



Brief Report

Watchful Waiting is a Safe Strategy Until four Weeks of age in Mild Developmental Dysplasia of the Hip

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Abstract

Introduction: Developmental dysplasia of the hip (DDH) varies from a mild instability to a complete dislocation of the femoral head. Ortolani and Barlow signs are widely used among clinicians to describe the stability of the hip joint. Whilst immediate abduction treatment is mandatory in Ortolani positive hips, there is still controversy in treatment protocol among infants with mild hip instability.

Material and methods: All children diagnosed with DDH and treated at Tampere University hospital in the years 1998-2018 were included. Data were collected retrospectively from the medical records. All with Ortolani positivity, late diagnosed DDH and/or teratological dislocations were excluded from the study. Total of 535 patients with mild DDH were included.

Results: Barlow positivity (OR 3.95, CI95% 2.69-5.77) ($p < 0.001$) and female sex (OR 1.74, CI95% 1.20-2.53) ($p = 0.003$) were positively associated with commencement of abduction treatment. Other studied risk factors did not have an effect on clinicians' decision considering treatment method. Barlow positivity ($p = 0.024$), female sex ($p = 0.025$) and initially started treatment ($p < 0.001$) were associated with longer abduction treatments. In multivariable analysis only female sex ($p = 0.003$) and immediate treatment initiation ($p < 0.001$) remained statistically significant as Barlow positivity ($p = 0.147$) did not. Delayed start of abduction treatment did not increase the risk of operation or spica casting ($p = 0.915$).

Conclusion: Our results suggest that waiting the initiation of the treatment for four to six weeks in mild DDH is a safe strategy and does not increase the duration of the possible abduction treatment later. However further longitudinal studies are needed to confirm this strategy. Girls tend to have longer abduction treatments than boys and they seem to need abduction treatment more often after the period of watchful waiting.

Keywords: Abduction treatment; DDH; Developmental dysplasia of the hip; Pavlik harness; Watchful waiting

Introduction

Developmental dysplasia of the hip is a condition which varies in severity. Mildest form is mild hip instability in provocation tests. The most severe form is rigid dislocation of the femoral head. Clinicians test hip stability with Ortolani and Barlow maneuvers. Ortolani sign is positive, when while flexing and abducting the hip the femoral head returns to acetabulum making a 'clunk'. Ortolani positive hip means that hip is loose enough to dislocate without any outside force. A hip is defined as Barlow positive when a clinician can provoke dislocation or subluxation with minor axial force during flexion and adduction of the hips and while abduction, femoral head again returns to acetabulum. In general, Ortolani positive hips are considered to be looser than Ortolani negative hips, and thus the treatment is started right away with the Pavlik harness or abduction brace [1,2] Treatment protocol varies between hospitals. Usually harness is worn 23-24 h/day and changed weekly/every other week in the pediatric surgery department or clinic. [3,4] Ultrasound is used to monitor the treatment of the condition and help clinician to decide the treatment protocol. Selective secondary ultrasound screening at the four to six weeks of age is recommended for those infants with minor instability or known risk factor for DDH. In Tampere University hospital, the Pavlik harness treatment protocol involves the dynamic ultrasound by a pediatric radiologist and clinical evaluation by a pediatric surgeon to confirm the diagnosis before initiation of the treatment by the pediatric surgeon and for later follow up. The harness is worn 24 h/day and changed every other week. The treatment response is controlled after four weeks by dynamic ultrasound and clinical evaluation. If the findings are not normalized, the treatment is continued for another four weeks until the next ultrasound and clinical evaluation of the response. After three months of age, alpha angle of 60 degrees together with the bony coverage of at least 50% and stability in dynamic examination is considered normal (Graf type I) [5,6]. With Ortolani positive

hips treatment protocol is clearer whilst there is still controversy with Ortolani negative hips. Previous studies suggest that it is safe to wait with Barlow positive hips, as many of the mild DDH recover spontaneously [7] Available research data also suggests that it is necessary to control all the normal hips with an x-ray and clinical examination in 6 months of age and again in 12 months of age to detect residual acetabular dysplasia [8-10].

