based on Graf's method at the time of initial admission to our department. The mean age of the children in the beginning of the PH treatment was 17 weeks (range, 14–22); the mean follow-up was 48 months (range, 24–84) (Table 2). On admission, the mean alpha angle was 46 (range, 35–58).

Table 2: Demographic characteristics of the study participants

Mean age at the start of PH* treatment (week)	17 (range, 14–22)
Gender	25 females, 8 males
Side, R/L	21/13
Bilateral involvement	1
Unilateral involvement	32
Follow-up duration (month)	48 (range, 24–84)

*PH: Pavlik harness

Management protocol and primary outcome parameters

The patients' unstable hips were treated using the PH and closely followed by weekly clinical examination. The PH was applied by a single pediatric orthopedic surgeon

Table 1: Eligibility criteria for inclusion and exclusion of the study participants

Inclusion criteria	Exclusion criteria
A diagnosis of typical DDH*	<3 months old at the time of diagnosis
Children with unstable hips (Type IID, III, IV**) who were diagnosed after 3 months of age	<2 years of follow-up
Being willing to participate the study	Lost to follow-up
	Concomitant neuromuscular comorbidities
	Teratological dislocations
	Previous failed orthosis treatment
	Unwilling to participate the study

*DDH: Developmental dysplasia of the hip, **The diagnosis of DDH was established based on the Graf's method of hip ultrasonography

for all patients, and the parents were advised regarding the proper use of the PH. Concentric reduction of unstable hips was assessed using ultrasonography with a three-week-interval. All patients were also evaluated with a hip radiograph to assess the ossific nucleus of the femoral head and hip morphology. Additionally, patients who developed the ossific nucleus of the femoral head were also evaluated radiologically to assess the reduction after applying the PH.

Establishing success as a result of PH treatment in three to six month old children, who were diagnosed with unstable hips after performing a sonography according to Graf's method (Type IID, III, IV) was the main goal of the present study. Success was defined as achieving either a Type I hip after performing a hip sonography according to Grafs method or detection of a concentric reduction on hip X-ray.

The application of the PH continued until a stable hip was obtained or concentric reduction was determined by plain radiography. If stable reduction was obtained, but residual acetabular dysplasia was noticed on the final radiograph, the bandage was switched to a custom-made abduction splint for two or three months. If no reduction on plain radiography or no Graf-type improvement was observed within three weeks of PH treatment, the treatment was considered to have failed. The treatment was subsequently discontinued, and closed reduction combined with the application of a hip-spica cast was performed. As soon as use of the harness was ceased, a standard anteroposterior radiograph of the hip was taken to evaluate the reduction of the femoral head and acetabular development. The patients were then regularly monitored by radiographic examination at one year of age and then once annually.

Radiographic examination (anteroposterior and frog leg lateral X-rays) was performed after the cessation of the treatment with PH, at the end of the treatment with hip abduction orthosis, and at the final follow-up visit. In order to assess residual acetabular dysplasia, the acetabular index (AI) as described by Hilgenreiner was measured on all AP radiographs (11). The Kalamchi and MacEwen classification were also used to examine avascular necrosis of the femoral head (AVN) (12). In an effort to minimize observer and measurement bias, all radiographic assessments were carried out by a single pediatric orthopedic surgeon.

RESULTS

According to Graf classification, DDH was determined as Type D in 18 hips (52%), Type IIIa in 5 hips, Type IIIb in 3 (24%) and Type IV in 8 (24%). Of these 34 hips, 28 (82%) had been treated successfully with PH, with a mean application time of 11.24 weeks (range: 4–20). The mean

time from the beginning of treatment to stable reduction was 11 weeks (range: 4–20). Since a stable hip according to hip sonography or a concentric reduction on hip radiography was not obtained as a result of PH treatment in six unstable hips (3 with Type IIIB, 3 with Type IV) of five children; they were treated with closed reduction and a hip-spica cast, which was performed under general anesthesia. When these results were taken into account, the success rate of PH treatment was determined as 82% (28/34 hips) (Table 3).

