



Impact of Failed Pavlik Harness Treatment on the Outcomes Following Closed or Open Reduction in Developmental Dysplasia of the Hip

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Abstract

Purpose To investigate the impact of failed Pavlik harness (PH) treatment on the outcomes following closed reduction (CR) or open reduction (OR) in developmental dysplasia of the hip (DDH).

Methods Ninety-three DDH patients treated with CR or OR were enrolled. One group of which received previous PH treatment (F group) and the other (L group) not. The clinical outcomes were evaluated according to McKay's criteria. Radiographs were evaluated for acetabular index (AI) and the degree of dislocation of the hips.

Results A higher rate of CR was found in F group ($P=0.034$). Before CR/OR, the mean AI in F group was significantly lower than that in L group ($P=0.000$), while at the last follow-up, the AIs in both groups were all improved. In F group, there were 7 (16.67%), 18 (42.86%) and 17 (40.48%) hips were classified as Graf type II, III and IV pathologic changes, respectively, when PH treatment started, while the corresponding data were 17 (40.48%), 17 (40.48%) and 8 (19.05%) after PH treatment ($P=0.024$). At the last follow-up, no significant difference was found concerning the complications between the two groups ($P > 0.05$).

Conclusions PH treatment, even if failed, may have the ability of accelerating the development of the acetabulum and increasing the rate of successful CR. Thus we advocate a trial of PH treatment for all DDH patients less than 6 months of age. Meanwhile, a close monitoring by dynamic ultrasonography is required due to the risk of AVN.

Keywords Developmental dysplasia of the hip · Pavlik harness · Closed reduction · Open reduction · Avascular necrosis · Pelvic osteotomy

Introduction

Developmental dysplasia of the hip (DDH) is one of the most common orthopedic disorder in infants. The primary goal of the treatment is to achieve a stable and concentric

reduction as early as possible so as to facilitate normal development of all structures of the hip while avoiding complications [1]. Since 1950s initially described by Arnold Pavlik, Pavlik harness (PH) has proven to be the first line of treatment for initial management of DDH with high success rates in infants younger than 6 months of age, because of its persistent, spontaneous and functional mode of hip reduction [2–4]. Unfortunately, failure of PH treatment and late-diagnosed DDH are still commonly encountered [5, 6]. Usually, in these patients, a closed or open reduction is considered for further treatment [3, 4, 7].

Up to now, formulation of the optimal protocol for DDH remains controversial. To our knowledge, few studies reported the impact of previous treatment with PH on the clinical and radiographic outcomes following closed reduction (CR) or open reduction (OR). Furthermore, clinical data of these patients are still limited. Therefore, in this study, we investigated the clinical and radiographic outcomes of CR/OR in patients with late-diagnosed DDH and compared

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these results with those in patients who also underwent CR/OR for failed PH treatment. Meanwhile, the occurrence of femoral head avascular necrosis (AVN) and further surgery (pelvic osteotomy, PO) within the follow-up period was observed.

Materials and methods

After the Research Ethics Board of our hospital approved this study, we retrospectively reviewed the medical records of all patients who were treated with CR/OR because of DDH between January 2010 and June 2015. There were a total of 252 DDH patients younger than 6 months who received PH treatment and were closely monitored by ultrasonography every two weeks. All patients were required to follow the treatment protocol. If a successful reduction was not achieved after 3 consecutive time intervals follow-up, a failed PH treatment was defined. Of these patients, 54 (21.4%) cases failed and 42 cases received CR/OR treatment in our hospital who were included and designated as the failed PH treatment group (F group) finally. Fifty-one patients who were at 6–12 months of age at initial diagnosis, did not receive any previous treatment and hence underwent CR/OR directly were included and designated as the late-diagnosed DDH group (L group). The exclusion criteria were as follows: (1) presence of AVN before CR/OR; (2) genetic or neuromuscular disorders; (3) bilateral DDH; (4) incomplete clinical and radiographic data; and (5) less than 2 years of follow-up duration.