In this study we wanted to evaluate the initiation time of Pavlik harness treatment with Ortolani negative hips and see if it is wise to start the treatment right away versus wait for the spontaneous recovery for four to six weeks. We also wanted to evaluate, if there are any risk factors which might have an impact on clinician's decision making when deciding the treatment method. Our second aim for this study was to evaluate, if there are any relapses among Ortolan negative hips after normalization of parameters in the clinical examination and dynamic ultrasound.

Patients and Methods

All children with the diagnosis of DDH according to World Health Organizations International Classification of Diseases and Health Related Problems 9th and 10th revisions (ICD-9 and ICD-10), codes 7543.0-7543.5 (ICD-9) and Q65.0-Q65.5 (ICD-10), treated in Tampere University hospital in the years 1998-2018 were identified for the study and the data was collected retrospectively from their medical records. The children that had only received operative treatment in Tampere University hospital and were initially and postoperatively treated in some other location, were excluded. With these criteria, a total of 948 patients were found. All initially dislocated (Ortolani positive) hips ($n=389$), teratological dislocations ($n=3$) and late diagnosed (over 3 months of age) DDH ($n=28$) which of 7 were Ortolani positive, 20 Ortolani negative and 1 had information about first clinical status missing) were excluded. Total of 535 Ortolani negative patients were included to the analysis. Barlow positivity was defined as dislocation of femoral head in provocation. In Barlow negative mild DDH clinicians described hips to be little loose but without dislocation in provocation. The alpha angle over 60 degrees together with the

50% bony coverage of acetabulum and stability in the dynamic ultrasound and in clinical examination was considered as normal. Altogether 437 patients reached the normal findings according to these criteria.

Our Treatment Protocol

Approximately 4400 children are born in Tampere University hospital annually. Every newborn is examined by pediatrician. Suspected hip instability leads in the further examination by a pediatric surgeon within the first week of life. If there is mild instability in clinical examination with or without Barlow positive sign, it is up to clinician, if the abduction treatment is started. In Tampere University hospital we use Pavlik harness treatment, but before the year 2000, Frejka pillow was mainly used for the abduction treatment. All children with hip instability were subjected to ultrasound screening by pediatric radiologist and clinical examination by pediatric surgeon at the age of approximately one month (range in the study cohort from three to six weeks). If there is residual dysplasia in the ultrasound, the abduction treatment is continued/started. After having normal findings in the ultrasound the abduction treatment ends. Ultrasound is repeated every four weeks during the abduction treatment. After normalization of the findings, children are subjected to one more routine ultrasound (and/or x-ray) and clinical control approximately at the age of six months or later (range from six to ten months).

Statistical Analysis

We used cross-tabulations with chi-square statistics to evaluate associations with risk factors (Barlow positive sign, breech presentation, preterm birth, first born and positive family history) and undergoing abduction treatment as well as undergoing operation and/or spica casting. Positive family history was defined as one or more first degree relative with diagnosed DDH. Duration of treatment was first calculated as days. Because the harness

treatment is usually carried out in 4-week periods, we decided to separate the duration of a treatment in subgroups: 1-30 days, 31-60 days and over 60 days. Delayed onset for treatment was defined to be after 4 weeks of age. Relapse was defined as any new treatment after normal findings in the dynamic ultrasound and clinically or just as deterioration of sonographic findings after already normal findings. We used cross-tabulations with chi-square statistics to evaluate differences in duration of the treatment between different risk factors (Barlow positivity, preterm birth, birth weight, positive family history, sex, treatment method). The results were controlled in multivariable analysis in ordinal regression model. Statistical significance of all the presented analyses was set at $p < 0.05$.

