

Age of initiation of treatment for hip dysplasia with Pavlik harness and residual dysplasia

Edad de inicio del tratamiento de la displasia de caderas con correas de Pavlik y displasia residual

Francesca Moller^{a,d}, Ismael Cañete^{a,b}, Catalina Vidal^{a,e}, María Jesús Figueroa^{a,b}, Renato Navarro^{c,f}, Angélica Ibáñez^a, Felipe Hodgson^{a,b}

^aDepartamento de Ortopedia y Traumatología, Pontificia Universidad Católica. Santiago, Chile.

^bTraumatología Infantil, Hospital Sótero del Río. Santiago, Chile.

^cEscuela de Medicina, Facultad de Medicina, Pontificia Universidad Católica. Santiago, Chile.

^dResidente.

^eKinesióloga.

^fAlumno de Medicina.

Received: December 6, 2021; Approved: March 15, 2022

What do we know about the subject matter of this study?

Hip dysplasia is a common pathology, and its early diagnosis and timely treatment are essential to achieve the best functional outcomes. Between 3-33% of patients who achieve a good outcome at the beginning develop long-term residual dysplasia.

What does this study contribute to what is already known?

Our study showed an increase in the risk of residual dysplasia the older the age of treatment initiation, observing that starting treatment after 4.5 months of life increases the risk by 2.5 times, with early diagnosis and treatment being relevant.

Abstract

The successful treatment of hip dysplasia consists of achieving a concentric reduction and avoiding residual dysplasia. One of the essential factors is early diagnosis and treatment. **Objective:** Evaluate the relationship between the age at initiation of hip dysplasia treatment and the presence of residual dysplasia at one year of age. **Patients and Method:** Prognostic retrospective study. Patients with hip dysplasia treated with Pavlik harness in a tertiary healthcare center were selected. Residual dysplasia was defined as an acetabular index greater than 28 degrees at one year of age. An association of residual dysplasia with the age at treatment initiation, bilaterality, and acetabular index more than 36 degrees was determined. The T-Student, Chi-Square, and Youden index tests were used. A p-value < 0.05 was considered significant. The STATA v.16 software was used. **Results:** 153 patients

Keywords:

Developmental
Dysplasia of the Hip;
Hip Dysplasia;
Conservative
Treatment;
Neonatal Screening

(262 hips) were included, 84.3% (129) were females, and 71.2% (109) presented bilateral dysplasia. Fifty-nine hips (22.52%) presented residual dysplasia, finding a significant association with the age at treatment initiation ($p = 0.03$), bilateral dysplasia ($p < 0.01$), and acetabular index greater than 36 degrees ($p = 0.01$). Starting treatment after 4.5 months increases the risk of residual dysplasia by 2.5 times (95% CI 1.25-5.03). **Conclusion:** An increase in residual dysplasia was observed at the start of treatment after 4.5 months. It is relevant to consider this result in local clinical guidelines to achieve a successful diagnosis and treatment.

Introduction

Developmental dysplasia of the hip (DDH) includes a wide spectrum of pathologies, ranging from acetabular dysplasia to irreducible hip dislocation. The incidence of hip dysplasia ranges from 1.6 to 28.5 cases per 1000 newborns, depending on the definition and the population studied^{1,2}. In Chile, its incidence is estimated at 1 per 500 to 600 live newborns (LNB) in subluxation and dislocation forms, resulting in 400 to 460 cases per year throughout the country³.

In our country, DDH is a pathology included in the Explicit Health Guarantees (GES), which guarantees universal screening with an anteroposterior pelvic X-ray for all children at 3 months of life. In case of risk factors (family history or breech presentation) or suspicion of dysplasia in the physical examination, an ultrasound is performed between the fourth and sixth week of life, or an X-ray from one month of age if ultrasound is not available^{3,4}. In addition, GES determines deadlines for diagnostic confirmation by a specialist and initiation of treatment, defining the maximum starting age at 5.5 months³. After the implementation of this program, the incidence of major procedures for DDH (open reduction and osteotomies) is estimated at 0.18 per 1000 LNB, showing a significant reduction of these procedures with respect to minor surgeries for DDH⁵. This screening methodology agrees with that proposed by the Latin American Society of Child Orthopedics and Traumatology (SLAOTI) in 2016⁶.

Early diagnosis and timely treatment are essential to achieve the best functional outcomes⁷. The first-line treatment is Pavlik harnesses (PHs) which reports a success rate between 75-90%^{7,8} and is the standard treatment in children under 6 months^{8,9}, with a success rate between 46-65% in dislocated hips in patients older than 6 months^{10,11}.

