Double diapering facilitates hip maturation in newborns: a prospective randomised control study

Wei C. Lee  
Chang Gung Memorial Hospital

Hsuan K. Kao  
Chang Gung Memorial Hospital

Mei C. Chen  
Chang Gung Memorial Hospital

Wen E Yang  
Chang Gung Memorial Hospital

Shih M. Chu  
Chang Gung Memorial Hospital

Chia H. Chang (chiahchang@gmail.com)  
Linkou Chang Gung Memorial Hospital  https://orcid.org/0000-0002-7165-5659

Research article

Keywords: double diaper, Graf IIa immature hip, ultrasound

Posted Date: February 13th, 2020

DOI: https://doi.org/10.21203/rs.2.23393/v1

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Abstract

Background

Maintaining the hips in flexion and abduction posture is a common recommendation to facilitate hip maturation in infants. Double diapering helps to maintain a baby’s hips in flexion and abduction posture, but the efficacy of double diapers in hip development has never been verified. We investigated whether double diapering results in greater improvement of the alpha angle in the first months of life.

Methods

This prospective randomised control study enrolled newborns with Graf type IIa hips. Babies were assigned to the double-diaper or single-diaper group. Parents were instructed on proper hip positioning, except for diapering. Change in the alpha angle from newborn to 1 month after birth, rate of improvement to bilateral Graf type I hips in 1 month, and number of ultrasound examinations and orthopaedic clinic visits in the first year were compared between the two groups. For babies with bilateral IIa hips, we used the averaged data from both hips, and for babies with unilateral IIa hips, we used the data from the IIa hips.

Results

Seventy newborns with 102 type IIa hips were included from January to December 2017. They were allocated to the double-diaper group (N=33) and single-diaper group (N=37). With a comparable sex ratio, gestational age, and newborn alpha angle, the double-diaper group had a greater increase of alpha angles in 1 month than the single-diaper group (+7.9° vs. +5.2°, t-test, p=0.011). Twenty-eight babies in the double-diaper group (84.8%) and 20 babies in the single-diaper group (54.1%) improved to having bilateral Graf type I hips (chi-square test, p=0.006). Subsequent clinical visits and hip ultrasounds before 1 year were significantly reduced in the double-diaper group.

Conclusions

Our results support double diapering for enhancing hip maturation in babies with Graf type IIa hips. The amount of improvement may not indicate double diapering as a treatment for hip dysplasia, but its effects in immature hips are noteworthy in reducing further clinical and ultrasound follow-ups.

Background

Developmental dysplasia of the hip (DDH) is the most common neonatal musculoskeletal disease. Early diagnosis and management are a universal policy to prevent surgical interventions and anaesthetic risks of advanced dysplasia and dislocation due to late diagnosis [1]. Various hip screening protocols for early diagnosis have been designed and executed in different countries. In Taiwan, paediatric physicians perform physical examinations for hip instability by using the Barlow test and the Ortolani test in the newborn nursery. Babies with hip instability and babies with risk factors for DDH, such as family history,
breech presentations, and findings associated with intrauterine packing, are referred to paediatric orthopaedic clinic, and hip ultrasound examination is performed [2]. The ultrasound results are generally classified by the Graf method to guide further management [3].

The Graf classification of hip ultrasound examinations uses alpha and beta angle measurements of a standard coronal section of the hip. The alpha angle is formed between the acetabular roof and the vertical cortex of the ilium and reflects the development of the bony acetabular roof. A hip with alpha angle > 60° is classified as a mature type I hip. A child with an alpha angle between 50° and 59° and who is less than 3 months old at examination is classified as having a type IIa hip. Graf type IIa hips are in an immature state and found in 5–10% of newborn hip ultrasound examinations [3]. Type IIa hips are regarded as a physiological condition, and observation with ultrasound follow-ups is often recommended until the baby's hips become mature spontaneously [4–6].

Before a diagnosis of DDH is made, parents are instructed to maintain the hips in flexion and abduction position to facilitate hip maturation. Because the observation does not guarantee normal hip development in all babies, parents are often anxious during the observation period. In a clinical scenario when parents are informed that their baby's hips are not completely normal, and no formal treatment is required before visiting orthopaedic doctors, the primary physicians or health care practitioners may instruct parents to use double or triple diapers to facilitate hip abduction positioning. However, this method was not recommended for treating DDH in the Nelson’s Textbook of Pediatrics [7]. A clinical question is whether double diapering facilitates hip development for Graf type IIa hips in the first month of life. To our knowledge, there is no evidence for this question in the literature. Therefore, this study aimed to investigate the effects of the double diapering method in facilitating hip development by testing a null hypothesis that the increase in the alpha angle by using double diapers is the same as that by using a single diaper in the first month of life.

