SANAMED
2022; 17(3): 151–157
ISSN-1452-662X

DOI: 10.5937/sanamed0-40197
UDK: 616.728.2-007.23-76
ID: 83618313
Original article

OUTCOMES OF ULTRASOUND-MONITORED TREATMENT OF DIVELOPMENTAL DYSPLASIA OF THE HIP GRAF TYPE II

Djoleva Tolevska Roza,[1] Matveeva Niki,[2] Georgieva Daniela,[1]
Bojadzieva Stojanoska Biljana[2]

[1] University Clinic for Orthopedic Surgery, Faculty of Medicine,
Ss. Cyril and Methodius University, Skopje, RN Macedonia
[2] Institute of Anatomy, Faculty of Medicine,
Ss. Cyril and Methodius University, Skopje, RN Macedonia

Primljen/Received 17. 09. 2022. god. Prihvaćen/Accepted 06. 10. 2022. god.

Abstract: **Introduction:** The management of developmental dysplasia of the hips (DDH) type Graf IIa is still controversial. This study aims to examine the outcomes of ultrasound-monitored Pavlik harness treatment, as well as the effects of associated factors, such as gender, side of DDH, the age at the treatment start, and laterality on the treatment outcomes in different Graf type II subtypes.

Methods: A cohort retrospective investigation was performed on 88 ultrasound-screened infants or 125 hips diagnosed with Graf type II dysplasia during a six-month period at a single institution, the University Clinic for Orthopedic Surgery, Skopje. Subsequently, 47 infants (18 boys, 29 girls) or 73 hips who underwent Pavlik harness treatment with at least one follow-up throughout treatment monitoring were included in this study.

Results: The treatment success rate of the right DDH Graf type IIa (-) was higher (70.8%) compared to the rate of success (50%) in the treatment of left Graf type IIa (-) hips. The mean age of the infants at the treatment start in successfully treated Graf type IIa (-) hips was lower (9.12 ± 2.27 weeks) compared to the age of the infants with treatment failure at the last follow-up (11.33 ± 3.06 weeks), P = 0.04.

Conclusion: The age of treatment initiation and the side of DDH were the most relevant factors related to the treatment outcome. Infants with maturational deficit hips, Graf type IIa (-), should undergo early initiated, carefully guided, and monitored Pavlik harness treatment.

Key Words: Developmental dysplasia of the hip (DDH), Pavlik harness, Ultrasonography, Graf type II.

INTRODUCTION

Developmental dysplasia of the hip (DDH) has no single causative factor but is considered a multifactorial trait. Familiar positive history, certain racial predisposition, female gender, firstborn children, tweens, breech presentation, oligohydramnios, and presence of other orthopedic problems like postural deformities, foot deformities, torticollis, and other skeletal and muscular abnormalities are widely accepted as proven risk factors (1, 2, 3). Latest investigations suggest that prematurity is not a risk factor for DDH, but a rather protective factor for hip development (4).

The variation in the reported incidence of DDH among different populations leads to the lack of consensus regarding the treatment protocol for this condition. Many authors suggest implemetning a protocol that includes clinical and ultrasonography examinations for DDH in high-risk individuals (5, 6, 7). Because of the high incidence of DDH in our country, a combined protocol that includes universal mandatory physical examination and ultrasound hip screening up to 8 weeks of age has been accepted. Ultrasound examination of the hips enables the detection of abnormal position, instability, and dysplasia not evident by the physical examination. All infants undergo an ultrasound examination of the hips periodically (2 or 3 times after a 2 months period). Hips that featured sonographic pathology are subject to treatment and monitoring with ultrasonography. DDH treatment is still a controversial issue, and there is no current consensus on the best treatment approach. There are still controversial approaches to the treatment of Graf type IIa hips or physiologically immature hips. In these