Two aspects should be considered when defining successful treatment. The first is to achieve concentric reduction in subluxation and dislocation and adequate imaging control at the end of treatment^{12,13}. The second is to maintain proper hip development during childhood¹² and to avoid long-term hip osteoarthritis^{14,15}. Between 3-33% of patients who achieve adequate

te results with PHs develop long-term residual dysplasia^{12,16-19}. However, the literature is not clear regarding the risk factors for its development.

The objective of this study is to evaluate the relationship between the age at the start of PHs treatment and the presence of residual dysplasia at one year of age. Secondarily, risk factors associated with residual dysplasia are evaluated.

Patients and Method

Retrospective prognostic study approved by the institutional ethical-scientific committee.

Patients with DDH treated between 2018 and 2019 with PHs in a tertiary public hospital were selected by convenience sampling method. Patients included were those with a clinical and radiological diagnosis of DDH, with an acetabular index ≥ 30 degrees on the initial radiograph, who were treated with PHs, and who completed a minimum follow-up of 1 year of live. Patients with neuromuscular pathologies or associated genetic syndromes, who did not complete treatment at our center, who reported insufficient time of daily use, or who required surgical treatment during follow-up were excluded.

The following clinical data of the patients were collected: date of birth, date of treatment initiation, sex, and major risk factors (first-degree family history, breech presentation). Based on the diagnostic radiograph, laterality and degree of dysplasia were determined according to the International Hip Dysplasia Institute (IHDI) classification²⁰. Patients with indication of PHs treatment had to use them for 23 hours a day until the treating physician decided to withdraw them or until another treatment was needed. In case of patients who did not tolerate PHs due to age, it was decided to use an abduction orthosis to continue treatment, as suggested in the literature²¹.

The total duration of treatment and the progressive withdrawal if indicated after the end of treatment (use of harness at night for 1 to 2 months) were recorded. Radiographs of the patients were evaluated at the end of treatment and at one year of age. Residual dysplasia

was defined as an acetabular index > 28 degrees at one year of age, as proposed by the literature^{12,13} and according to local guidelines³.

Statistical analysis

Categorical variables are presented as absolute and relative frequency and quantitative variables as median and minimum-maximum range. Normality was tested with the Shapiro-Wilks test. The sample size was calculated based on the study by Novais et al.¹² to determine the proportion of patients with residual dysplasia at one year of age. A sample size of 160 hips was estimated, with a confidence interval of 95% and a 5% margin of error.

The association between residual dysplasia and age at treatment initiation, sex, bilateral involvement, acetabular index at treatment initiation > 36 degrees⁹, degree of dysplasia according to IHDI, family history, breech presentation, and progressive removal of PHs was evaluated with the t-student test for independent samples and chi-square test. The Youden index was used through a ROC curve to identify the threshold of numerical variables, in which sensitivity and specificity are maximal for predicting residual dysplasia. A bivariate and multivariate correlational analysis was performed using stepwise logistic regression, reporting

odds ratio (OR). Values $p < 0.05$ were considered significant. STATA v16 software was used.

Results

A total of 153 patients were included. Table 1 shows their demographic characteristics. Since 109 patients presented bilateral dysplasia, 262 hips were considered in the analysis. Table 2 shows radiological characteristics.

At one year of age of the patients, residual dysplasia was observed in 59 hips (22.52%). A statistically significant difference was observed between the mean age at treatment initiation of patients with residual dysplasia (5.20 ± 0.15 months) and those without residual dysplasia (4.88 ± 0.08 months) ($p = 0.0327$). It was determined that an age greater than 4.5 months (136 days) presented the highest sensitivity (74.6%; CI 95%) and specificity (43.3%; CI 95%) in relation to residual dysplasia.

In the bivariate correlational analysis, a statistically significant association was observed between residual dysplasia and bilateral dysplasia ($p = 0.002$) and acetabular index at the beginning of treatment > 36 degrees ($p = 0.011$). No significant differences were observed by sex ($p = 0.513$), family history ($p = 0.061$), breech presentation ($p = 0.799$), or progressive removal of PHs ($p = 0.993$). 23.66% of the hips were classified as subluxated (IHDI II) at the beginning of the treatment; of these, 18 (29.03%) presented residual dysplasia at the end of the treatment. No statistically significant differences were found between the degree of dysplasia according to IHDI and residual dysplasia ($p = 0.16$).