Results

Total of 535 children with DDH, initially diagnosed as Ortolani negative, were found. Majority (69.9 %) of these children were girls. There were 226 children with the positive Barlow sign and 291 patients had only minor instability, without the positive Barlow sign, in the first clinical examination. Information about Barlow positivity was missing in 18 patients. Altogether 307 children (57.4 %) had abduction treatment. Of these, 151 (28.2 %) children had initially started treatment and 156 (29.2 %) had the treatment started after four weeks of age. Nine (1.7 %) of the children underwent operation/ spica casting. There was no difference between the treatment groups and undergoing operative / casting treatment ($p = 0.915$). Five patients had abduction treatment prior to operation/ casting but did not response to treatment. Three patients had ether abduction restriction or very low alpha angle (40 degrees) according to their first ultrasound after four weeks of age and were for that reason straight planned for operation/casting. One child was diagnosed with clinically normal hips at the age of 3 days (no ultrasound) but was sent back at the age of 6 months with residual dysplasia and was straight planned for operation (Table 1).

Variable		N (%)	N included in analysis (%)
Sex	Girls	374 (69.9%)	535 (100%)
	Boys	161 (30.1%)	
Barlow positivity	Unilateral	180 (33.6%)	520 (97.2%)
	Bilateral	49 (8.6%)	
	Barlow negative	291 (54.4%)	
	information missing	18 (3.4%)	

Breech presentation	Yes	150 (28.0%)	532 (99.4%)
	No	382 (71.4%)	
	information missing	3 (0.6%)	
Positive family history	Yes	78 (14.6%)	338 (63.2%)
	No	260 (48.6%)	
	information missing	197 (36.8%)	
Gestational age	Preterm	25 (4.7%)	523 (97.8%)
	37-42 weeks	473 (88.4%)	
	over 42 weeks	25 (4.7%)	
	information missing	12 (2.2%)	
Birthweight	under 2500g	9 (1.7%)	530 (99.1%)
	2500-4500g	510 (95.3%)	
	over 4500g	11 (2.1%)	
	information missing	5 (0.9%)	
First born birth	Yes	103 (19.3%)	170 (31.2%)
	No	67 (12.5%)	
	Information missing	365 (68.2%)	
Abduction treatment	No	228 (42.6%)	535 (100%)
	Initially started	151 (28.2%)	
	Delayed start	156 (29.2%)	

Table 1: Patient demographics.

Barlow positivity was detected in 226 infants. Of these, 180 had unilateral dislocation and 46 had bilateral dislocation. Barlow positivity (OR 3.95, CI95% 2.69-5.77) was statistically significantly, $p < 0.001$, associated with the initiation of abduction treatment. Among Barlow positive children 172 (76.1 %) had abduction treatment. Of these, 123 (54.4 %) got treated initially, and 49 (21.7 %) after four weeks of age compared to 28 (9.6%) initially treated and 102 (35.1%) after four weeks in Barlow negative infants. On the other hand, 161 (55.3%) of Barlow negative infants avoided abduction treatment compared to 54 (23.9%) of Barlow positive infants. In further analysis, it seemed more common that abduction treatment was started initially in infants with bilateral Barlow positivity (63.0 %) compared to infants with unilateral Barlow positivity (52.2 %). Delayed start for treatment was more common in unilateral (24.4 %) than in bilateral Barlow positive group (10.9 %). However, the difference was not statistically significant ($p=0.134$). Female sex was also associated with increased risk of abduction treatment (OR 1.74, CI95% 1.20-2.53), $p = 0.003$. In further analysis, a spontaneous recovery was more common in boys (52.2 %) compared to girls (38.5 %). No difference was found between the sexes in the numbers of infants with initial start of the treatment (27.3 % for boys and 28.6 % for girls) but the girls were more likely to need abduction treatment after a period of watchful waiting (32.9 %) than boys (20.5 %). There was no difference in the prevalence of Barlow positivity (bilateral or unilateral) between the sexes ($p = 0.947$). The other known risk factors of DDH (breech presentation, positive family history, first born status or birthweight) were not associated with greater risk of abduction treatment (see Table 2).

