

Intérêt de la traite du cordon chez les Nouveaux-nés prématurés (<30SA)



**ETUDE PROSPECTIVE RANDOMISÉE
AU CHU DE NICE**



GEN-PACA le 24 mai 2014

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Intérêt de l'étude



- Augmentation du nombre de transfusion sanguines chez les grands prématurés
- 50% des <32SA transfusés au moins une fois (28 premiers jours de vie) [1]
- Origine de l'anémie multifactorielle: [1] [2]
 - Immaturité système hématopoïétique
 - Synthèse d'EPO inadaptée
 - Spoliations sanguines
 - Processus inflammatoires



- Placenta: « jumeau » du fœtus.
- Clampage et section du cordon : acte « hautement symbolique » .
- Avant clampage recèle une quantité non négligeable du sang fœtal: 100ml chez le NNé à terme.
- Sang oxygéné , riche en Hb , et cellules souches Hématopoïétiques. [5]



- Délai de clampage du cordon: Controversé [3][4]
 - Clampage précoce?
 - ✦ 10 à 15 s
 - ✦ Clamp de barr à 25cm
 - Clampage retardé ?
 - ✦ 1 à 3 min
 - ✦ Nné placé 20cm sous le niveau utérin
 - ✦ Pendant 45 à 60s



- Nné prématuré ne dispose que de la moitié du volume sanguin total placentario-foetal au contraire du nouveau-né à terme qui en dispose des 2/ 3 .
- Cette vulnérabilité circulatoire peut s'aggraver en cas de clampage immédiat, privant le prématuré d'un volume sanguin important [5]
- Un CR de 45 s, peut générer une augmentation de 22 à 28 % du volume sanguin total.
- Mercer et al. [6] ont évalué l'apport sanguin placentaire:
 - 10 à 28 mL/kg pour les nourrissons nés par VB
 - 2 à 16 mL/kg par césarienne

Données bibliographiques



*“A systematic review and meta-analysis of a brief delay in clamping the umbilical cord of preterm infants. »
Rabe H, Reynolds G, Diaz-Rosselo J., Neonatology
2008;93:138–44*

Avantages du CR chez le prématuré

10 publications retenues

A Systematic Review and Meta-Analysis of a Brief Delay in Clamping the Umbilical Cord of Preterm Infants

Rabe H. · Reynolds G. · Diaz-Rossello J.
Neonatology 2008



● Résultats

- 5 études avaient observé une augmentation de l'**hématocrite** à 1 h de vie ($p = 0,0007$)
- 4 études avaient montré une baisse du nombre de **transfusion** sanguine ($p = 0,0004$)
- 3 études avaient montré une meilleure TA et moins de supports volémique et inotropique dès les premières 24 h
- 7 études avaient observé une diminution de l'HIV ($p = 0,002$) ; 1 étude [18] avait montré une diminution des infections tardives ($p = 0,03$)
- **Aucune morbidité** liée au CR

Quelle alternative?



- Mais que penser du risque d'hypothermie?
Et/ou du retard de prise en charge en salle de naissance?
- Nouvelle alternative au CR
→ **milking du cordon**



- Qu'est ce que le « cord milking »?

Séquence et déroulement:

- Clampage habituel du cordon (Clamp de Barr 25cm)
- Puis Nné placé en table chauffante ou peau à peau
- Maintenir le cordon à la verticale
- Puis le traire depuis l'extrémité distale sur 15-20 cm ,
à 10cm/s à 3 reprises [7] [8]

Support bibliographique



Effect of umbilical cord milking in term and near term infants: randomized control trial

Amit Upadhyay, DM, MD; Sunil Gothwal, MD; Rajeshwari Parihar, DCH; Amit Garg, MD; Abhilasha Gupta, MD; Deepak Chawla, DM, MD; Ish K. Gulati, MD, FAAP

J Obstet Gynecol (fevrier 2013)

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Essai contrôlé randomisé
Monocentrique
Avril 2010 à septembre
2011