Table 3: Rates of successful treatment

DDH* type **	Success rate
Type D	17/18 (95%)
Type IIIa	3/5 (60%)
Type IIIb	2/3 (66%)
Type IV	6/8 (75%)

*DDH: Developmental dysplasia of the hip

**DDH was categorized according to Graf classification

During the follow-up period, four unstable hips (four children) were treated successfully with the PH. However, the ultrasonographic examination could not be performed due to the development of the femoral head ossification center. In these hips, PH treatment was ceased when the stable and concentric reduction was determined based on plain radiography and physical examination. In the remaining 24 unstable hips of 24 patients, the mean alpha angle improved from 46° (range, 35°–58°) on admission to 62° (range, 60°–65°) at the end of the PH treatment.

The average AI of children treated successfully with the PH significantly improved from 34.5° (range: 30°–38.5°) after PH treatment to 18.2° (range: 14°–22°) at a mean follow-up of 48 months (range: 24–84 months). According to Tönnis's criteria regarding the DDH in pediatric population, only one child had a mild dysplasia (13). Furthermore, the final radiographic examination revealed that two hips of patients (1 with type IIIB and 1 with Type IV), in whom PH failed and closed reduction and a hip-spica cast was performed, had developed AVN according to the Kalamchi and MacEwen classification (1 hip with Type I, 1 hip with Type IV). Otherwise, the children treated successfully by PH showed no signs of AVN. Additionally, no other complications including femoral nerve palsy or skin breakdown occurred during the follow-up.

DISCUSSION

Many authors have referred to the PH as the first-choice of treatment in children younger than months of age due to its dynamic role in terms of hip reduction (2, 14-16). Nonetheless, the literature lacks consensus regarding the optimal age to begin PH treatment. Although most

authors have proposed that substantially higher success rates can be expected if the treatment is initiated prior to the age of two to three months (4-8), some studies have suggested that the age at the start of treatment was not an indicator of success for PH treatment (9, 10). Besides, most studies regarding this topic have included a heterogeneous group of patients in terms of hip stability (Graf type), and a limited number of studies in the literature have specifically focused on the success rate of PH in unstable hips (Type D-III-IV as per Graf classification) after three months of infancy (1, 4-9).

Unlike most studies on the topic, we more specifically asked if the PH is a safe and effective nonsurgical treatment for children with unstable hips diagnosed after three months of infancy. Therefore, our study specifically focused on a certain group of patients with severe problems and reflected the results of PH treatment for these unstable hips. The evidence from the present study demonstrated that the PH may be an influential technique in achieving stable reduction with a low rate of complications for children with unstable hips (Graf Type IID, III, IV) who are diagnosed with DDH and treated between three and six months of age.

Lerman et al. assessed predictors of treatment failure for PH in 93 patients (137 hips) with DDH (9). Seventeen patients (26 hips) failed the PH treatment, and the authors found no correlation between initiation of treatment and rates of failure. However, in the failed group, only two patients were aged three months or older. Therefore, their results could not be extrapolated to the whole late-diagnosed DDH. In contrast, in a study which included 31 cases of DDH of Graf Type IIc or more severe cases, Atalar et al. found Graf type, age at start of treatment, and bilaterality as the success indicators of PH treatment (4). In their study, the mean age at the start of treatment was eight weeks, with age ranging from 4 to 20 weeks. In this study, children aged seven weeks and under exhibited a higher rate of success than those aged eight weeks and over. Furthermore, patients with Type IIc, D or III hips presented a higher rate of treatment success than patients with Type IV hips, and patients with bilateral DDH had a lower rate of treatment success than patients with unilateral involvement (4). They emphasized that the beginning of PH treatment before the 7th week of infancy was the key aspect for successful outcomes in the management of DDH. Similarly, in another study which analyzed the factors affecting the success rate of this treatment modality in 153 children (≤ 6 months of age) with DDH treated using the PH, Ömeroğlu et al. found the treatment starting age as the only patient-related variable (5). In their study, although more than 90% of patients under three months of age (37 of 40) were treated successfully, the treatment failed in one-third of patients older than five months of age (9 of 24). Additionally, Ömeroğlu et al. stated that both a lower initial alpha an-

