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Pavlik harness and Frejka pillow: compliance affects results of outpatient treatment

Michal Zídka[1,2] · **Valér Džupa**[2]

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Abstract

Purpose of the study Outpatient treatment of hip dysplasia in newborns has excellent results. A combination of general screening with early treatment with a functional abduction device works well. Treatment with the Frejka pillow and the Pavlik harness is frequently used in our region. The aim of the study is to compare efficiency and treatment duration, related to the brace used, and to prove that the choice of an abduction device implies parental compliance with the treatment protocol.

Materials and methods Data of 286 treated children were analyzed. The diagnosis was made in the first weeks of life by clinical and sonographic examinations during general screening. The choice of treatment device was expert dependent and was involved by many variables. The experience, type of clinical finding and sonographic pathology according to Graf, availability of a treating facility, and the potential cooperation of individual parents were major parameters. The Frejka pillow was used to treat 145 children and the Pavlik harness was used in 137 children. The treatment duration and percentage of infants lost from follow-up in relation to the device used was documented.

Results The success rate of outpatient treatment was 98.6%. In six patients, the type of device had to be changed during the treatment period. Physiological sonographic findings were achieved in all hips by the end of the treatment. The Frejka pillow was used as the preferred device in milder stable dysplastic hips, while unstable and decentered hips were treated more frequently with the Pavlik harness. Treatment lasted, on average, 95 days and 119 days in the Frejka and in the Pavlik group, respectively; there was no statistical significance in treatment duration of comparable sonographic pathologies. We observed statistically greater parental non-compliance with the treatment protocol in the Pavlik harness group ($p = 0.0279$; OR 2.7; 95% CI 1.07; 8.5).

Conclusions Neither of the abduction devices was inferior with regard to treatment efficiency. We found that parental cooperation was an important factor during screening and treatment. The treatment decision and the choice of the brace must be made with full consent of the parents, keeping in mind that comfort during the nursing care may have a significant influence on compliance with the treatment protocol.

Keywords DDH treatment · Pavlik harness · Frejka pillow · Hip sonography · Non-compliance

Introduction

In the era of early diagnosis of developmental hip dysplasia (DDH), abduction treatment is a safe method that yields excellent results, with expected treatment success approaching 100%. The choice of an abduction brace is performed on the basis of many factors. The age of the child at diagnosis, the severity of hip involvement, clinical findings, the physician's experience and education, practices at the institution and its availability, level of cooperation with the parents, and the price of the device are the essential factors influencing decision-making.

The Frejka pillow (FP), a simple soft abduction brace, was introduced by its inventor Frejka [1] in 1941 and has gained worldwide popularity. The Pavlik harness (PH), invented by Arnold Pavlik, was used for the first time in 1945 and became now the most frequently used DDH treatment device worldwide [2, 3]. Since both inventors are of

✉ Michal Zídka
michal.zidka@mediterra.cz

[1] Department of Orthopaedics, CLPA-Mediterra, Sokolovská 304, 190 61 Prague 9, Czech Republic

[2] Department of Orthopaedics and Traumatology, Third Faculty of Medicine, Charles University, University Hospital Kralovske Vinohrady, Prague, Czech Republic

Czech origin, we have extensive experience in treating of the fourth generation of DDH patients, using these devices, in our country. Furthermore, the nationwide general screening system "of threefold orthopedic net" was started more than 60 years ago. In the 1990s, hip sonography was successfully incorporated into the nationwide functional screening system [4] used in the Czech Republic. Patients are diagnosed by early and repeated clinical and sonographic examinations; any treatment can be started early, often within the first weeks of a newborn's life.

The general awareness of DDH is high in the Czech Republic thanks to a long tradition of assessing hip function in newborns by orthopedic specialists. Additionally, there is a longstanding tradition of excellent cooperation with parents and pediatricians. These factors have made our general screening program feasible, and treated children are followed on during the treatment period and afterward, by specialized orthopedic outpatient clinics, favorably until they reach skeletal maturity [4]. However, we noticed that some patients we started to treat do not attend scheduled visits; and the loss from follow-up that was observed was greater than might be expected due to natural migration.

Many authors have already investigated the success of treatment and frequency of complications associated with treatment using a variety of abduction devices. We have documented the efficiency of our treatment with the Pavlik harness and the Frejka pillow as well. Above this, we have tried to (1) determine the extent to which the choice of device and subsequent comfort during nursing care affects the willingness of the parents to cooperate with the treatment protocol and (2) if device choice affects program compliance, even to the point of children being lost to follow-up.