hips, the risk of developing true dysplastic hips is about 10% (8). In Graf IIa (+) hips' physiological maturation is acceptable (alpha angle is between 55°-59° at 6 weeks of age), on the other hand, in Graf IIa (-) hips' physiological maturation is beyond acceptable limits (alpha angle is between 50°-54° at 6 weeks of age). Bilgili et al. determined the cut-off value of 55° on initial sonography as an independent predictor of worsening sonographic findings (9). It has been reported that 85% of Graf type IIa (-) hips have developed into normal hips without any treatment by the age of 3 months and then enter a plateau period during the 4 to 6th month (10). Anyway, many infants with DDH Graf type IIa remain at risk of developing true dysplastic hips if not treated, so our protocol includes Pavlik harness treatment of the maturational deficit Graf type IIa (-) hips. Our study aimed to examine the outcomes of ultrasound-monitored Pavlik harness treatment of Graf type II hips, as well as the effect of associated factors, such as gender, side of DDH, age at the treatment start, and laterality on the treatment outcome in different Graf type II subtypes (Graf IIa (-), IIb and IIc).

AIM

This study aims to examine the outcomes of ultrasound-monitored Pavlik harness treatment, as well as the effects of associated factors, such as gender, side of DDH, the age at the treatment start, and laterality on the treatment outcomes in different Graf type II subtypes.

MATERIALS AND METHODS

An institutional review board-approved retrospective investigation was performed on 88 ultrasound-screened infants, or 125 hips diagnosed with Graf type IIa(-), IIb, and IIc dysplasia during a six-month period (from September 2020 to February 2021) at a single institution, the University Clinic for Orthopedic Surgery, Skopje, R. North Macedonia. Subsequently, 47 infants (18 boys, 29 girls) with 73 DDH Graf type II hips (54 IIa (-), 9 IIb, and 10 hips IIc) who had their first ultrasound hip scan, and at least one follow-up examination throughout treatment monitoring during this period were included in the study. All infants underwent ultrasonography examination with the ultrasound system Phillips, affinity 30, Sonda L12.4. Infants with skeletal dysplasia, metabolic bone disease, and congenital coxa vara were excluded. Informed consent was obtained from the parents of the children included in the study. The data obtained from the infants' medical records were evaluated again by two independent observers. Inter-observer reliability was assessed using ICC (intra-class correlation coefficient), and the agreement was considered excellent. The Ethics Committee of the Faculty of Medicine in Skopje approved the design and the content of this study. All procedures performed in study were in accordance with the institutional and national research committee's ethical standards and with the 1964 Helsinki declaration and its later amendments.

All newborns in our country are subject to a physical examination of the hips immediately after birth in the hospital neonatology departments using Ortolani and Palmen Barlow tests carried out by an orthopedic professional to assess hip stability. Also, gluteal fold asymmetry and passive range of motion are checked for normal or reduced hip abduction. Infants with abnormal physical examination findings are referred to earlier mandatory ultrasound hip examination up to 4 weeks after delivery. Each newborn, in addition to the clinical examination, undergoes an ultrasound examination of the hips up to 8 weeks of age. The examination is carried out by orthopedic professionals trained in performing ultrasound examinations by Graf's technique (Figure1) (11). The centricity of the femoral head, the bony and cartilaginous acetabular rim, the shape of the acetabulum and its labrum, and the alpha and beta angle for measurement of the acetabular dysplasia are notified and analyzed. Data on age, sex, the existence of hereditary predisposition, the presence of risk factors during labor (breech presentation), and the diagnosis of other orthopedic abnormalities or hip instability are evidenced in the medical records and kept in the Clinic for Orthopedic Surgery.