CR/OR was performed under general anesthesia. In all cases, a trial of CR combined with percutaneous adductor tenotomy was performed under fluoroscopic guidance and with the aid of arthrography. When a stable concentric reduction was achieved and confirmed by the radiograph, the CR was defined as “successful”. Otherwise, an OR was performed during the same session through an anterior approach using the bikini incision. During the procedure, the iliopsoas tendon was routinely sectioned followed by a capsulorrhaphy including removal of the ligamentum teres and transection of the transverse acetabular ligament. Moreover, all of the intra-articular soft tissue obstruction was removed so as to make the reduced hip more stable. The surgeries were performed by one senior surgeon (J. S.).

The patients were immobilized in a modified human position cast with the hips 90°–100° flexion and 60°–70° abduction for 12 weeks after CR, and for 6 weeks after OR. On postoperative day 2, the stable concentric reduction of the hips was reconfirmed using MRI. After removal of the cast, the patients were required to wear a full-time (24 h/day) walking orthosis for 12 weeks, and then to wear only at night time for 12 weeks. Follow-up pelvic radiographs were analyzed at every 3-month interval within the first

year postoperatively, 6-month interval within the second year postoperatively, and then once a year up till skeletal maturity of the hips.

Clinical outcomes were evaluated according to McKay’s criteria [8] at the last follow-up. In both of the two groups, radiographs taken prior to CR/OR and at the last follow-up were evaluated for the acetabular index (AI), meanwhile, the degree of dislocation of the hips was categorized using Tönnis classification system [9] prior to CR/OR. In F group, dysplasia of the hips were evaluated according to Graf’s method [10] by dynamic ultrasonography pre- and post-PH treatment. The occurrence of AVN was determined using the Kalamchi and McEwen classification system [11] in all cases, among which only grades II–IV were considered significant and included in the analysis. The incidence of PO within the follow-up period was also recorded. These evaluations were performed by one senior surgeon (L. K.) who was not involved in the surgery.

Data were analyzed using SPSS version 17.0 (SPSS Inc., Chicago, Illinois, USA). Normally distributed continuous variables were presented as the mean \pm standard deviation. Non-normally distributed variables were presented as the median. For categorical variables, counts and percentages of each category were presented. Within groups, comparisons of continuous variables were made using paired *t* test. While an independent *t* test was used when comparing the continuous variables between groups. The chi-square test was used in the comparisons for categorical variables. A *P* value less than 0.05 was considered statistically significant.

Results

All of the 93 unilateral DDH patients with a mean age at CR/OR of 8.12 months (range 5–12) completed the follow-up. The median follow-up time was 27 months (range 24–45). There were 42 patients in F group and 51 patients in L group. No statistically significant differences between the two groups was found in terms of age at CR/OR, sex ratio, affected side distribution and follow-up duration ($P > 0.05$). The rate of CR/OR was 36/6 in F group and 34/17 in L group, which was significant different between the two groups ($P = 0.034$). The general characteristics of the study population are presented in Table 1.

At the last follow-up, 35 (83.3%) of the 42 hips in F group were in excellent or good condition when evaluating according to McKay’s criteria, while 41 (80.4%) of 51 hips were rated excellent or good in L group. There was no statistically significant differences between the two groups ($P > 0.05$) (Table 2). The mean AI in F group before CR/OR was $31.69 \pm 3.27^\circ$, and that in L group was $35.47 \pm 4.43^\circ$. The difference was found to be statistically significant between the two groups ($P = 0.000$). At the last follow-up, the AIs in

Table 1 General characteristics of the study population

	F group (n=42)	L group (n=51)	F/ χ^2	P value
Age at CR/OR (months)	7.88 ± 1.86	8.31 ± 2.16	2.837	0.309
Sex (male/female)	6/36	8/43	0.035	0.851
Affected side (left/right)	24/18	28/23	0.047	0.829
follow-up duration (months)	29.31 ± 5.05	29.40 ± 4.90	- 0.127	0.899
CR/OR	36/6	34/17	4.489	0.034