In the multivariate correlational analysis, the association between residual dysplasia at one year of age and the start of treatment after 4.5 months was evaluated according to sex, bilateral dysplasia, and acetabular index > 36 degrees at the start of treatment, showing a statistically significant association ($p = 0.001$). The age at treatment initiation after 4.5 months increases the risk of residual dysplasia by 2.5 times (OR 2.5; CI 95% 1.25-5.03).

Discussion

The objective of this study was to evaluate the relationship between the age of initiation of treatment with the Pavlik harnesses and the incidence of residual dysplasia at one year of age. A total of 262 hips were evaluated and 22.52% presented residual dysplasia. An increase in the risk of residual dysplasia was determined the older the age of initiation of treatment, observing that an age of initiation > 4.5 months increases the risk by 2.5 times.

Table 1. Demographic characteristics of the included patients (n=153 patients)

Variable	n (%) / Median (Range)
Female	129 (84.3%)
Bilateral dysplasia	109 (71.2%)
First degree family history	33 (21.6%)
Breech presentation	11 (7.2%)
Limitation of abduction on physical exam	18 (11.8%)
Age of onset of treatment	4.7 months (3.0 a 9.1 months)
Progressive withdrawal	96 (62.8%)
Use of abduction braces	23 (15.0%)

Table 2. Radiological characteristics of the included hips (n=262).

Variable	n (%) / Median (Range)
Lateralidad	
Right	127 (48.47%)
Left	135 (51.53%)
IHDI	
I	200 (76.34%)
II	62 (23.66%)
III and IV	0
Acetabular index at start of treatment	32 degrees (30-43)
Acetabular index > 36 degrees	26 (9.92%)

IHDI: International Hip
Dysplasia Institute Classification

In relation to epidemiological characteristics, the literature reports a higher incidence of DDH in women²² which agrees with our data, however, a higher incidence of left and then bilateral dysplasia is reported⁷, which contrasts with our data where bilateral dysplasia was more frequent. In relation to risk factors, breech presentation was between 17.3% and 32% of children^{23,24} and family history was present in 30% of cases²²; values higher than those found in our data.

Between 3-33% of patients who complete treatment with PHs develop long-term residual dysplasia^{12,16-19}. However, the definitions of residual dysplasia used in the studies are variable and there are limited and contradictory data on the associated risk factors. In our case, the incidence of residual dysplasia at one year of age (22.5%) agrees with the literature and may be partly explained by the fact that at one year of age the hip is still developing.

Regarding the age of initiation of treatment with PHs, some studies have shown that late initiation is associated with treatment failure^{8,9,25}. In relation to residual dysplasia, the study by Fujioka et al.²⁶ evaluated 129 hips treated with PHs with an average follow-up of 20 years. Patients were subdivided into those who used PHs before and after 4 months of age, and no significant differences were found between age at treatment initiation and final center-edge angle. However, a systematic review²⁷ in this regard states that given the variability of the studies, it is not possible to determine the effect of age at initiation on the progression to residual dysplasia with the available evidence.

Our analysis showed that treatment initiation > 4.5 months would be a predictor of residual dysplasia, which is consistent with studies that have reported greater treatment failure in patients older than 4 months^{8,9,25}. It is relevant to highlight that our study considers mostly patients with acetabular dysplasia, that are not considered in most of the international studies mentioned, which evaluate patients with subluxation or dislocation diagnosed early with ultrasound; therefore, it would be the first study to report data in this matter.

The GES guidelines define 5.5 months as the maximum starting age³; however, it allows initiation of treatment with PHs up to 10 months of age. It is worth mentioning that, despite the current regulations, more than half of our patients started treatment over this age (median of the sample 4.7 months), so it would be relevant, given the results of our study and what is reported in the literature, to shorten the time between screening (3 months), confirmation, and initiation of treatment to favor early initiation of treatment.

Other risk factors that could be related to residual dysplasia have been evaluated, for example, one study¹⁸ mentions that there is no relationship between residual dysplasia and sex. Another case-control study²⁸ that compared progressive PHs removal found no significant differences in reintervention or acetabular index at one and two years of age. Both studies agree with our results. Family history has been associated with a higher acetabular index at one year of age²⁹, a variable that was not significant in our analysis.

