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Femoral nerve palsy during Pavlik harness treatment for developmental dysplasia of the hip is not an indication for harness abandonment

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Abstract

Objectives: The aim of this study was to report the incidence of femoral nerve palsy in developmental dysplasia of the hip children treated with Pavlik harness, to identify any possible associated risk factors, and to evaluate its outcome without any specific strap release.

Methods: A retrospective chart review was conducted on all cases of femoral nerve palsy in a consecutive series of children who underwent Pavlik harness treatment for developmental dysplasia of the hip. In unilateral cases, the developmental dysplasia of the hip was compared to the contralateral side. All hips with femoral nerve palsy were compared to the remaining hips of the series and any possible risk factor for paralysis was recorded.

Results: In total, 53 cases of femoral nerve palsy of various severity were identified from a group of 473 children with 527 hips treated for developmental dysplasia of the hip at an average age of 3.9 months. However, 93% occurred during the first 2 weeks of treatment. Femoral nerve palsy was more common in older and larger children with the most severe Tonnis type, and a hip flexion angle in the harness above 90° ($p < 0.03$ for all). All of them resolved spontaneously before completion of treatment without any specific measures. We found no correlation between the presence of femoral nerve palsy or the time taken for spontaneous resolution and treatment failure using the harness.

Conclusion: Femoral nerve palsy is most observed with higher Tonnis types and high hip flexion angles in the harness, but its presence by itself is not predictive of treatment failure. It resolves spontaneously before completion of treatment and does not require any strap release or harness discontinuation.

Level of evidence: Level III.

Keywords: Developmental dysplasia of the hip, Pavlik harness, femoral nerve palsy

Introduction

Since its first description in 1953, Pavlik[1] harness has gradually become the gold standard for the treatment of developmental dysplasia of the hip (DDH) before the age of 5 months. It was introduced as a "new functional method" for the treatment of congenital hip dislocation, based on the philosophy that the hip must have motion to achieve reduction and correction of acetabular dysplasia. The hips would spontaneously reduce through the child's own movements,[2] provided free hip motion is allowed within a certain range of hip abduction–adduction, flexion–extension, and rotation. Recently, Pavlik harness treatment has been demonstrated to be a safe and sensible first-line treatment for infants with dislocated irreducible (D/I) hips, but with higher failure rates reported in this particular population (International Hip Dysplasia Institute, IHDI study) [3].

Predictors of treatment failure reported in the literature are the absence of an Ortolani sign (irreducible hip), age greater than 7 weeks at the beginning of treatment, male

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gender, bilaterality, parental noncompliance, inappropriate application of harness by the physician, Graf type IV on ultrasound, less than 22% coverage of the femoral head on ultrasound, multigravida, foot deformity, and higher Tonnis grades.[3–9] Complications of Pavlik harness include reduction failure, avascular necrosis, inferior dislocation of femoral head, brachial plexus palsy, and femoral nerve neuropathy.[10–13]

Although femoral nerve palsy (FNP) is reported as a potential complication of Pavlik harness treatment for DDH, only very few papers address this issue specifically.[14] It is known to be transient, as it always resolves following strap release to decrease hip flexion, or harness discontinuation which may jeopardize the treatment success. Various theories were suggested to explain the cause of FNP, the most accepted is the forced hip flexion greater than 90° that produces a possible entrapment of the femoral nerve under the inguinal ligament.[15–17]

The natural history of untreated FNP is unknown. Whether irreversible damage to the nerve occurs over time remains a mystery since no studies reporting the fate of quadriceps function without any specific management exist in the literature. Our first hypothesis is that this complication may spontaneously resolve without any need for harness removal or excessive strap release, owing to the free hip motion in adduction–abduction and rotations, and to the viscoelasticity (biomechanical creep property) of living organs. Another uncertainty relates to the nature of the problem itself; since no electromyographic (EMG) study was performed to authenticate the paralysis in any child, the authors of the current study had always doubts concerning the etiology of active knee extension deficit, designated as FNP. Based on this hypothesis and a personal early experience of few cases not included in the current study, the senior author decided many years ago to modify his practice concerning excessive release of the flexion straps, or temporary or definitive abandonment of the harness, if a clinical deficit of active knee extension is identified.

The purpose of this study was to report the incidence of this potential complication to identify any possible associated risk factors and to evaluate its outcome without any specific modification in the treatment course.