Risk factor (n)	p value	No treatment	Initially started abduction	Delayed start for abduction
Barlow positive	<0.001			
Yes (226)		54 (23.9%)	123 (54.4%)	49 (21.7%)
No (291)		161 (55.3%)	28 (9.6%)	102 (35.1%)
Bilaterality	0.134			
Unilateral (180)		42 (23.3%)	94 (52.2%)	44 (24.4%)
Bilateral (46)		12 (26.1%)	29 (63.0%)	5 (10.9%)
Sex	0.04			
Girl (374)		144 (38.5%)	107 (28.6%)	123 (32.9%)
Boy (161)		84 (52.2%)	44 (27.3%)	33 (20.5%)
First born	0.93			
no (67)		26 (38.8%)	32 (47.8%)	9 (13.4%)
yes (103)		42 (40.8%)	49 (47.6%)	12 (11.7%)
Breech presentation	0.154			
no (382)		169 (44.2%)	98 (25.7%)	115(30.1%)
yes (150)		58 (38.7%)	51 (34.0%)	41(27.3%)
Family history	0.871			
no (260)		107 (41.2%)	71 (27.3%)	82 (31.5%)
yes (78)		33 (42.3%)	19 (24.4%)	26 (33.3%)
Birthweight	0.995			
under 2500g (9)		4 (44.4%)	2 (22.2%)	3 (33.3%)
normal (510)		218 (42.7%)	144 (28.2%)	148 (29.0%)
over 4500g (11)		5 (45.5%)	3 (27.3%)	3 (27.3%)
Gestational age	0.386			
preterm (25)		12 (48.0%)	8 (32.0%)	5 (20.0%)
37-42 weeks (473)		207 (43.8%)	125 (26.4%)	141 (29.8%)
over 42 weeks (25)		7 (28.0%)	10 (40.0%)	8 (32.0%)

Table 2: Risk factor analysis on the clinicians' decision making.

Almost all (94.8 %) of the abduction treated children had 60 days or shorter duration of treatment. Barlow positivity was associated with longer abduction treatment, compared to Barlow negativity ($p = 0.024$). In Barlow negative children the treatment duration of 1-30 days was more common (66.2 %) than in Barlow positive children (48.8 %). Treatment duration of 31-60 days (44.8 %) and over 60 days (6.4 %) were more common in Barlow positive than in Barlow negative children (30.0 % and 3.8 %), respectively ($p=0.024$). In further analysis bilaterality seemed to increase the risk for longer treatments, as duration of 31-60 and over 60 days were more common in bilateral group (52.9 % and 8.8 %) compared to unilateral group (42.8 % and 5.8 %), but the difference was not statistically significant ($p=0.625$). Girls had longer abduction treatments than boys ($p = 0.025$). It was more common in girls to have 31-60 days (42.5 %) and over 60 days duration of the treatment (6.1 %) than boys (26.0 % and 2.6 %), respectively. Boys were more likely to have 1-30 days

duration of the treatment (71.4 %) than girls (51.3 %). There was also a statistically significant ($p = 0.020$) difference in duration of the abduction treatment between those who received treatment initially, and those who received treatment after four weeks. In delayed start (DS) group abduction treatment was more often 1-30 days (67.3 %) than in initial start (IS) group (45.7 %), respectively. In the IS group 31-60 days was most common duration of the treatment (47.0 %), in the DS group it was not that common (29.5 %). Duration of 61 days or more was again more common in IS group (7.3 %) than in DS group (3.2 %) The results are presented in Table 3. The other risk factors studied (breech presentation, positive family history, first born birth or birthweight) were not associated with longer abduction treatments, although positive family history had the trend towards it ($p = 0.055$).