Our protocol used in decision-making for the treatment of hip dysplasia Graf type II is as follows: Graf type I and Graf type IIa (+) hips are discharged, Graf type IIa (-), Graf type IIb and Graf type IIc hips receive Pavlik harness treatment immediately and are closely monitored by repeated ultrasound scans (in 3-4 weeks

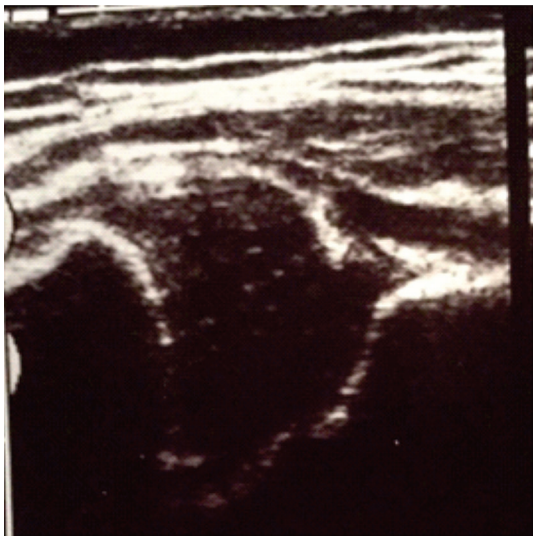

Figure 1. *Ultrasound image of DDH Graf type IIa(-)*

intervals) during the treatment period. The treatment is discontinued if the ultrasound examination reveals Graf type I or IIa+ hip. Following the termination of the treatment, we recommend a one-month extension of the treatment with 12 hours (during the night) of Pavlik harness treatment per day. First radiography for the validation of the dysplastic hip is recommended at five months of age. If residual hip dysplasia persists, radiographic follow-up of such hips is recommended at the 1st and 2nd year of age, although the risk of avascular necrosis of the femoral head is negligible in Pavlik harness treatment of Graf type II hips.

Data were statistically analyzed with SPSS for Windows (version 23 SPSS, Chicago, IL, USA). Chi-squared or Fisher's exact test was used to detect differences in treatment outcomes (success or failure) related to gender, side of pathology, and laterality. Student t-test was used to determine differences in outcomes associated with the infants' age at treatment initiation. Statistical significance was defined as $p < 0.05$.

RESULTS

During the six-month period, a total of 2958 infants underwent an ultrasound examination of the hips. In the medical records of 93 infants (29 boys, 64 girls), at least one DDH was diagnosed. On the first ultrasound scan, 99 hips in 65 infants were detected as Graf type IIa (-), 13 hips in 12 infants as Graf type IIb and 13 hips in 11 infants as Graf type IIc. Seven newborn infants had positive familial history, 25 newborns were delivered by a cesarean section and 6 newborns had a confirmed breech presentation during delivery. Subsequently, 47 infants (18 boys, 29 girls), or 73 hips with DDH Graf type II (54 hips Graf type IIa (-), 9 hips Graf type IIb, and 10 hips Graf type IIc) who underwent treatment and had at least one follow up throughout the treatment period were included in the study. Infants with at least one-sided DDH Graf type IIa (-), IIb, and IIc were subject to abduction brace and Pavlik harness treatment. The abduction brace and Pavlik harness treatment commenced immediately after establishing the diagnosis. Of the total of 47 infants with DDH Graph type II, who were monitored for a minimum of 1 to a maximum of 6 months (mean monitoring time 2.58 ± 1.31 months), success in the treatment in at least one-sided DDH Graf II hip was achieved in 25 (53%) infants. Throughout the treatment period, 42 (57.5%) of 73 monitored Graf II hips developed into normal hips. 31 hips were still considered as DDH on the last follow-up. The treatment of DDH Graph IIa (-) and Graf IIb hips showed higher success rates, 32/54, (60.4%) Graf type IIa (-) hips and 6/9, (66.7%) Graf type IIb hips developed into normal hips. Of the total of 22 Graf type IIa (-) hips diagnosed as treatment failure on the last follow-up, only 3 hips were still observed as hips with a maturational deficit, while most of these hips, 19/54 turned into true dysplastic hips Graf type IIb. The success rate of treatment of Graf type IIc hips was lower, only 4/10 (40%) of Graf type IIc hips developed into normal hips during the monitoring period.

The mean length of the ultrasound monitoring treatment period in infants with successfully treated DDH was 2.48 ± 1.07 months, almost the same as the mean length of the treatment period in infants with failure of DDH treatment on the last follow-up, 2.46 ± 1.26 months.