Methods

Study population

Following IRB approval, a retrospective chart review was conducted on all DDH patients who underwent Pavlik harness treatment between August 1997 and June 2015 by a single physician. The records of 502 consecutive children were identified. Patients whose treatment was commenced in another institution, those with teratologic dislocation or incomplete medical records, and those who were diagnosed with any underlying neuromuscular or connective tissue disease during the course or after the end of treatment were excluded. In cases where the femoral epiphysis was not ossified (38 hips), the cartilaginous femoral head contour (its shadow on the X-ray) was outlined using a pencil to determine its position with regard to the acetabulum, and subsequently classify it according to Tonnis. No ultrasound was performed to classify the hips since most children included in this study were older than 2 months, and pelvic radiographs are usually considered diagnostic in this age group; also, the original Tonnis publication was based solely on radiographs.[18,19] However, the expertise for hip ultrasound was not always available mainly for those children living in distant rural areas.

Overall, 473 children with 527 hips treated for DDH using a Pavlik Harness met the inclusion criteria for this study: 419 with unilateral DDH, 54 with bilateral DDH, 140 Tonnis 1, 159 Tonnis 2, 208 Tonnis 3, and 20 Tonnis 4.

Treatment method

The same harness was used for all children and resembles the one described by its promotor. Our method of harness application is slightly different from literature reports in which the stirrups are gradually tightened over several days to reach 90° of hip flexion. In our patients, we deliberately chose a one stage 100° flexion at first application because of local and regional socioeconomic factors. In fact, many families live far away from our facility, and have many children, and therefore cannot afford a daily or biweekly drive to have the stirrups tightened, either because of a low income or of the difficulty to frequently find someone to babysit their other children while they are away from home.

Our treatment protocol includes a 24/7 regimen of harness wear regardless of DDH severity. The parents are instructed not to release the straps for any reason, and to consult every 2 weeks for anterior and posterior strap adjustment by the physician, and evaluation of bilateral active knee extension as an indirect indicator of FNP, during the entire treatment. Although the authors are aware that most "FNP" occur 3–4 days of application of harness, some of them would still occur in the following weeks. Our criteria for a good strap length are a rectilinear horizontal position of both thighs, when held in abduction and maximum strap tension in hip extension (Figure 1). At each follow-up, hip flexion was evaluated by the physician, and when it was increased due to the child's growth, straps were released to reach the desirable position. FNP was defined as a partial or total deficit in active knee extension (DAKE) spontaneously or in response to gentle stimulation of the foot, anytime during or following the completion of Pavlik harness treatment. Partial FNP was defined as an incomplete knee extension while total deficit was defined as the absence of extension. This classification and the examinations were all made by the same physician. The diagnosis of FNP was clinical only, and no EMG study was done in any case to confirm it, and this is similar to previous literature reports.[14,15] Treatment duration was 3 months in

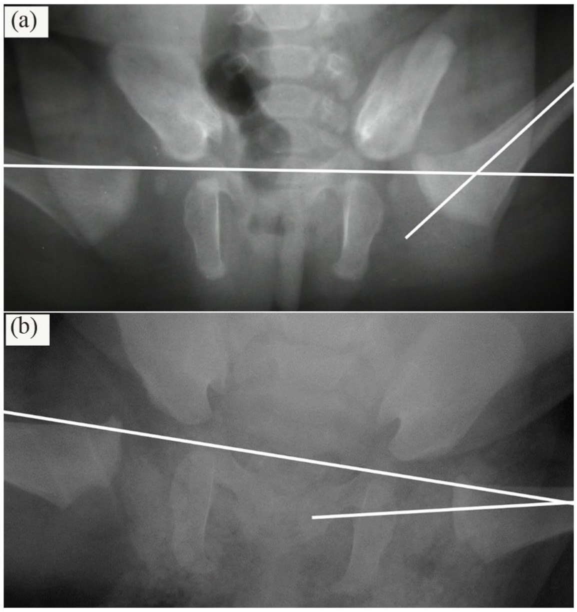

Figure 1. (a) Left DDH. Undesirable position of the left thigh in the harness: flexion >110°; (b) another case of left DDH. Desirable position with left hip flexion around 100°.

average without any weaning. Since there is no worldwide evidence-based consensus concerning the duration of harness wear, the senior author chose deliberately to keep it on for a total duration of 3 months, once he had the confirmation that the hip was reduced on the first pelvic radiograph. This was to make sure that the joint capsule had become sufficiently tight to hold the femoral head in place once the harness is discontinued.