Given the scarce literature reporting risk factors for residual dysplasia, variables that have been associated with treatment failure such as bilateral dysplasia^{25,30-32}, subluxation³³, and an acetabular index > 36 degrees⁹ were considered in our analysis, finding a significant association with bilateral dysplasia and an acetabular index > 36 degrees.

One of the main limitations of our study is that the definition of residual dysplasia is not clear in the literature. It is also not known whether patients with residual dysplasia at one year of age can progress and require treatment or whether it resolves spontaneously, so it would be relevant to have a precise definition and long-term studies. In addition, it is possible that our study presents selection bias, having used a convenience sampling method with a short-term follow-up, and that there are confounding variables that have not been considered in our analysis. It is worth mentioning that, to avoid measurement and classification error, these were performed by a single investigator, blinded to clinical data.

Conclusions

This study shows an association between the age of initiation of treatment with Pavlik harnesses and residual dysplasia, observing a significant increase in those older than 4.5 months, consistent with data reported in the literature.

In addition, considering that more than half of our patients started treatment over this age, we consider relevant to evaluate the deadlines of local guidelines to ensure early initiation of treatment.

Ethical Responsibilities

Human Beings and animals protection: Disclosure the authors state that the procedures were followed according to the Declaration of Helsinki and the World Medical Association regarding human experimentation developed for the medical community.

Data confidentiality: The authors state that they have followed the protocols of their Center and Local regulations on the publication of patient data.

Rights to privacy and informed consent: The authors have obtained the informed consent of the patients and/or subjects referred to in the article. This document is in the possession of the correspondence author.

Conflicts of Interest

Authors declare no conflict of interest regarding the present study.

Financial Disclosure

Authors state that no economic support has been associated with the present study.