Materials and methods

We retrospectively evaluated data of 286 children with different degrees of hip dysplasia diagnosed by the authors; 212 children were treated at a university clinic (1994–1997) and 74 were treated at a separate specialized outpatient facility (2010–2013). All the children were diagnosed and classified using a clinical examination and sonography (according to the Graf scheme) [5] and were treated on an outpatient basis. We excluded four children in which the failure of outpatient abduction treatment led to hospital admission and traction treatment (which was successful in all cases). Patients first treated and then referred from other institutions and children with neurogenic etiology of hip disease and arthrogryposis were excluded from our study as well. We also did not include four infants operated on for irreducible hip dislocations during the evaluated period; all were patients referred from different institutions after some treatment and none had been primarily diagnosed and treated using our protocol.

Treated children were sent for examination from cooperating maternity hospitals and from local pediatric practitioners as part of the ongoing general screening program. A family history was obtained and risk factors were documented. Clinical testing of the hips was immediately followed by a sonographic examination using the Graf technique and a sonographic assessment of hip stability [6, 7].

Indications for the treatment included pathological clinical findings (presence of hyperlaxity, muscle contractures, asymmetries, Barlow or Ortolani signs) and sonographic pathology based on the Graf classification system [5] related to the age of the child, or the absence of the immature hip development when compared to previous sonography. The visits, examinations, treatment, and follow-up always took place with the presence and participation of parents in a specialized outpatient clinic reserved for infant hip sonography. Parents were informed about assessment results. The functionality, size, and adjustment of the abduction device were always checked and the next visit was always scheduled.

The choice of the abduction device was decided by the attending physician. The treatment of simple acetabular dysplasia (Graf type IIa, IIc) started immediately after sonography, only if there was a simultaneous presence of clinical pathology (i.e., limitation of abduction or hip asymmetry) in children with a positive family history. In all other Graf II hip subtypes, treatment started after subsequent ultrasound follow-ups, if no signs of physiological maturing of the joint were present [8]. The majority of these milder deformities (e.g., acetabular dysplasias without instability) were indicated for treatment using the Frejka pillow. More severe degrees of dysplasias (e.g., unstable and decentered hips) were more frequently treated using the Pavlik harness. The numbers of treated sonographic pathologies with respective abduction devices are documented in Table 1. If re-centering of the femoral head did not happen within 2 weeks of abduction treatment (confirmed by sonography), then inpatient distraction treatment was recommended. All the other successfully centered hips were treated using the FP or PH on an outpatient basis.

We applied the Frejka pillow in sizes measured by a comfortably reachable distance between abducted popliteal grooves; re-examinations were planned at 3–6 weeks intervals, at which time, and if needed, we exchanged the pillow

Table 1 Distribution of hips treated by type of brace

Sonography (Graf type)	Frejka pillow	Pavlik harness
2a	69 (80%)	17 (20%)
2c	50 (41%)	72 (59%)
D	20 (49%)	21 (51%)
3a	6 (19%)	26 (81%)
4	0 (0%)	1 (100%)

for a larger one. During infant treatment, 2–3 sizes were typically used.

The Pavlik harness was used to position children within a safe range of motion, i.e., the straps passively controlled hip flexion beyond 100°; posterior belts preventing crossing the midline, i.e., preventing full adduction; and a non-constraining thoracic belt was placed at the level of the nipples. We instructed parents of smaller babies (i.e., if the smallest available harness size was too loose), to improve the device by shortening and then stitching the straps to ensure proper fit and correct function. We checked the function of the harness 1 week after adjustments; the baby was then followed at 3–4-week intervals.

The effectiveness of abduction treatment was monitored and documented sonographically in all patients; we performed Graf and dynamic ultrasound examinations to determine the morphology and stability of the joint. Treatment lasted until we measured an alpha angle of at least 60° on an ultrasound examination, i.e., until the ultrasound finding of the hip joint became normal (Graf type I). The data obtained were evaluated using descriptive statistical methods; the chi-quadrat test was performed at the 0.05 significance level.

We documented the migration of treated children during data collection. We tried to analyze whether the medical device used determined if the patient did not comply with follow-up (i.e., switching to another specialist office or neglecting treatment).

Results

Treatment was successful on an outpatient basis in 282 of 286 children (98.6%). We used the Frejka pillow in 151 children in the cohort of the 282 conservatively treated children; in six of them, we exchanged the device for the Pavlik harness during the treatment phase (4%)—three times (2%) because it was poorly tolerated by the child or at the parents' request and three times (2%) for sonographically documented ineffectiveness. A total of 137 children were treated using the Pavlik harness until the end of the treatment; there were no cases in which the PH was exchanged for the Frejka pillow; the tolerance and effectivity of PH were excellent.