Gender

Of the total of 29 newborn girls with DDH Graf type II included in the investigation, success in the treatment of at least one DDH was achieved in 17 (58.6%) girls. Of the 18 included newborn boys with DDH Graf type II, success was achieved in 13 (72.2%) boys. Almost the same success was achieved in the treatment of DDH Graf type IIa (-) in male and female infants; 59% of the hips with a maturational deficit in boys and 59,4% of IIa (-) hips in girls developed into normal hips throughout the treatment monitoring period (Figures 2 and 3).

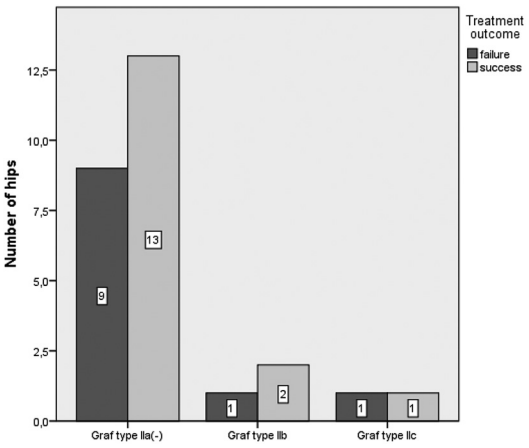

Figure 2. *Treatment success/failure by Graf type in male infants*

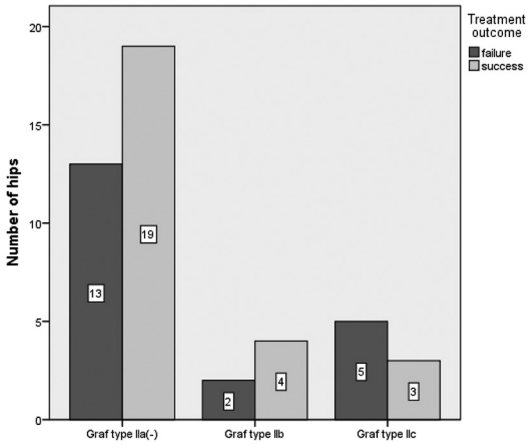

Figure 3*. Treatment success/failure by Graf type in female infants*

Side of DDH

Pavlik harness treatment was more successful in the right-sided DDH compared to the left-sided DDH. Of the total of 34 right-sided DDH Graf type II, 21 (61.8%) hips developed into normal hips, and of 39 left-sided DDH Graf type II, 21 (53.8%) hips turned into normal hips on the last follow-up (Figures 4 and 5). Even more, the treatment success rate of the right DDH Graf type IIa (-) was higher (70.8%) compared to the rate of success (50%) in the treatment of left Graf type IIa (-) hips.