The first anteroposterior (AP) pelvic radiograph is taken with the harness, at 6 weeks, in bilateral hip abduction and 90° flexion. No radiographs or ultrasound to document that the hip had been reduced were performed prior to 6 weeks because of the lack of evidence-based consensus regarding this issue. The senior author does not believe that any imaging finding prior to 6 weeks would have changed the treatment plan; according to the treatment rationale in our institution, if the femoral head is supposedly not reduced at 2 or 4 weeks, no further action would be taken apart from making sure that the anterior and posterior straps are in good status; in fact, the senior author's early experience with radiographs every 3 weeks showed that a non-reduced femoral head at 3 weeks may be seen in the socket at 6 weeks. Recent evidence suggests that in certain cases, a prolonged harness treatment could be beneficial.[20,21] Moreover, Gornitzky et al.[22] showed that there was no significant association between negative changes in acetabular alpha angle or subsequent treatment compromise and prolonged treatment duration in harness of dislocated hips. These publications may support the aforementioned senior author's practice. Thus, the treatment is discontinued in our patients only if the femoral head is still dislocated at 6 weeks and then, adductor tenotomy with closed reduction and spica casting, with or without pre-reduction traction, is undertaken. The second AP radiograph is requested at 3 months, that is, end of treatment, without the harness, in neutral position of both hips. Treatment failure is defined as a persistent or recurrent dislocation occurring anytime during Pavlik harness application or later after removal, requiring another type of treatment. Treatment success was defined by a concentric reduction of the hip that lasts till the last follow-up.

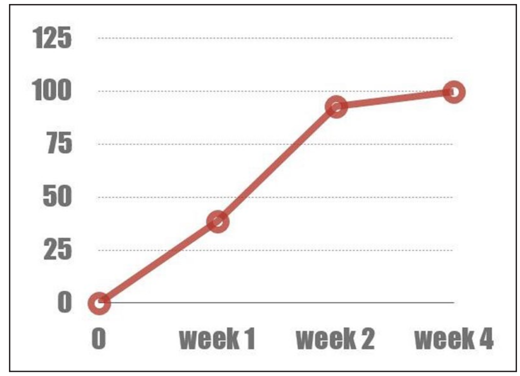

Figure 2. A diagram showing the time of harness wear during which FNP occurred.

All cases of FNP were identified and reviewed. In unilateral cases, the DDH hip was compared to the contralateral side. All hips with FNP were compared to the remaining non-affected hips of the series and any possible risk factor for paralysis was recorded, including age, patient's size, severity according to Tonnis, and hip flexion angle in the harness.

Statistical analysis

The two independent groups (FNP versus non-FNP hips) were compared using an unpaired Student's *t* test. Logistic regression was used to evaluate outcome following the course of treatment. Analysis was performed using SPSS 16.0 statistical software; p-value of less than 0.05 was considered statistically significant.

Results

In total, 53 cases of FNP of various severity were identified (10%). Average age at treatment onset was 3.9 (2.8–4.8) months in the FNP group and 1.9 (1.5–3.2) months in the non-affected group. Average age at last follow-up was 13.2 (3.5–21.2) years. All femoral nerve palsies occurred either on the affected side of a patient with unilateral DDH or on one side of a patient with bilateral DDH. There were no cases in which FNP occurred on the contralateral side of a patient with unilateral DDH.

The DAKE occurred during the first 2 weeks of treatment in 49 hips (93%), and during the first month in all hips (Figure 2). The DAKE was partial in 46 cases and total in 7. FNP was more common in older and larger

Table 1. Correlation of age at treatment onset, weight, body mass index, and bilateral condition with the development of FNP.