In dysplastic hips (Graf types IIa, IIc), treatment was started when there was a combination of dysplasia + positive family history and/or clinical pathology and a lack of improvement between visits (in total 208 patients). Unstable hips (Graf type D) were treated in 41 patients over 4 weeks of age, decentered hips (Graft type IIIa) in 32 patients, and in one case a dislocated reducible hip (Graf type IV). We did not see any cases of Graf type IIIb hips, probably due to the early diagnosis in the investigated group.

The abduction treatment continued until there was an improvement in the sonographic finding, i.e., achieving stable hips with the development of the acetabular coverage reaching the Graf's category I criteria (alpha more than 60°). This objective was successfully achieved in all followed patients. In the Frejka pillow group, treatment started at an average patient age of 40 days and the average duration of splinting was 95 days (4–28 weeks). In the Pavlik harness group, treatment started at an average age of 35 days and lasted, on average, 119 days (5–34 weeks).

Detailed statistical data on treatment related to sonographic pathology and device type (e.g., max, min, median, and quartiles of treatment duration) are summarized using whisker box plots (Fig. 1). In treatment of Graf IIa and IIc hips using the Frejka pillow and Pavlik harness, the average treatment duration was 13.2 and 16.3 weeks, respectively, and the standard deviations (SD) were 4.5 and 5.6 weeks, respectively. Treatment of unstable Graf D hips using FP and PH averaged 14.3 and 18.7 weeks with an SD of 3.7 and 4.0 weeks, respectively; treatment of decentered Graf III hips using FP and PH averaged 19.6 and 18.7 weeks with an SD of 4.4 and 4.3 weeks, respectively. None of these differences were statistically significant, indicating that neither treatment (i.e., FP vs. PH) was potentially inferior to the other. In our set of 282 children, 23 patients failed to complete the treatment at our outpatient clinics (8%) and these children were lost to standard follow-up. When lost to follow-up, seven were being treated using the Frejka pillow (4.8% of the FP group), and 16 were being treated using the Pavlik harness (13.9% of the PH group). We found a statistically significant correlation between non-compliance with the treatment regimen in patients treated with a Pavlik harness compared to patients treated with a Frejka pillow ($p = 0.0279$; OR 2.7; 95% CI 1.07; 8.5).

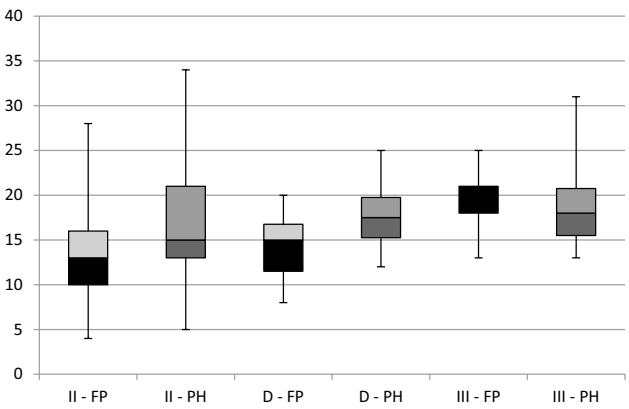

Fig. 1 Whisker box plot—duration of treatment (based on sonographic pathology) with the Frejka pillow (FP) and Pavlik harness (PH) (max, min, median, and quartiles). *Y*-axis: Weeks of treatment; *X*-axis: Graf type and device type

Discussion

Both examined medical devices are considered to be sufficiently effective, as is confirmed by our study. Despite the different leg position after application (abduction with a slightly flexed hip position with FP vs. a more "human" flexed and freely abducted hip position with PH), both devices can be used to treat a whole spectrum of DDH deformities—both having a retention effect in acetabular dysplasia [9] up to a reduction effect in dislocations [10–12]. Ischemic necrosis of the proximal femur is the most serious risk of treatment; comparing the Frejka pillow and the Pavlik harness relative to its frequency is very complicated due to the unequal parameters used in various studies [13–16].

There are no clear criteria for the selection of a specific treatment aid for a particular pathology or particular patient. The physician's decision depends mainly on personal experience with the device, the severity of involvement, the child's size, the presence of possible muscle contractures, and last but not least, on the level of expected cooperation with the individual parents of the treated infant. Our statistical analysis of the treatment of groups with comparable sonographic pathologies did not prove inferior results of either device. In our facilities, we preferred the FP for patients with milder degrees of dysplasia, without muscle contractures, and in an outpatient facility. Treatment using a PH was indicated more often in unstable hips, for children with muscle contractures, as well as for patients treated on an outpatient basis at a hospital clinic with 24/7 availability.

The use of the Pavlik harness or the Frejka pillow for treatment of dislocated hips is, in our opinion and in contrast to many authors [10, 11, 14, 15, 17], quite controversial; it should be practiced strictly individually. The attempts to reduce hips with an abduction device should only be done in the very early days/weeks of life [18]; however, despite its little popularity [2], we prefer to treat hip dislocations with traction.