gle and a higher Graf hip type decreased the success rate of PH treatment, since unsuccessful results were obtained in more than two-thirds of Graf Type III hips and two of four Graf Type IV hips (5). Therefore, they concluded that the threshold values for increased risk of treatment failure with PH were an age older than four months and an alpha angle less than 46°. Lastly, in a more recent study in this topic, Larson et al. reported a study which included 176 children with 38 patients (21.6%) failing PH treatment (17). In that study, patients were divided based on the age at which the PH was initiated (group 1 \leq 30 days, group 2=30 to 60 days, group 3 \geq 60 days). They concluded that there was no difference in the failure rates by age.

AVN, the most catastrophic complication of DDH treatment, still poses a complicated diagnostic and treatment challenge for orthopedic surgeons. What is more, because of the complex and multifactorial etiology, the development of this devastating complication remains difficult to predict (18). Although the rate of AVN following successful reduction is reported to be low, ranging from 0% to 22%, higher rates of AVN are attributed to fixed dislocation, unsuccessful reduction, bilateral hip involvement as well as presentation beyond three months of age (9, 18-20). In a retrospective study which set out to analyze 100 children with distinct levels of hip instability treated using PH, Kokavec et al. drew the conclusion that Pavlik's method is safe and accurate for all dysplastic and subluxated hips, together with the great majority of dislocated hips (1). However, the authors emphasized that late onset and prolonged duration of the PH treatment were associated with higher rates of treatment failure and AVN. In our study, we observed no evidence of AVN in children with unstable hips treated successfully by PH; however, AVN occurred in two hips (1 hip with Type I, 1 hip with Type IV) in whom closed reduction using a hip spica cast was applied because of failure of PH. Therefore, we believe that the major predictive factor for AVN in the treatment of DDH may be the failure of PH as well as the severity of the pathology. Nonetheless, although the present study displayed satisfactory outcomes of PH treatment, the likelihood of complications including AVN and late acetabular dysplasia may compromise the results at the long term follow-up (10, 21, 22).

Residual acetabular dysplasia has been implicated as one of the most prevalent complications following the treatment of DDH (23). In our series, at the end of a median follow-up duration of four years, no residual acetabular dysplasia was observed based on radiographic measurements except for one child who had a mild acetabular dysplasia. However, Fujika et al. reported a severe dysplasia rate of 19% in a series of 380 patients with a follow-up duration of more than 20 years (21). Similarly, Tucci et al. warned against late acetabular dysplasia in patients with hip instability treated with PH and suggested that all such patients should be monitored until skeletal maturity (22).

Therefore, patients in the present study seem to need further follow-up evaluations in order not to miss probable residual dysplasia.

In a comparative study, Westacott et al. found no significant difference with regard to results or complications between staged and immediate cessation after successful treatment using PH (3). In our study, the treatment was stopped as soon as a stable hip was obtained according to ultrasonographic examination, or concentric reduction was observed on plain radiography. We observed no recurrence or re-intervention after immediate cessation in our case series. However, based on the present study, due to the lack of a control group, whether or not immediate cessation was superior to staged cessation could not be determined.

This study has several important limitations. The first limitation was the retrospective nature of the study. Second, the follow-up period in this study was limited to the middle-term outcomes. Third, this study did not include a control group. Lastly, the Barlow and Ortoloni examinations in the initial evaluation of these patients were not included.

CONCLUSION

With successful outcomes and low morbidity, favorable outcomes can be expected from PH treatment for children with unstable hips (Graf Type IID, III, IV) who are diagnosed between the age of three and six months. Otherwise, there certainly needs to be much more research to clarify the safety and effectiveness of the PH for this particular group of patients.

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