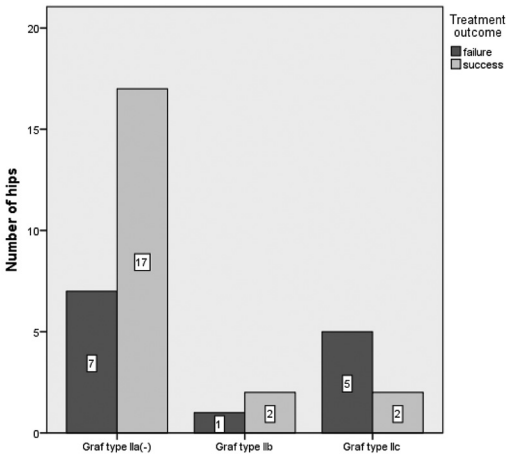

Figure 4. *Treatment success/failure by Graf type in right DDH*

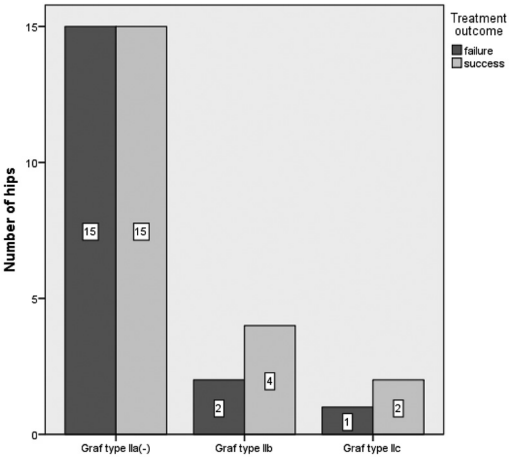

Figure 5*. Treatment success/ failure by Graf type in left DDH*

Age at the treatment start

The age of the infants at the treatment initiation was found to be statistically different (p = 0.02) between successfully treated infants, 9.52 ± 3.69 weeks, and infants with treatment failure on the last follow-up, 11.74 ± 4.02 weeks in DDH Graf type II.

The mean age at the treatment start in successfully treated infants with DDH Graf type IIa (-) was significantly lower (9.12 ± 2.27 weeks) compared to the mean age of the treatment start in infants with treatment failure at the last follow-up (11.33 ± 3.06 weeks), P = 0.04. The mean age of the treatment initiation in successfully treated infants with DDH Graf type IIb was 15 ± 4.69 weeks, while in infants with treatment failure was 18.67 ± 6.11 weeks. In infants with DDH Graf IIc, the mean age of the treatment start was significantly lower (4.5 ± 1 weeks) in infants with treatment success compared to the age of the treatment start (11 ± 1.67 weeks) in infants with treatment failure on the last follow-up, p = 0.00 (Figure 6).

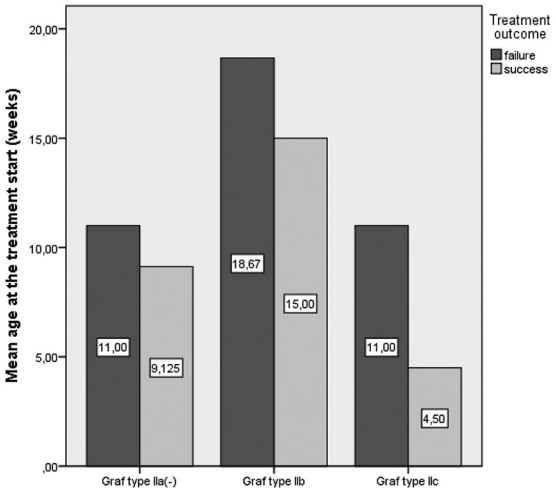

Figure 6. *Mean age of the infants at the treatment initiation in treatment failure/success of DDH Graf type IIa-, IIb and IIc*

Laterality

From 27 infants with bilateral DDH Graf type II, success in the treatment was evidenced in 14 (52%) infants. From 20 infants with unilateral DDH Graf type II, success in the treatment was evidenced in 11 (55%) infants.

DISCUSSION

Ultrasonography is not only a sensitive method for early diagnosis of DDH but a method of choice for treatment monitoring while treating DDH as well. It is a non-invasive sensitive method for visualization of bony and cartilage structures of newborn infants' hip joints. When used in treatment monitoring, it gives a possibility for multiple performances and for detecting minimal abnormalities of the hips that could not be diagnosed by a physical examination. In our country, ultrasonography is used for mandatory screening of infants' hips and treatment monitoring as well. Many European countries have also adopted universal ultrasound screening to confirm clinical findings. In North America, selective ultrasound screening is used only for infants with defined risk factors (breech presenta-

