A comparative study on the effectiveness of two different devices in the management of developmental dysplasia of the hip in infants

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Aim. **The aim of this paper was to compare the results of treatment of developmental dysplasia of the hip (DDH) with two different devices.**

Methods. **In 118 DDH, authors employed, in a blinded randomized study, Teuffel-Mignon (TF) and Coxa-Flex (CF) devices. In this study checked 51 hips type IIC; 43 type IID; 15 type IIIA; 9 type IIIB, by Graf classification.**

Results. **Hips Graf's type C were recovered in median 60.09 days, with TM in 50, with CF in 63,45; hips type D in 100 days, with TM in 58,50, with CF in 89.00; hips type IIIA in 103.60 days, with TM in 122, with CF in 94.50; hips type IIIB in 108.66 days, with TM in 121, with CF in 102.50.**

Conclusion. **The linear multiple regression model shows a statistically significant associations between outcome and pathological type (P value<0.001), age at diagnosis (P<0.001) and device (P<0.02). The statistical model shows that on average for each day of delay in the diagnosis is needed more than half a day for the patient to recover. The model confirmed that patients with more serious pathologies need more time to recover. Authors think that importance of the treatment of DDH isn't only the type of device employed, but a precise and correct sonographic diagnosis. Very important is starting the treatment as soon as possible, when the infant's bone of hip is more plastic and easy to treat. The authors' opinion is that employing a device instead of another isn't important, fundamental is the choice of the right device derived to a long time clinical experience.**

Key words: **Dysplasia - Hip – Ultrasonography.**

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For over thirty years of experience into the detection and management of developmental dysplasia of the hip (DDH) in infants, there is a large consensus that sonography is useful in the diagnosis and screening of pathological hips.[1-5] Controversial is the use of sonography in universal or selective screening of neonatal hips.[3-8]

In every case sonography can detect many DDH, which are missed on clinical examination and can exclude any pathology in many hips which clinically silent.

However there are few data in literature about the use of sonography to assess the results and to compare splinted and untreated hips. About the real efficacy of dif-

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ferent harness and protocols for treatment [7-9, 10] there are few data too.

One of the most controversial problems is: when must we treat the hips? The literature shows generally that pathological hips at the US examination can improve with out treatment.[10] But the real problem arises when we must decide which hips will improve or not improve without treatment.[7]

It was suggested that not splint a newborn with DDH is unethical.[7] Moreover splinting in abduction in not risk-free because employing the splint, the medical literature reports case of avascular necrosis of the femoral head in a high percentage.[11] Furthermore ultrasound screening for DDH and early conservative treatment might prevent possible hip operations [5] and consent at the same time to reduce the percentage of "late diagnosed" pathological hips.[12]

We treat the pathological hips on the ground of clinical data and sonographic classification of Graf.

Always, for this reason, we decide ethically to treat all the type of dysplasic hips showed by sonography.

The evolution of this treatment was monitored by sonography at first once a month with recovery, demonstrated with pictures type Ia or Ib, in our hospital and then at the end of treatment performing pelvis X-ray. We think that the average length of our follow-up is enough for considerer once for all restored and normal hips studied and that is impossible a later development of residual dysplasia.

The aim of this randomised study is evaluation of the real effectiveness of the two harness employed in the management of DDH.

Materials and methods

From 1 January 1990 to 31 December 2004 (15 years) we have studied by sonography over 25.000 hips in infants under 6 months of life for the DDH screening.

We consider 6 months as the right cut-off for the sonographic screening of DDH, because after this ages the ossification of hip's tissues don't permit a correct US evaluation of hip.

We have detected 2 155 DDH of Graf types IIC, IID, IIIA and IIIB (10.7%). In this study the 89% of infants presented one or more clinical signs of dysplasia and/or history data suspected for DDH. In this cases, we found many factors that were associated to pathology, like: premature birth in 560 cases (25,9%), birthplace of parents with high incidence of DDH in 406 cases (18.8%), bottom position at birth in 344 cases (15.9%), familiarity in 299 cases (13.8%), other orthopaedic pathologies (like clubfoot and congenital stiff neck) present in 133 cases (6.1%), dry labour in 102 cases (4.7%), obstructed labour in 35 cases (1.6%), twin-birth in 36 cases (1.6%).

During the study an orthopaedic surgeon has examined clinically all babies at the same moment with US exam, with Ortolani and Barlow tests and abduction of the thighs. These tests were positive in only 78 hip (3.6%) and only in baby less than 2 months of life. Moreover after the clinical exam we have take notice of the length of limbs and asymmetry of skin folds of buttock and thighs, the last test poor meaning.