**Methods**

This prospective, randomised controlled study enrolled newborns with Graf type IIa hips. The study was approved by the institutional review board of the authors' hospital and adheres to CONSORT guidelines. For study purposes, we arranged hip ultrasound examination in the newborn nursery to enrol study candidates. Babies with positive Ortolani test or Graf type IIc, D, III, and IV hips and babies with neurologic or other congenital disorders were not included. Parents of babies with Graf type IIa hips were invited to join the study after reading the related information and signing consent document. All parents were instructed to maintain baby's hips in flexion and abduction position whether they joined the study or not.

Babies with Graf type IIa hips were grouped by the day of birth in a week. Babies who were born on Monday to Thursday were assigned to the double-diaper group, and babies who were born on Friday to Sunday were assigned to the single-diaper group in the first 6 months in 2017. The arrangement was reversed in the second 6 months in 2017. All parents received the same instructions on baby wrapping, clothing, and hip positioning by a research nurse. Parents in the double-diaper group were instructed to
apply two diapers, with a larger-sized diaper outside, to maintain the hips in flexion and abduction all day long. Babies were scheduled for a visit to the paediatric orthopaedic clinic 4 weeks later, and the same doctor who performed the hip ultrasound examinations at the newborn nursery performed the follow-up ultrasound examination again. Four paediatric orthopaedic doctors entered the newborn nursery by turns to check newborns’ hips and ultrasound examinations. They were blinded to the grouping during follow-up sonography. A research nurse executed parent instructions, collected birth data and DDH risk factors, and conducted telephone consultations for any problems associated with double diapering.

The outcomes included change in alpha angle from birth to 1 month old, rate of improvement to bilateral Graf type I hips in 1 month, any problems or morbidities in the study period, and number of ultrasound examinations and orthopaedic clinic visits in the first year. Based on a previous study about the natural development of the alpha angle in newborns [8], more than 11 babies were needed in both groups to achieve a statistical power of > 0.8.

For statistical analysis, for babies with bilateral IIa hips, we used the averaged data from both hips, and for babies with unilateral IIa hips, we used the data from the IIa hips. Comparative analysis of the two groups was performed using SAS version 9.2 (SAS Institute Inc., Cary, NC) and Microsoft Excel 2017 software. A p-value of less than 0.05 was defined as statistically significant.

Results

From January to December 2017, a total of 993 newborn underwent hip ultrasound examination in the newborn nursery. Among these babies, 163 had Graf IIa hips, and 70 of them (18 boys, 52 girls) participated in this study. A total of 32 babies had bilateral IIa hips and 38 babies had unilateral IIa hips (right hips in 27 babies, left hips in 11 babies). According to the above grouping method, 33 babies were assigned to the double-diaper group and the other 37 babies to the single-diaper group.

The two groups had comparable sex ratio, gestational age, birth weight, risk factors, and ratio of unilateral/bilateral type IIa hips. After 1 month, 28 babies in the double-diaper group (N = 33) recovered to having bilateral type I hips. Five babies (6 hips) continued to have type IIa hips, and follow-up was required. No diaper rash or eczema was reported by parents in this group. In the single-diaper group (N = 37), 20 babies recovered to having bilateral type I hips, 16 babies (23 hips) continued to have type IIa hips, and one baby was noted to have one type IIc hip, for whom a harness was applied for 2 months along with regular follow-up in the orthopaedic clinic. Twenty-eight (84.8%) babies in the double-diaper group and 20 (54.1%) babies in the single-diaper group recovered to having bilateral Graf type I hips in 1 month. The ratio of babies who required further follow-up or ultrasound examination was significantly reduced by using double diapers (5 in 33 babies in the double-diaper group vs. 17 in 37 babies in the single-diaper group, chi-square test, p = 0.006) (Table 1).
Table 1
Comparison between babies of the two study groups

|                                      | Double diapering (N = 33) | Single diapering (N = 37) | p value |
|--------------------------------------|----------------------------|---------------------------|---------|
| Male:Female sex                      | 9:24                       | 9:28                      | 0.778   |
| Breech                               | N = 0                      | N = 1                     |         |
| Family history                       | N = 1                      | N = 1                     |         |
| Gestational age (weeks)              | 38.6                       | 38.5                      | 0.824   |
| Side of IIa hips (right:left:bilateral) | 15:8:10              | 12:3:22                   | 0.959   |
| Improving to bilateral Graf type I hips in 1 month | 28 (84.8%)   | 20 (54.1%)                | 0.006   |

With regard to the alpha angle in the 102 type IIa hips, the two groups had similar initial alpha angle at birth. Hips in the double-diaper group had greater alpha angles in 1 month than those in the single-diaper group (+7.9° vs. +5.2°, independent t test, p = 0.011) (Table 2).

Table 2
Comparison of the Graf type IIa hips in the two study groups

| Mean (°) (SD) | Double diapering (N = 43) | Single diapering (N = 59) | p value |
|--------------|---------------------------|---------------------------|---------|
| Alpha angle at birth | 55.9 (2.2)           | 55.5 (2.0)                | 0.402   |
| Alpha angle at 1 month old | 63.8 (3.0)       | 60.6 (5.3)                | 0.003   |
| Change in alpha angle | +7.9 (3.2)          | +5.2 (5.3)                | 0.011   |

SD, standard deviation

From the end of the study at 1 month old to age 1 year, babies in the double-diaper group underwent four hip ultrasound examinations and visited 39 orthopaedic clinics; babies in the single-diaper group underwent 15 hip ultrasound examinations and visited 53 orthopaedic clinics. Except for the baby with the harness treatment for Graf type IIc hip, no other baby in this study had hip dysplasia (Fig. 1).