	Control group	FNP group	p value
Age at treatment	1.9 (1.1–2.7) months	3.9 (3.6–4.5) months	0.009
Weight	3.6 (3.4–3.9) kg	5.0 (4.6–5.8) kg	0.002
BMI	13.9 kg/m^2	15.6 kg/m^2	0.025
Bilateral	35%	38%	0.84

FNP: femoral nerve palsy; BMI: body mass index.

children with the most severe Tonnis grade ($p < 0.03$ for all), and there was no statistically significant difference between unilateral and bilateral DDH as a possible causative factor for FNP (Table 1 and Figure 3). At the time of diagnosis of FNP (53 hips), 45 hips had a flexion angle of more than 110° and 8 hips had a flexion angle between 90° and 110°, whereas in the non-affected group (474 hips), 15 hips only had a flexion of more than 110°, and 52 hips had a flexion angle between 90° and 110° ($p = 0.004$) at either one of the two first follow-up visits. The measurement of hip flexion angle was only visual based on the expertise of the senior author, and the results of a previous study assessing visual estimation of passive range of motion in the child's lower limb.[23] It is worth mentioning that we are lacking a clear threshold value for hip flexion causing FNP. While Kalamchi and MacFarlane recommended initially to avoid flexion of more than 90°,[17] Weinstein et al.[24] stated that maintaining a hip flexion beyond 120° is a risk factor to develop FNP.

All FNP cases of this study resolved spontaneously before completion of treatment (2 days–2 weeks according to the parents and confirmed by the physician 2 weeks following diagnosis of FNP and strap adjustment) without any release of the harness straps other than those required regularly in the absence of FNP (Figure 4). None of them necessitated treatment discontinuation because of FNP. There was a complete return to quadriceps function with recuperation of normal active knee extension against gravity, and no clinically evident long-term motor or sensory deficit in any of the affected hips.

Outcome: treatment success

The success rate of Pavlik harness treatment in our entire population was 96% (506 hips) and was highly dependent on the initial severity of DDH ($p < 0.009$). Treatment failure existed only in Tonnis grades 3 and 4, regardless of the presence or absence of FNP. In fact, 15 FNP occurred in Tonnis grades 1 or 2, despite success of treatment in all hips with these grades. This was most probably due to increased hip flexion angle. The success rate was 97% in our control group and 91% in our FNP group ($p = 0.12$). Logistic regression analysis of the time taken for return of normal active knee extension, Tonnis grade, and the probability of treatment success found no correlation between

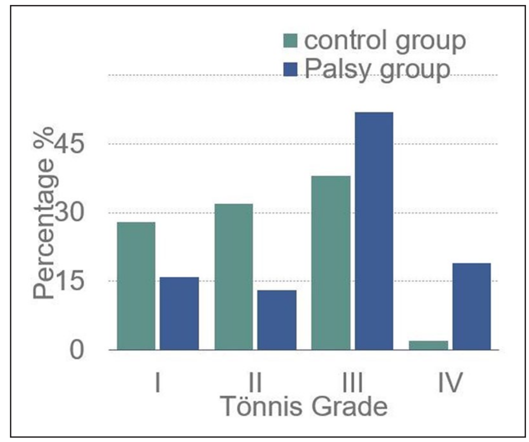

Figure 3. Distribution of non-affected control and FNP affected hips with regard to Tonnis classification.

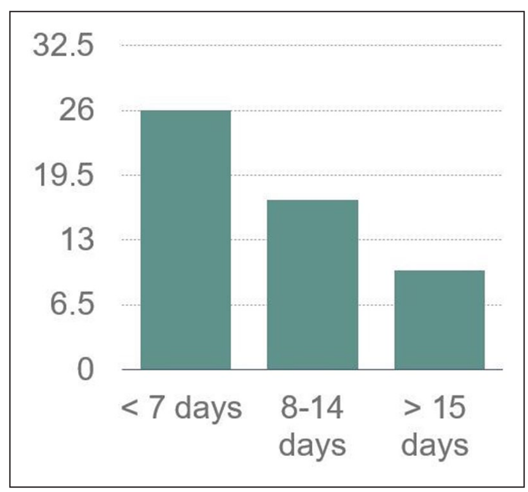

Figure 4. Time to complete return to normal active knee extension.

late recovery of quadriceps function and the initial DDH severity or the treatment failure (Table 2).

Discussion

FNP is a fairly common complication of Pavlik harness treatment for DDH and seems to occur more frequently than what is reported in the literature. Although the

Table 2. Correlation between treatment failure (TF), FNP, and time for complete resolution (TCR) of FNP.