CR closed reduction, OR open reduction

Table 2 Clinical outcomes evaluated according to McKay classification

	F group (n=42)	L group (n=51)	χ^2	P value
Excellent (n)	22	26	0.133	0.715
Good (n)	13	15		
Fair (n)	6	9		
Poor (n)	1	1		

both groups were significantly improved ($P=0.00$ in F group and $P=0.00$ in L group), and no significant difference was found between the two groups ($25.45 \pm 3.20^\circ$ in F group vs $26.82 \pm 4.42^\circ$ in L group, $P > 0.05$). Regarding the Tönnis grade distribution before CR/OR, there were 10 hips of mild acetabular dysplasia (Tönnis I grade) and 32 hips of severe acetabular dysplasia (Tönnis II to IV grade) in F group. The corresponding data was nine and 42 in L group. Although no statistically significant difference was found between the two groups, the ratio of Tönnis I grade in F group was higher than that in L group (23.8% vs 17.6%, $P > 0.05$) (Table 3).

In F group, the mean age was 3.2 months (range 1.5–4.8) when PH treatment started. Among these hips, 7 (16.7%) were classified as Graf type II, 18 (42.9%) as Graf type III and 17 (40.5%) as Graf type IV pathology, while 17 (40.5%) were rated as Graf type II, 17 (40.5%) as Graf type III and 8 (19.0%) as Graf type IV after PH treatment. Statistical significant difference was found regarding the Graf grade distribution between pre- and post-PH treatment ($P = 0.024$) (Table 4).

Table 3 Radiographic results in the two groups

	F group (n=42)	L group (n=51)	t/ χ^2	P value
Acetabular index				
Prior to CR/OR ($^\circ$)	31.69 ± 3.27	35.47 ± 4.43	6.166	0.00
At the last follow-up ($^\circ$)	25.45 ± 3.20	26.82 ± 4.42	- 1.679	0.097
Tönnis grade prior to CR/OR				
Grade I (n)	10	9	0.538	0.463
Grade II (n)	13	10		
Grade III (n)	10	12		
Grade IV (n)	9	20		

In our series, a total of 6 (14.3%) hips in F group (two cases of grade III and four cases of grade IV) and 4 (7.8%) hips in L group (two cases of grade II, one case of grade III and one case of grade IV) developed AVN. Six patients (14.3%) in F group and seven patients (13.7%) in L group underwent PO. Although the incidence of PO and AVN in F group were higher than those in L group, no significant difference was found between the two groups ($P > 0.05$) (Table 5).

Discussion

Early detection and nonsurgical management is currently gold standard in the treatment of DDH [3]. PH treatment has proven to be the first choice for DDH in infants less than 6 months of age because of its dynamic mode of hip reduction, which can stimulate the acetabular growth so as to normalize the acetabular development. Although more and more patients have been detected and received treatment soon after birth with the prevalence of dynamic

Table 4 Evaluation according to Graf's method in F group

Graf grade	pre-PH treatment (hips)	post-PH treatment (hips)	χ^2	P
Type II (n)	7	17	7.435	0.024
Type III (n)	18	17		
Type IV (n)	17	8		

PH Pavlik harness

Table 5 Occurrence of femoral head avascular necrosis and pelvic osteotomy in the two groups

	F group (n=42)	L group (n=51)	χ^2	P value
<i>Avascular necrosis (AVN)</i>				
Yes (n)	6	4	0.996	0.318
No (n)	36	47		
<i>Pelvic osteotomy</i>				
Yes (n)	6	7	0.006	0.938
No (n)	36	44		

ultrasonography, failure of PH treatment and late-diagnosed DDH remains common. Normally, CR or OR is a preferable treatment option for these patients. However, to the best of our knowledge, a number of previous reports regarding PH treatment have focused on issues such as treatment initiation, weaning, application and follow-up, outcomes, complications, end of treatment and so on [3, 12, 13], while few studies have reported the correlation between previous PH treatment and the outcomes of CR or OR, accordingly, the corresponding data are still limited.