Risk factor (n)	p value	Treatment time in days			p value in multivariable design
		1-30	31-60	over 60	
Barlow positive	0.024				0.147
Yes (172)		84 (48.8%)	77 (44.8%)	11 (6.4%)	
No (130)		86 (66.2%)	39 (30.0%)	5 (3.8%)	
Bilaterality	0.473				
Unilateral (180)		71 (51.4%)	59 (42.8%)	8 (5.8%)	
Bilateral (46)		13 (38.2%)	18 (52.9%)	3 (8.8%)	
Sex	0.025				<0.001
Boy (77)		55 (71.4%)	20 (26.0%)	2 (2.6%)	
Girl (230)		119 (51.7%)	97 (42.2%)	14 (6.1%)	
Treatment method	0.02				0.003
IS (151)		69 (45.7%)	71 (47%)	11 (7.3%)	
DS (156)		105 (67.3%)	46 (29.5%)	5 (3.2%)	
First born	0.642				
no (67)		18 (43.9%)	20 (48.8%)	3 (7.3%)	
yes (103)		29 (47.5%)	30 (49.2%)	2 (3.3%)	
Breech presentation	0.224				
no (41)		114 (53.5%)	85 (39.9%)	14 (6.6%)	
yes (61)		59 (64.1%)	31 (33.7%)	2 (2.2%)	
Family history	0.055				
no (153)		91 (59.5%)	58 (37.9%)	4 (2.6%)	
yes (45)		24 (53.3%)	16 (35.6%)	5 (11.1%)	
Birthweight	0.989				
under 2500g (5)		3 (44.4%)	2 (22.2%)	0 (33.3%)	
normal (292)		166 (56.8%)	110 (37.7%)	16 (5.4%)	
over 4500g (6)		5 (45.5%)	3 (27.3%)	3 (27.3%)	
Gestational age	0.834				

preterm (13)	9 (69.2%)	4 (30.8%)	0 (0%)	
37-42 weeks (266)	150 (56.4%)	102 (38.3%)	14 (5.3%)	
over 42 weeks (18)	9 (50.0%)	7 (38.9%)	2 (11.1%)	

Table 3: Risk factors' effect on the duration of abduction treatment.

As in Barlow positive children it was more common that the treatment was initially started, and girls were more likely to need abduction treatment after waiting, we controlled the results of the treatment duration with Barlow positivity and female sex using multivariate analysis. The initially started treatment remained statistically significantly associated with longer durations of the treatment ($p = 0.003$) and male sex was associated with shorter abduction treatments ($p < 0.001$) whereas Barlow positivity did not remain statistically significantly associated with longer abduction treatments ($p = 0.147$). 438 (81.9 %) patients reached normal findings according to Graf's classification and had the information in their medical records. 97 (18.1 %) patients did not reach normal findings in sonographic follow up or had the information about Graf's criteria missing. Of the 438 patients, majority (84.7 %) recovered by the four months of age. There were no relapses defined as any new treatment after already normal ultrasound findings. Six children (1.1%) had minor deterioration in their alpha angles after previously normal ultrasound findings, but all recovered spontaneously.

Discussion

According to our findings, over half (57.4 %) of the Ortolani negative clinically unstable hips in our clinic get treated. The percentage was even higher among Barlow positive hips (76.1%). This finding indicates that we may have a slight tendency to overtreat mild DDH. In a recent study by Cook *et al.*, the authors found, that waiting for onset of the treatment resulted in spontaneous recovery in 63% of the infants with Barlow positive hips.[7] However, there might be different standards in different clinics to report Barlow positivity, and all the Ortolani negative hips included, the treatment rate was lower in our clinic. It is well documented, that mild forms of DDH have excellent rates of spontaneous recovery in the first few weeks of life [2,11-13]. It has also been documented that it is safe to wait at least 4-6 weeks for the onset of the treatment with Barlow positive and clinically unstable hips. [7,14] Despite of that, 54.4 % of the Barlow positive and 9.6 % of the milder DDH got treated initially in Tampere university hospital. In Tampere University hospital it is up to clinician if the treatment is started right away or if the child is seen again in four weeks. First dynamic ultrasound is usually performed at the age of four weeks, and if there is still immaturity or instability according to the ultrasound and clinical evaluation, the abduction treatment is started/ continued. According to our findings, Barlow positivity

affected the most to clinicians' decision to start abduction treatment initially. Any other common risk factors for DDH did not seem to affect the decision. This indicates, that in Tampere University hospital the looseness of the hip joint is the major factor for which clinicians' base their decision of the treatment.