On the other hand, we do not hesitate to use early device loading in cases of decentered hips. The effectiveness of the therapy, however, should be confirmed as soon as possible. If a release of the muscle contractures and a centric head reduction into the acetabulum are not recorded within 1 or 2 weeks (verified using sonography) [2], we recommend starting traction treatment as well.

We are skeptical of treatment of hip dysplasia with a rigid brace or a spica cast [15]; in our opinion, the PH and FP devices allow movement of the hips, either by design (PH), or while caring for the child's hygiene (FP), which reduces the risk of iatrogenic infant hip joint damage. Furthermore, we advise parents to stimulate the infant's lower leg activities during the day.

The practical usage of both investigated abduction devices, however, have additional specifics.

Frejka pillow (Fig. 2)

We confirmed the excellent efficiency of the FP in DDH treatment in our studied patients and it is our preferred device for less serious forms of dysplasia. The advantage of the pillow is the simplicity of application, good tolerance by the child, low cost, and simplicity of use [12]. In the literature, the disadvantages are deviances from the treatment protocol by parents [19] and a lower efficiency compared to rigid braces [15, 20].

Especially during hot summer months, we noticed a reluctance to use the FP due to a higher incidence of skin affections under the blanket. Elevation of the buttocks may initially worsen gastric stability, and partial restriction of limb movements then causes difficulties with flatulence. Bigger babies may have a problem with the Velcro strips being inadequate to properly secure the device and resist the leg force of a growing infant; however, it can be easily addressed individually by modifying the equipment. The need for a change to a larger pillow size, as a result of the child's growth, increases the medical costs of the treatment. These disadvantages cannot be underestimated since they can lead to non-compliance by the parents, which can slow the course of the improvements of the hip pathologies. However, we were able to address parental concerns and follow the treatment protocol in more than 95% of treated infants.

Pavlik harness (Fig. 3)

The Pavlik harness is the most commonly used tool worldwide for the treatment of DDH [21]. It is very flexible in terms of appropriate uses and is very effective in the treatment of simple dysplasia, as previously described by Pavlik [22], who originally designed the harness as an aid to reduce hip dislocations using a controlled motion [23]. In our study,

Fig. 2 Frejka pillow

Fig. 3 Pavlik harness

we confirmed its excellent effectiveness in the treatment of decentered and unstable hips.

Loading the stirrups is, unlike the Frejka pillow, a bit more complicated. Additionally, parental non-compliance with the treatment protocol (nearly 14% of infants were lost to follow-up) poses a serious problem. We agree that the first few weeks of application are a particularly problematic period [24]. Overall, understanding the principle and the necessity of treatment by the newborn's parents at this treatment phase is crucial for the overall success of the treatment period [25]. Parents need to be familiar with the features of the aid and must respect the correct settings of the individual belts. Marking the ideal position of the buckles directly, using a pen, on the stirrups has proven best; the position should be checked repeatedly at each visit and, as needed, the distances should be extended adequately to the child's growth. Sometimes shortening of the straps may also be needed since straps can stretch by the child's physical activity.

If correctly applied, newborns tolerate the Pavlik harness very well; the stirrups allow uncomplicated hygiene (unlike the FP, which has to be removed); additionally, the stirrups can be individually adjusted to fit the growth of the child or clinical findings. We consider femoral nerve palsy [13, 19] to be only a theoretical complication in correctly supervised care.

Conclusion

Conservative treatment of DDH initiated during the first weeks after birth is highly effective. In the Czech Republic, we have a functional screening system, reliable sonographic diagnostics, and certified medical tools that are safe, effective, and available. When the treatment protocol is followed, we are able to successfully normalize hip joint morphology in almost all patients during the first year of life. We failed to show that one device (Pavlik harness vs. Frejka pillow) was statistically inferior to the other based on sonographically monitored early treatment of DDH.

The comfort and use of an abduction device, however, can be an important factor in treatment success. A significant tendency to neglect the treatment protocol (i.e., spontaneous interruption of treatment or "switching" to another specialist) was detected in patients treated with the Pavlik harness, while treatment with the Frejka pillow showed no such tendency. Therefore, when the Pavlik harness was used, we strongly recommend an individualized approach with close communication between physician and parents in an effort to maximize treatment compliance and ensure the most effective treatment outcomes.

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Compliance with ethical standards

Conflict of interest Michal Zídka and Valér Džupa declare that they have no conflict of interest and had gained no benefits concerning the study.

Ethical approval This article does not contain any studies with human participants or animals performed by any of the authors.

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