	TF 21 hips	FNP 53 hips	TCR (days)			p1 value TF/FNP p2 value TF/TCR
			<7 26 hips	7–14 17 hips	>15 10 hips	
Tonnis 1 140 hips	0	8	4	2	2	N/A
Tonnis 2 159 hips	0	7	4	1	2	N/A
Tonnis 3 208 hips	15	28	12	12	4	p1 = 0.160* p2 = 0.387*
Tonnis 4 20 hips	6	10	6	2	2	p1 = 0.999* p2 = 0.999*

TF: treatment failure; FNP: femoral nerve palsy; N/A: not applicable.
*$p > 0.05$.

majority of studies dealing with Pavlik harness warn against FNP, we found sporadic reports in the literature of only very few cases listed within the complications of this treatment in DDH. To the best of our knowledge, there is only one published study in the literature solely dedicated to this complication. Murnaghan et al.[14] reported 30 cases of FNP out of a group of 1218 treated DDH patients with an incidence of 2.5%. It is not clear if this reported number relates to those patients with complete loss of active knee extension or to all patients with knee extension deficit of various severity since the incidence of FNP identified in our current study is four times greater and includes cases with partial and total impairment of quadriceps function. Whether the high incidence in our study is related to immediate hip flexion at the day of harness installation or the prolonged time between one control visit and the other during the first month of treatment (2 weeks) is still to be proven since variable regimens have been reported in the literature with no significant difference between them.[25–27] One of our study's limitations is that we have documented the recovery, but not the temporal occurrence of FNP after harness application. In fact, most FNP were diagnosed at the first 2-week visit, but had the first follow-up been earlier, a more accurate time of occurrence of this complication may have been possible.

The major point worth debating is the one related to the name of this particular complication. Since there is no electrophysiological evidence that the DAKE observed in extreme hip flexion is due to femoral nerve compromise under the inguinal ligament, it may not be appropriate to qualify this complication as a nerve palsy. The results of our study, that is, the full recovery of the quadriceps function in all our cases, with strap adjustment only, but still to a hip flexion angle in the harness greater than 90°, and with no need for complete harness removal as advocated in the literature[14,17,28] are in line with a possible lever arm dysfunction of the quadriceps muscle in extreme hip and knee flexion, and our hypothesis concerning the biomechanical creep property of living organs mainly viscoelasticity.

In this study, DAKE was most observed in higher Tonnis grades, and in larger and older children, similar to the findings by Murnaghan et al.[14] who identified 30 cases of "FNP" out of 1218 infants. They showed that the palsy group patients were older (56 versus 22 years), taller (55 versus 51), and heavier (4.8 versus 3.7 kg) than the control group, and their DDH was of higher severity. However, in our study, the presence of DAKE by itself was not predictive of treatment failure, and this is in opposition to Murnaghan's results or rather to their interpretation. In fact, 24/30 "FNP" reported in their series were treated by either a temporary suspension of Pavlik treatment until complete recovery of femoral nerve function or definitive abandonment of the harness. This is what probably contributed to the increased number of failed cases among the group of children who developed "FNP" and led to the conclusion that FNP is highly predictive of treatment failure. However, we did not find any correlation between the time taken for spontaneous resolution and the treatment failure using the harness, in opposition to the results by Murnaghan et al.[14]

The most significant risk factors for DAKE seem to be DDH severity and hip flexion angle in the harness. DAKE resolves spontaneously before completion of treatment without any specific measures, and therefore does not require any strap release other than the one required to bring the thighs to 90° flexion. The results of the current study cannot support the known practice of harness abandonment if a deficit of active knee extension occurs during the course of treatment.

In conclusion, this study offers a fair amount of new information pertaining to FNP as a possible complication of Pavlik harness use in DDH. The first one relates to the known name of the condition to which we prefer the "DAKE" in the absence of evidence of nerve compromise.

It is most observed in higher Tonnis types, but its presence by itself is not predictive of treatment failure. The most significant risk factors for DAKE seem to be DDH severity and hip flexion angle in the harness. DAKE resolves spontaneously before completion of treatment without any specific measures, and therefore does not require any drastic strap release or harness discontinuation.

Author contributions

I.G. is the principal investigator, contributed to the study design and article writing; G.K. participated in data collection; D.G. participated in data analysis; and I.S. provided critical feedback.

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.

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Ethical approval

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. This study was approved by the Institutional Review Board of Saint Joseph's University (CEHDF 2127).

Informed consent

Not required.

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