tion, family history, or clinical positive findings of hip instability). Distribution and implementation of DDH guidelines are necessary to improve the decision-making processes of pediatricians regarding the diagnosis and management of DDH (12, 13). In our study, 3.14% of infants who underwent ultrasound examination of the hips during the six-month period had at least one-sided DDH. Between the infants with DDH Graf type II, hips with maturational deficit Graf type IIa (-) were the most frequent finding (74% of DDH Graph type II) in our study. Many authors reported that 85% of DDH Grapf IIa (-) reached normality without any treatment at the end of the 3rd month of age (10). A greater number, even 35% of the hips with maturation deficit in our investigation turned into true dysplastic hips throughout the treatment monitoring period. A lot of infants with maturational deficit hips remain at risk for the development of true dysplastic hips, so we prefer to treat rather than follow up and include a routine Pavlik harness and abduction brace treatment of Graf type IIa (–) hips. For most of the infants included in the study, the treatment process had not been finished, therefore, only 57.5% of DDH Graf type II hips developed into normal hips. Our results confirm the necessity and significance of ultrasound hip screening. Experienced orthopedists can always detect dislocated and subluxated hips (Graf type III and IV), but the risk of missing Graf type IIa and Graf type IIb hips by physical examination always exists. Despite the earlier initiation of the Pavlik harness treatment in infants with DDH Graf type IIc (positive physical examination findings referred these infants to earlier ultrasound examination of the hips), the treatment success rate was lower (40%) compared to the success rate of the treatment of Graph IIa (-) and Graph IIb hips. The relatively low success rate of the treatment of Graph IIc hips in our investigation may have been due to the small number of infants included in the study and the relatively short period of treatment monitoring. Many authors reported that female gender and left-sided DDH were associated with the Pavlik harness treatment failure (10). For the hips with maturation deficit Graf type IIa (-), a lower rate of spontaneous maturation was reported in newborn girls (14,15). Our findings showed that the risk for the development of maturation deficit hips to true dysplastic hips was not associated with the infants' gender. Although Graf type IIa (-) hips have a potential for maturation, at least one follow-up after the initial diagnosis until the age of 3 months is required in order not to miss failure in the development of normal hips that remains is not a negligible number of these hips. These findings support our protocol according to which every newborn infant is referred to an ultrasound screening of the hips up to 8 weeks of age with close monitoring by repeated ultrasound scans (in 3-4 weeks intervals) during the treatment period. Graf type IIa (-) hips receive Pavlik harness treatment immediately and are closely monitored during the treatment period to avoid possible complications such as residual hip dysplasia and avascular necrosis. The entire system consists of early diagnosis, prevention, and treatment of dysplastic hip joints. The implementation of national and regional programs that promote ultrasound screening for DDH in both rural and urban areas can contribute to the early diagnosis and treatment of DDH in newborns and infants (16). Our findings showed that the treatment of physiologically immature Graf IIa (-) hips was more successful (70.8%) in the right hips compared to the rate of success (50%) in the treatment of the left DDH or the right DDH Graf type IIa (-) achieved earlier maturation and development into normal hips throughout the treatment monitoring period. Some authors found an increased rate of treatment failure in bilateral DDH (17,18), while others found no association between treatment failure and bilateral DDH (19, 20). Our findings showed no association between the treatment success and the laterality of DDH.

Most authors reported that successful treatment of DDH was associated with an early newborn hip screening at 4 to 8 weeks (21). German authors recommend replacing the current German screening guidelines for high-risk neonates with a general newborn screening for all neonates in the first week of life (22). Late detection causes an increased treatment complexity and a sevenfold increase in the short-term costs of treatment, compared to early detection and successful management in a Pavlik harness treatment (23). Our findings support the results of these studies, the younger age of the infant at the initial evaluation and treatment initiation was associated with a higher success rate of Pavlik harness treatment. The association between the treatment results and the age of treatment initiation was particularly evident in treating DDH Graf IIa (-) and IIc hips. Earlier treatment initiation could be the result of the positive physical examination in the maternity hospitals in more severe Graf types of DDH or the positive and responsible attitude of the parents who follow the instructions of orthopedic specialists and pediatric neonatologists. The parents who complied with the recommendations for early ultrasound examination of the hips are more responsible, more adapted to the use of Pavlik harness during the treatment period, and have a more serious and responsible approach to the treatment of their children. A mandatory ultrasound screening program is a sufficient tool for successful treatment results (24). Developing a program for wide health education of the newborns' parents that will in-

dicate the importance of early diagnosis and treatment of DDH could contribute to better treatment results. The limitations of this study were its retrospective design and a comparatively small number of patients.