We have not observed hips type IV of Graf: dislocated hip.

On 2155 sonographic DDH detected, we have observed 1187 (55.0 %) hips type IIC, 769 (35.7 %) type IID, 155 (7.2 %) type IIIA and 44 (2.0 %) type IIIB, according to classification of Graf.

We found 2155 DDH in 1902 infants (1115 females and 792 males), 253 cases were bilateral. The age of babies was under 6 months of life, and we observed, in general, types IIC and IID in babies older and on the contrary types IIIA and B in babies younger: 67% of types IIIA and B were present in babies under 1 month of life.

We employed two harnesses for treatment: Coxa-flex (Figure 1) (Thamert Gmgh, Burgwedel, Germany) and Teuffel Mignon (TM) (Figure 2) (Teuffel Gmbh, Stuttgart, Germany).

The Coxa-flex harness (CF) allows of placing hips in flexion of 90°-100° degrees and abduction of about 50°. These position

Figure 1.—Image of the harness for treatment.

Figure 2.—Image of the harness for treatment.

permits to keep femoral head well-balanced and well-aimed in the bottom of the acetabulum, so that achieves its correct remodelling with time. The flexion also exploits the well-balanced and well-aimed action of ileopsoas muscles; this harness is like the Pavlic one.

The TM harness allows of placing hips in controlled abduction about 60°, with a flexion about 80°; that keeps in any case the well-balanced and well-aimed femoral head in the bottom of the acetabulum.

Usually in the clinical practice, our choice of harness was determined of Graf sonographic type of hip and age of infant, as a rule our protocol of treatment is:

1. Graf type C at any age is treated with TM harness.

2. Graf type D before 3 months of life is treated with CF harness and after 3 months with TM harness.

3. Graf types III A and B always at any age were treated with CF harness.

The choice between both the harnesses was performed on the ground of secure restraints of CF and of more rigid device of TM. In the neonates under three months of life and with severe DDH, we prefer a harness of secure restraint; in the others cases we make a choice of a more rigid device for babies stronger and with a low grade of DDH.

For this study, from 1 January 2001 since 31 December 2003, we have treated 118 DDH with one of both harnesses abovementioned in a double blinded randomised study: 59 hips with TM and 59 hips with CF device (Table I). The choice of device is made before performing the sonographic exam, without knowing its result.

Statistical method of analysis: a linear multiple regression models was adapted to describe the relationship between time to remission (outcome) and available predic-

TABLE I.—*DDH treated with 2 different devices.*

Type of Graf	n.	TM device N. treated	CF device N. treated
IIC	51	31	20
IID	43	20	23
IIIA	15	5	10
IIIB	9	3	6

tive variables (covariates). Covariates included in the model where: type of device used (reference category: CF), pathological type (reference category: IIC [sonographic type of Graf]), age at the beginning of treatment and sex (reference category: female). This kind of model allows to describe the relationship between several covariates and outcome and to predict the time to remission for patients with known characteristics.

Results

All pathological hips were recovered. We define a hip as recovered when the sonographic appearance is like the type Ia or Ib according to classification of Graf. The length of the treatment was at least 35 days on maximum 120 days, with median length of 86.11 days. The treatment, on the average, started after 43.03 days of life (minimum 1 days on maximum 99 days). Time of recovery was fairly in relation to age of infant and of start of treatment. We have never changed harness because hip not improved. In all hips treatment was finished with the same harness: TM harness mean recovered hips in 72.76 days and CF harness in 84,35 days (Table II).

Statistical analysis shows a significant associations between remission and pathological type (P value <0.001), age at diagnosis (P<0.001) and device (P<0.02). Moreover during the study we have never observed significant association with sex (P=0.63).

At the same time we have never found any case of avascular necrosis; all babies are also clinically controlled after three months before walking.

Only one case of hip staged as type IIIA of Graft's classification, shows at 25 days of life, it was immediately treated with CF splint. After two sonographic examinations at 50 and 80 days of life, do not show any improvement. But rather than have the danger of a plain instability, we decided to perform a plaster cast in human position, in anaesthesia. The X-ray exam is performed at the end of the treatment, with normal sonographic pictures, always confirmed the recovery.

Both harnesses seemed to be well tolerated by infants and well managed by parents.