In the present study, we enrolled two groups of DDH patients who were treated with CR or OR. One group of which received previous PH treatment and the other not. The overall results of both groups were satisfactory and consistent with previous reports [14, 15]. While in F group, the rate of successful CR was higher and the mean AI before CR/OR was much lower comparing with those in L group. At the last follow-ups, the mean AI in F group was lower than that in L group, despite no statistical significant difference was found between the two groups. In addition, the Graf grade distribution was significantly improved after PH treatment in F group.

Studies have demonstrated that the initial type of hip dysplasia is the most important influence factor for the final outcomes [16], and AI is a reliable indicator for evaluating the development of acetabulum, meanwhile an important basis for further surgical intervention [17, 18]. Also, pre-operative AI is the best predictor of final radiographic outcomes [19]. Decrease of AI signifies improvement of the acetabular morphological structures [20], and may predict a satisfactory outcome [19, 21]. CR, as one of the primary treatment options, has been advocated by many authors for its minimal invasion, high success rate and low complications, meanwhile may provide similar results with OR in appropriate patients [15, 22]. However, pathological changes of DDH could make CR difficult to perform in many cases [23]. Besides, prolonged use of PH after failed PH treatment may aggravate the acetabular dysplasia: so-called ‘‘Pavlik harness disease’’, result in difficulty in CR and then increase the rate of OR [24–26].

Our results showed that previous PH treatment, even though failed, may have the ability of decreasing the AI, increasing the rate of successful CR and improving the Graf grade distribution. The main reason for our findings may be the improvement of acetabular development following the PH treatment. Besides, in F group, all hips were closely monitored by ultrasonography every two weeks. If a successful reduction is not achieved after three consecutive time intervals follow-up, the PH treatment should be abandoned aiming to avoid the occurrence of PH disease. This may partly explain the higher rate of successful CR in F group.

AVN of the femoral head is one of the most serious complications associated with the treatment of DDH, and the etiology of which is multifactorial. The reduction of blood supply caused by iatrogenic injury may be the primary reason for its occurrence which is currently accepted [27, 28]. Although varies potential risk factors for AVN have been reported in the literature, there has been no consensus achieved. In a meta-analyses performed by Novais et al. [29], the authors found no association between CR or OR and an increased risk of AVN in patients ≤ 12 months of age. Pospischill et al. [30] concluded that OR with PO may increase the risk of AVN. While Huang et al. reported a lower rate of AVN when OR with PO was performed in the treatment of DDH [31]. Our study showed no significant difference regarding the occurrence of AVN and PO in both groups, although it was higher in F group. If the fact that OR may decrease the risk of AVN, our results could be associated with the difference of CR/OR ratio between both groups.

In conclusion, both CR and OR yielded favorable clinical and radiographic outcomes in selected DDH patients. Moreover, even if it failed, PH treatment may have the ability of accelerating the development of the acetabulum and increasing the rate of successful CR. Thus we advocate a trial of PH treatment for all DDH patients less than 6 months of age. Meanwhile, a close monitoring by ultrasonographic examination is required due to the risk of AVN.

There are some limitations in this study. First, this was a retrospective case–control study. Second, all the included cases were not divided into subgroups according to the degree of dislocation due to small sample sizes. Third, all patients in this study were unilateral DDH and bilateral DDH patients were excluded.

Author Contributions All authors contributed to the study conception and design. Material preparation, data collection and analysis were performed by YL, LK, JS and YZ. The first draft of the manuscript was written by LK and YL commented on previous versions of the manuscript. All authors read and approved the final manuscript. The authors YL and LK contributed equally to this work and should be considered as co-first authors.

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Data Availability The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Declarations

Conflict of Interest The authors have no conflicts of interest to disclose.

Ethical Approval This is an observational study. The Research Ethics Committee of the Affiliated Provincial Pediatric Hospital of Anhui Medical University has confirmed that no ethical approval is required.

Consent to Participate Written informed consent was obtained from the parents.

Consent to Publish The authors affirm that the parents provided informed consent for publication of the present study.

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