CONCLUSION

The success in the treatment of DDH Graf type II is multifactorial, the age of treatment initiation and the side of DDH are the most prominent factors related to the treatment outcome. Infants with maturational deficit Graf type IIa (-) hips should undergo early treatment initiation, with carefully guided and monitored Pavlik harness treatment immediately after the diagnosis was established up to 8 weeks of age.

Abbreviations

ICC — Intra-class correlation coefficient
DDH — Developmental dysplasia of the hip

Acknowledgment None.

Conflict of Interests: The authors declare no conflicts of interest related to this article.

Funding: None

Licensing

Sažetak

REZULTATI ULTRAZVUČNO PRAĆENOG LEČENJA RAZVOJNE DISPLAZIJE KUKA GRAF TIP II

Djoleva Tolevska Roza,[1] Matveeva Niki,[2] Georgieva Daniela,[1] Bojadzieva Stojanoska Biljana[2]

[1] Univerzitetska klinika za ortopedsku hirurgiju, Medicinski fakultet, Univerzitet Sv. Ćirilo i Metodije, Skoplje, Severna Makedonija
[2] Institut za anatomiju, Medicinski fakultet, Univerzitet Sv. Ćirilo i Metodije, Skoplje, Severna Makedonija

Uvod: Lečenje razvojne displazije kukova (DDH) tipa Graf IIa je još uvek kontroverzno. Ova studija ima za cilj da ispita rezultate ultrazvučno nadgledanog lečenja Pavlikovim remenima, kao i efekte povezanih faktora, kao što su pol, strana DDH, starost na početku lečenja i lateralnost na ishode lečenja kod različitih podtipova Graf tipa II.

Materijal i Metode: Retrospektivna kohortna studija je sprovedena na 88 ultrazvučno pregledanih novorođenčadi ili 125 kukova kojima je dijagnostikovana Graf tip II displazija tokom šestomesečnog perioda u jednoj ustanovi, Univerzitetskoj klinici za ortopedsku hirurgiju, Skoplje. Potom je u ovu studiju uključeno 47 novorođenčadi (18 dečaka, 29 devojčica) ili 73 kukova koji su bili podvrgnuti lečenju sa Pavlikovim aparatom uz najmanje jedno praćenje tokom lečenja.

Rezultati: Stopa uspešnosti lečenja desnog DDH Graf tip IIa (-) bila je veća (70,8%) u poređenju sa stopom uspeha (50%) u lečenju levih Graf tip IIa (-) kukova. Prosečna starost odojčadi na početku lečenja u uspešno lečenim kukovima Graf tipa IIa (-) bila je niža (9,12 ± 2,27 nedelja) u poređenju sa uzrastom odojčadi sa neuspešnim lečenjem na poslednjem praćenju (11,33 ± 3,06 nedelja) , P = 0,04.

Zaključak: Starost početka lečenja i strana DDH su bili najrelevantniji faktori u vezi sa ishodom lečenja. Novorođenčad sa nerazvijenim kukovima, Graf tip IIa (-), treba da se podvrgnu rano započetom, pažljivo vođenom i praćenom lečenju Pavlikovim remenima.

Ključne reči: Razvojna displazija kuka (DDH), Pavlikovi remeni, Ultrasonografija, Graf tip II.

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Correspondence to/Autor za korespondenciju
Assoc. Prof. D-r Roza Djoleva Tolevska
University Clinic for Orthopedic Surgery, Faculty of Medicine, Ss. Cyril and Methodius University,
Vodnjanska 17, 1000 Skopje, RN Macedonia;
e-mail: dzoleva@yahoo.com; phone: +38970555656

How to cite this article: Djoleva Tolevska R, Matveeva N, Georgieva D, Bojadzieva Stojanoska B. Outcomes of ultrasound-monitored treatment of Divelopmental Dysplasia of the Hip Graf type II. Sanamed. 2022; 17(3): 151-157. Doi: 10.5937/sanamed0-40197.