Statistical analysis

The linear multiple regression model shows a statistically significant associations between outcome and pathological type (P value<0.001), age at diagnosis (P<0.001) and device (P<0.02). No significant association was found with sex (P=0.63) (Table III).

The estimated model shows that a patient treated with a TM device on the average needs about 7 days more to recover compared to a patient treated with CF. While this difference results statically significant, instead the clinical impact of the device's choice can 't be considered meaning full.

It was found that age at diagnosis is an important predictor from both statistical and clinical point of view. The model shows that on average for each day of delay in the diagnosis more than half a day is needed for the patient to recover. This would imply, for instance, that a patient who had a diagnosis month earlier than another patient with the same characteristics will need 15 days less to recover.

Also pathological type is shown statistically and clinically significant in the pre-

TAB. II.—*Time of recovery of the DDH on the base of the Graf's type and the device employed.*

Graf's type of hip	Median days of recovery	Median days of recovery with TM device	Median days of recovery with CF devices
Type C	60,09	50	63,45
Type D	100	58,50	89,00
Type IIIA	103,60	122	94,50
Type IIIB	108,66	121	102,50

TABLE III.—*Statistical analysis: linear multiple regression model for describe the relationship between time to remission (outcome) and available predictive variables (covariates: type of device, age, sex).*

	Estimate	Std. Error	T value	Pr (>|t|)
(Intercept)	48.16	3.87	12.44	< 2e-16 ***
Device (TM°)	7.37	3.07	2.40	0.0180 *
Age	0.55	0.06	8.76	2.41 e-14***
type Graf (IID)	8.35	3.27	2.55	0.0121*
Type Graf(IIIA)	31.39	4.69	6.68	9.67e-10 ***
Type Graf(IIIB)	37.09	5.80	6.38	4.11e-09***
Sex (M)	1.44	2.99	0.48	0.6300

Significance codes: 0 '***' 0.001 '**' 0.01 '*' 0.05 '.' 0.1 ' ' 1
Residual standard error: 15.65 on 111 degrees of freedom
Multiple R-Squared: 0.59, Adjusted R-squared: 0.57
F-statistic: 27.45 on 6 and 111 DF, p-value: < 2.2e-16
° Teuffel Mignon device.

TABLE IV.—*Estimated time to remission at median age for male patient treated with TM.*

DDH Graf type	Median age	Estimated remission time (days)
IIC	42	80
IID	39	87
IIIA	33	107
IIIB	49	121

diction of time to remission. The model is confirmed that patients with more serious pathologies needs more time to recover. For instance, the remission of an IIIA patient will take on average about a month longer than for a patient of type IIC. A pair of wise comparisons showing that pathological types IIC and IID had a different effect on time to remission (P<0.05), while IIIA and IIIB did not (P=0.40). There is a significantly different effect between pathological types II and III (all pair wise comparisons with P<0.001).

Example: Estimated time to remission at median age for male patient treated with TM (Table IV).

The model is able to explain about the 60% of the variation in the data. This would suggest that other important covariates might exist and should be included in the model. (Possibly parental attitude to treatment).

Discussion

Just from the beginning, we decide ethically to treat all dysplasic hips checked by sonography. The management of developmental dysplasia of the hip was sufficient codified by Graf in his classification.[14] If we consider the Graft's classification and his protocol of treatment, we have rare failed interpretation of Ia or Ib sonographic picture. In the recovery of dysplasic hip.[15] For this event a large number of them shows a spontaneous improvement,[16] and this thing complicates certainly every studies on the effectiveness of treatment. But that may depend if we always consider the Graft's immature hips as pathological hips to treat, and this is impossible in every case.

Sometimes these are hips must be observed for a long time, and treated only if one of them could develope in a dysplasic Graft's type. The controversial problem is what device is better to employ during the treatment.

We may employ two types of harnesses:

1) harness,[7, 11, 13, 15, 17] that exploits the action of the ileopsoas muscles over the head of femur well balanced into acetabulum: the founder of this devices is the Pavlic harness. The CF is a device of this type.

2) Harness, as TM, who allows only the abduction and flexion of the hips about 60° degrees; but who permits at baby the voluntary, active and free greater flexion of the hips.

In this study we have compared the efficacy of treatment with CF versus TM harness in a randomized population of developmental dysplasia of the hip.

We have not observed during this study

any different improvements in the two devices compared. The mean time of recovery of all hips are statistical the same in the two groups of the study (P value <0.001) in any case if we consider the different degrees of pathology for both harness.