Barlow positivity and female sex were associated with the risk of longer abduction treatment in all the Ortolan negative children, respectively. When we controlled our findings with the initiation of abduction treatment in a multivariate model, Barlow positivity did not remain associated suggesting, that the initiation of the treatment explains the previously found association. According to our findings it seems, that watchful waiting before the onset of a treatment is associated with a shorter duration of the abduction treatment. We think that this is due the excellent spontaneous recovery rate of mild DDH in combination with successful clinical decision making when selecting the patients for Pavlik harness treatment. Our results indicate that even if harness treatment is needed after waiting, it seems that there may have already been spontaneous recovery and/or the cases selected for watchful waiting truly are milder and have better recovery potential also after four weeks of age as the duration of the treatment was shorter in those children with delayed treatment onset. According to these findings, it is safe to use watchful waiting strategy as a part of the treatment protocol, as there was no difference in ending up to operative treatment and the duration of the treatment did not lengthen after waiting, conversely, it was shorter. Our findings support the earlier research in terms of safety of waiting the onset of the treatment [7,14] and adds to existing knowledge regarding the differences in duration of the abduction treatment.

Female sex was found to be a risk factor for longer abduction treatment, as in multivariable analysis sex remained statistically significantly associated with the duration of the treatment. Female sex is a well-known risk factor of DDH [15-18]. In our previous study we found that there was also a trend that female sex might be an independent risk factor for Ortolani positivity. In this study with Ortolani negative infants only, we found that boys are more likely to recover spontaneously than girls, girls tend to need abduction treatment more often and they are more likely to need longer abduction treatments in duration. These findings further support the idea that the girl sex may be related to more severe forms of DDH and girls tend to need more robust treatments than boys. In our data, only six children had minor deterioration

of alpha angles after normal findings (Graf I) in ultrasound and all of them recovered spontaneously without any new treatment. There is evidence that normal initial ultrasound in patients with risk factors for DDH does require further follow-up at least by the age of six months [19]. Mulrain et al found, that the incidence of late presenting DDH in infants with initially normal ultrasound was 8%, and based on this evaluation, in their protocol all infants with major risks of DDH (breech presentation or positive family history) are further evaluated by six months of age, even after a normal initial ultrasound [20] In our protocol we have further followed all the patients with diagnosis of DDH by six months of age with sonographic and clinical follow-up, but we do not have routinely follow-up protocol for children with risk factors neither routinely x-ray follow up after six months to avoid unnecessary radiation exposure. Despite of differences in our follow-up protocol, our data shows very low rate of late presenting DDH (defined as after three months of age), as there were only 28 late presented cases among all the patients diagnosed with DDH in Tampere University hospital in 20 years of time, and only half of the late presented cases (n = 14) ended up to casting / operation. These findings indicate that our treatment protocol with the 6 months sonographic and clinical follow up of patients with mild hip instability is effective. However, radiographic follow-up is recommended by some authors to detect any residual acetabulum dysplasia after successful treatment [21,22] Residual Acetabular Dysplasia (RAD) remains debated, and although it's prevalence in DDH after primary treatment has reported to be as high as 17% [9], it is still debated when RAD requires operative treatment in childhood [8,23]. The length of follow-up of DDH after a successful treatment has not been well established [24], some authors suggesting radiographic follow-up until skeletal maturity, some indicating that after 2 years, follow up is not necessary [21].

There are some limitations in this study. The data was collected retrospectively, and for that reason the information about some of the risk factors (first born birth, positive family history and preterm birth) was incomplete. It might be due to this factor that we did not find association between first born birth or preterm pregnancy and duration of the treatment in the Ortolani negative DDH. The most important risk factors of DDH have been reported to be breech presentation, female sex, side of the hip (left) and positive family history.[17] Of these risk factors only the information about the family history was vastly incomplete, which might explain the fact that we did not find any association between family history and duration of the abduction treatment. In our data the Barlow positivity was defined by clinical status, ultrasound was not used to define the baseline of the condition. However, this is common practice globally, as the early ultrasound screening of DDH is not recommended since it leads to overtreatment of the condition [25-29]. Despite of our treatment protocol, very low percentage of the initially diagnosed children ended up needing

more robust treatments. This is in line with the previous studies of success rates of Pavlik harness treatment [7,30,31]

Conclusion

It is safe to wait for the initiation of the abduction treatment in Ortolani negative DDH and waiting for the treatment onset seems to shorten the duration of the abduction treatment needed. Girls tend to need abduction treatment more often than boys and the treatments tend to be longer in duration.

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