Discussion

In this study, newborns with the Graf type IIa hips were selected as subjects as they are commonly observed to undergo maturation of the acetabular roof. Considering spontaneous resolution in most of the babies, double diapering resulted in greater increase of the alpha angle, and more babies soon recovered to having bilateral Graf type I hips in 1 month. The number of following clinic visits and hip ultrasounds was reduced due to the faster maturation of the hip in the first month of life.
The spectrum of DDH ranges from severe dislocation to mild ultrasonic dysplasia without clinical instability. We agree that double diapering cannot treat dislocated or dislocatable DDH because it could delay the golden time for other definite treatments, such as harness, spica cast, and open surgery [7]. For stable hips with ultrasonic dysplasia in which the alpha angle is < 55°, treatments could be observation or harness depending on physicians’ decisions [9]. For Graf type IIa hip without clinical instability, the so-called ‘physiological immature’ state, follow-up is still recommended until a type I hip is presented by sonographic examination before 3 months of age [10, 11]. One study reported that only 79% of babies developed normal hips at 6–7 weeks of age, and there was a high missing rate of required follow-up due to parents’ insensitivity to type IIa hip [11]. In the observation period, double diapering could be one of the recommendations for early maturation and for reducing costs in clinical and ultrasound follow-up.

Hip positioning and swaddling have been regarded as post-natal risk factors for DDH. The incidence of DDH was very high in areas using swaddling with the baby’s hips in extension and adduction position [12]. In a recent report from Malawi, flexion and abduction hip positioning by ‘back-carrying’ significantly reduced the surgeries for DDH [13]. Double diapering aims to maintain babies’ hips in a more flexed and abducted position. Although our data do not prove that the hip abduction angle was greater in the double-diaper group, we believe that double diapering is a practical method to continuously remind parents of proper hip positioning. The study results showed that instructions for parents to carry out a task like double diapering could work better than oral instructions of hip positioning.

This study had a few limitations. One limitation is that the study subjects had immature state of the hips rather than true DDH. The results, thus, cannot be used as a treatment guideline for hips with positive Ortolani or Barlow tests or Graf type IIc, D, III, and IV hips. Second, the type IIa hips in the two groups had equally good results at 1 year of age. Almost all type IIa hips in the single-diaper group spontaneously resolved to mature hips, but double diapering enhanced hip maturation and reduced the requirement of further follow-up. Whether universal use of double diapering in early life can reduce surgeries for DDH, as the ‘back-carrying’ method did, requires further study. Third, the first ultrasound examination was performed in a newborn nursery for collecting study candidates of the same age. The protocol did not selectively screen by risk factors, and the results may be different when ultrasound examination was performed at 4–6 weeks of age. Further studies of babies with risk factors and of older babies with Graf type IIa hips are warranted. Fourth, inter-rater reliability was not a problem because in this study hip ultrasound examination was performed by the same doctor in the newborn nursery and outpatient clinic, but minor inconsistency from intra-rater variability may exist [14–17].

Conclusions

This is the first prospective study to investigate the effect of double diapering on hip development. Evidence supports that this simple method can enhance hip maturation in babies with Graf type IIa hips and reduce costs for further clinical and ultrasound follow-ups. A practical instruction for parents to carry out a task may continuously remind parents of proper hip positioning. As clinical impact, simple
instruction of double diapering imparted to the parents would lead to fewer clinical visits and hip ultrasound examinations.

**Abbreviations**

DDH, developmental dysplasia of the hip

**Declarations**

**Ethics approval and consent to participate:** All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee (Institutional Review Board of Chang Gung Medical Foundation; IRB No. 201601161B0C501) and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. Consent to participate was obtained from all participants’ parents in this study.

**Consent for publication:** Informed consent was obtained from all individual participants in the study.

**Availability of data and materials:** The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

**Competing interests:** The authors declare that they have no competing interests.

**Funding:** Not applicable

**Authors' contributions:** WC and CH conceptualised and designed the study, drafted the initial manuscript, and reviewed and revised the manuscript. HK, WE, SM, and MC designed the data collection instruments, collected the data, conducted the initial analyses, and reviewed and revised the manuscript. All authors approved the final manuscript as submitted and agree to be accountable for all aspects of the work.

**Acknowledgements:** Not applicable

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**Figures**
Figure 1

Subsequent clinical visits and hip ultrasound examinations from 1 month to 1 year of age

**Supplementary Files**

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- ConsortForm2of2Flowchart20200207.pdf
- ConsortForm1of2Checklist20200207.pdf