References

- Bialik V, Bialik GM, Blazer S, et al. Developmental Dysplasia of the Hip: A New Approach to Incidence. *Pediatrics*. 1999;103(1):93-9.
- Dezateux C, Rosendahl K. Developmental dysplasia of the hip. *Lancet*. 2007;369(9572):1541-52.
- Ministerio de Salud, Chile. Guía GES: Displasia luxante de caderas. 2010; <http://www.bibliotecaminal.cl/wp/wp-content/uploads/2016/04/Displasia-de-Cadera.pdf> última visita 10-11-2021
- Graf R. Fundamentals of Sonographic Diagnosis of Infant Hip Dysplasia. *J Pediatr Orthop*. 1984;4(6):735-40.
- Sepúlveda MF, Pérez JA, Saban EA, et al. Developmental dysplasia of the hip screening programme in Chile. *J Child Orthop*. 2021;15(1):35-41.
- Sociedad Latinoamericana de Ortopedia y Traumatología infantil. Propuesta de Recomendación para Detección Precoz de la Displasia del Desarrollo de Caderas SLAOTI. 2016; <https://slaoti.org/wpcontent/uploads/2020/Docs/4%20Tefa%20PESQUISA%20SLAOTI.pdf> última visita 10-11-2021
- Kotlarsky P. Developmental dysplasia of the hip: What has changed in the last 20 years? *World J Orthop*. 2015;6(11):886.
- Ömeroğlu H, Köse N, Akceylan A. Success of Pavlik Harness Treatment Decreases in Patients ≥ 4 Months and in Ultrasonographically Dislocated Hips in Developmental Dysplasia of the Hip. *Clin Orthop Relat Res*. 2016;474(5):1146-52.
- Inoue T, Naito M, Nomiya H. Treatment of developmental dysplasia of the hip with the Pavlik harness: factors for predicting unsuccessful reduction. *J Pediatr Orthop B*. 2001;10(3):186-91.
- van de Sande MAJ, Melis F. Successful Pavlik treatment in late-diagnosed developmental dysplasia of the hip. *Int Orthop*. 2012;36(8):1661-8.
- Pollet V, Pruijs H, Sakkars R, et al. Results of Pavlik Harness Treatment in Children With Dislocated Hips Between the age of six and Twenty-four Months: *J Pediatr Orthop*. 2010;30(5):437-42.
- Novais EN, Sanders J, Kestel LA, et al. Graf Type-IV Hips Have a Higher Risk of Residual Acetabular Dysplasia at 1 Year of Age Following Successful Pavlik Harness Treatment for Developmental Hip Dysplasia. *J Pediatr Orthop*. 2018;38(10):498-502.
- Tönnis D, Brunken D. Eine Abgrenzung normaler und pathologischer Hüftpfannendachwinkel zur Diagnose der Hüftdysplasie. Auswertungen von 2294 Pfannendachwinkeln kindlicher Hüftgelenke [Differentiation of normal and pathological acetabular roof angle in the diagnosis of hip dysplasia. Evaluation of 2294 acetabular roof angles of hip joints in children]. *Arch Orthop Unfallchir*. 1968;64(3):197-228.
- Harris WH. Etiology of osteoarthritis of the hip. *Clin Orthop*. 1986;(213):20-33.
- Terjesen T. Residual hip dysplasia as a risk factor for osteoarthritis in 45 years follow-up of late-detected hip dislocation. *J Child Orthop*. 2011;5(6):425-31.
- Nakamura J, Kamegaya M, Saisu T, et al. Treatment for developmental dysplasia of the hip using the Pavlik harness: LONG-TERM RESULTS. *J Bone Joint Surg Br*. 2007;89-B(2):230-5.
- Tucci JJ, Kumar SJ, Guille JT, et al. Late Acetabular Dysplasia Following Early Successful Pavlik Harness Treatment of Congenital Dislocation of the Hip. *J Pediatr Orthop*. 1991;11(4):502-5.
- Alexiev VA, Harcke HT, Kumar SJ. Residual Dysplasia After Successful Pavlik Harness Treatment. *J Pediatr Orthop*. 2006;26(1):8.
- Prospective A, Cashman JP, Round J, et al. The natural history of developmental dysplasia of the hip after early supervised treatment in the Pavlik harness. *J Bone Joint Surg Br*. 2002;84(3):8.
- Narayanan U, Mulpuri K, Sankar WN, et al. Reliability of a New Radiographic Classification for Developmental Dysplasia of the Hip: *J Pediatr Orthop*. 2015;35(5):478-84.
- Sankar WN, Nduaguba A, Flynn JM. Ilfeld Abduction Orthosis Is an Effective Second-Line Treatment After Failure of Pavlik Harness for Infants with Developmental Dysplasia of the Hip: *J Bone Joint Surg Br*. 2015;97(4):292-7.
- Jashi RE, Gustafson MB, Jakobsen MB, et al. The Association between Gender and Familial Prevalence of Hip Dysplasia in Danish Patients. *Hip Int*. 2017;27(3):299-304.
- Barlow TG. Early diagnosis and treatment of congenital dislocation of the hip. *J Bone Joint Surg Br*. 1962;44-B(2):292-301.
- Dunn PM. Perinatal observations on the etiology of congenital dislocation of the hip. *Clin Orthop*. 1976;(119):11-22.
- Atalar H, Sayli U, Yavuz OY, et al. Indicators of successful use of the Pavlik harness in infants with developmental dysplasia of the hip. *Int Orthop*. 2007;31(2):145-50.
- Fujioka F, Terayama K, Sugimoto N, et al. Long-term results of congenital dislocation of the hip treated with the Pavlik harness. *J Pediatr Orthop*. 1995;15(6):747-52.
- Shaw KA, Moreland CM, Olszewski D, et al. Late acetabular dysplasia after successful treatment for developmental dysplasia of the hip using the Pavlik method: A systematic literature review. *J Orthop*. 2019;16(1):5-10.
- Westacott DJ, Mackay ND, Waton A, et al. Staged weaning versus immediate cessation of Pavlik harness treatment for developmental dysplasia of the hip. *J Pediatr Orthop B*. 2014;23(2):103-6.
- Theunissen WWES, van der Steen M, van Douveren FQMP, et al. Timing of Repeat Ultrasound Examination in Treatment of Stable Developmental Dysplasia of the Hip. *J Pediatr Orthop*. 2021;41(4):203-8.
- Viere RG, Birch JG, Herring JA, et al. Use of the Pavlik harness in congenital dislocation of the hip. An analysis of failures of treatment. *J Bone Joint Surg Am*. 1990;72(2):238-44.
- Lerman JA, Emans JB, Millis MB, et al.

Early failure of Pavlik harness treatment for developmental hip dysplasia: clinical and ultrasound predictors. *J Pediatr Orthop.* 2001;21(3):348-53.

32. Kitoh H, Kawasumi M, Ishiguro N. Predictive factors for unsuccessful treatment of developmental dysplasia of the hip by the Pavlik harness. *J Pediatr*

Orthop. 2009;29(6):552-7.

33. Suzuki S. Ultrasound and the Pavlik harness in CDH. *J Bone Joint Surg Br.* 1993;75-B(3):483-7.