The estimated model shows that with a TM device on average needs 7 days more to recover compared to a patient treated with CF. While this difference results statistically significant, the clinical impact of device's choice can't be considered important (P<0.02).

Another important comparison showed from statistical analysis is the meaningful association between age and diagnosis (P<0.02), as predictor of recovery.

A very significant acquisition showed from statistical analysis is the possibility to estimate the time of recovery on the grounds of sonographic type of hip (P<0.001). The length of recovery is shorter when hip considered is staged like an initial grade of Graf's classification, but in any case these data haven't relation with age of diagnosis.

We can also assert that the safety of both devices is excellent. We have never observed any avascular necrosis of the head in our study. This good result depends on the choice of the right device, the accuracy and frequent clinical and sonographic check-up of hips and on important compliance of parents, and finally on co-operation with paediatrics.

And we can also affirm that both CF and TM harness have maintained the femoral head in the centre of a dysplasic acetabulum, allowing our correct remodelling.

Conclusions

We think that the importance in the treatment of DDH isn't only the type of device that exactly employed, but the correct sonographic diagnosis with Graf's method, and this is possible with experience for a long time in sonography of the hip in infants.

Sonography certainly has some limitations: like is enough depending to medical executor. A sonographic experienced phisician is really indispensable to execute the correct exams of the hips, and to make a correct interpretation of pictures. We think that a better executor of sonography of the infant hip is the orthopaedic. Because, if the orthopaedic is experienced above all in sonography of the hip, he performs the sonographic and clinical diagnosis, and therapy of the pathological hips: without immediately starts the loosing time.

Therefore sonographic imaging according to Graf's method is considered now as an indispensable tool in guiding our treatment protocol in DDH.

Moreover is very important to begin treatment as soon as possible, when the bone of infant hip is more and fast plastic and modelling, also if statistically, estimated time of recovery isn't in precise relation to age of diagnosis.

We think that is useful subject at sonographic evaluation the others infants within three months of life too.

Ethically we consider correct to treat all pathological hips showed by sonography.

Last but not least is the accuracy and frequent clinical and sonographic check-up of hips and good compliance of parents and co-operation with paediatrics: that reduces in a significant way, the incidence of very important complications like avascular necrosis of the head of the femur.

The treatment with harness is useful and resolutive in all the pathological hips showed by sonography. We think isn't fundamental the type of device employed but for us is important the choice of the right one for every case.

In any case the right choice of the devices is derived to experience of the orthopaedics with that specific one.

Moreover finally sonography permits the follow-up of hips in treatment.

Riassunto

Studio comparativo di due divaricatori nel trattamento della displasia congenita d'anca infantile

Obiettivo. Obiettivo del presente studio è stato quello di confrontare i risultati del trattamento della DCA con due diversi divaricatori.

Metodi. In 118 DCA, si sono utilizzati, in uno studio randomizzato in doppio cieco, i divaricatori Teuffel-Mignon (TM) e Coxa-Flex (CF) 51 anche erano tipo II C; 43 di tipo II D, 15 di tipo IIIA, 9 di tipo III B, secondo la classificazione di Graf.

Risultati. Anche le displasie di tipo C si sono normalizzate in media in 60,09 giorni, con TM in 50, con CF in 63,45; anche di tipo D in 100 giorni, con la TM in 58,50, con CF in 89,00; anche di tipo IIIA in 103,60 giorni, con TM in 122, con CF in 94,50; anche di tipo IIIB in 108,66 giorni, con TM nel 121, con CF in 102,50.

Conclusioni. Il modello di regressione lineare multipla si presenta con statisticamente significative associazioni tra normalizzazione e di tipo patologico (P value <0,001), età alla diagnosi (P<0,001) e divaricatore (P<0,02). Il modello statistico mostra che in media per ogni giorno di ritardo nella diagnosi è necessaria più di una giornata per l'anca per normalizzarsi. Il modello ha confermato che le anche più gravi hanno bisogno di più tempo per recuperare. Gli autori pensano che l'importanza del trattamento della DCA non è solo il tipo di divaricatore impiegato, ma una diagnosi ecografia precisa e corretta. Molto importante è iniziare il trattamento il più presto possibile, quando l'osso del bambino è più plastico e facile da trattare. Impiegare un dispositivo piuttosto che un altro non è determinante, fondamentale è la scelta del giusto dispositivo derivata da una lunga esperienza clinica.

Parole chiave: Displasia - Anca - Ultrasonografia.

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