NNés >34 SA+6j

2 groupes comparables de
100 nouveaux-nés

85 inclus

TABLE 1
Baseline characteristics

Characteristic	Intervention group (n = 100)	Control group (n = 100)	P value
Gestation, wks	37.3 (1.72)	37.3 (1.69)	.75
Birthweight, kg	2.75 (0.41)	2.64 (0.32)	.92
Sex, male ^a	44 (44%)	34 (34%)	.19
Vaginal delivery ^a	56 (56%)	66 (66%)	.20
Maternal age, 18-40 y ^a	90 (90%)	92 (92%)	.80
Maternal weight, kg	46.8 (1.1)	47.2 (0.3)	.68
Maternal Hgb, g/dL	9.93 (1.33)	9.55 (1.21)	.19
Maternal anemia, Hgb <9 g/dL ^a	54 (54%)	51 (51%)	.77
Antenatal iron supplements ^a	24 (24%)	28 (28%)	.83
Low socioeconomic status ^a	64 (64%)	61 (61%)	.77
Use of oxytocin ^a	100 (100%)	100 (100%)	1.00
Exclusive breast-feeding at 6 wks ^a	60 (70.5%)	58 (68%)	1.00

Mean (SD), value (percentage).

Hgb, hemoglobin, test of significance, Student *t* test (continuous data).

^a Fisher's exact test/ χ^2 test (non continuous data).

Upadhyay. Effect of UCM in term infants. *Am J Obstet Gynecol* 2013.

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- Critères d'exclusion :
 - Cordons trop courts (<25cm)
 - EMA
 - Inhalation méconiale
 - Césarienne en urgence pour cause foétale
 - Grossesse multiple
 - Mère Rhésus négatif
 - Anomalies congénitales
 - Prolapsus du cordon
 - Hydrops foetalis, placenta praevia

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- Formation de l'équipe

- 3 démonstrations
- Visionnage de la vidéo

- Technique

- Clamp de Barr 25cm
- Table chauffante ou peau à peau
- Cordon à la verticale
- Traite depuis l'extrémité distale sur 15-20 cm , à 10cm/s à 3 reprises

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- Critère de jugement principal:
 - Taux d'Hb et ferritinémie à 6 semaines de vie groupe milking vs CP
- Critères de jugement secondaires
 - Paramètres hémodynamiques
 - Paramètres cliniques tels que les besoins en O₂, ictère dans les 2 premières semaines de vie.

Effect of umbilical cord milking in term and near term infants: randomized control trial

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• Results

TABLE 2
Hematological parameters

Parameters	Overall infants		Term infants		Near term infants		P value for all groups
	Intervention group (n = 100)	Control group (n = 100)	Intervention group (n = 74)	Control group (n = 75)	Intervention group (n = 26)	Control group (n = 25)	
Hgb at 12 h, g/dL	15.1 (2.5)	13.5 (2.1)	15.3 (2.6)	13.4 (2.3)	15.1 (2.0)	13.9 (1.5)	< .05
Hgb at 48 h, g/dL	11.9 (1.6)	10.8 (0.9)	11.7 (1.7)	10.8 (1.3)	12.0 (1.3)	10.9 (1.1)	< .05
PCV at 12 h, n (%)	45.7 (7.4)	41.4 (6.6)	46.2 (7.35)	41.2 (7.2)	45.0 (6.8)	41.6 (4.4)	< .05
PCV at 48 h, n (%)	41.2 (6.3)	37.2 (6.0)	41.7 (7.1)	36.8 (6.5)	40.9 (5.8)	37.9 (3.9)	< .05
Serum bilirubin at 48 h	7.4 (3.1)	6.6 (2.3)	7.2 (3.2)	6.5 (2.4)	6.9 (3.1)	7.1 (1.8)	> .05
Hgb at 6 wks, g/dL	11.9 (1.5) (n = 85)	10.8 (0.9) (n = 85)	11.9 (1.6) (n = 63)	10.9 (1.0) (n = 65)	11.6 (1.2) (n = 22)	10.7 (0.6) (n = 20)	< .05
Ferritin at 6 wks, µg/L	355.9 (182.6) (n = 85)	177.5 (135.8) (n = 85)	404.7 (252.2) (n = 63)	188.6 (143.4) (n = 65)	311.3 (169.7) (n = 22)	167.5 (132.8) (n = 20)	< .05

Mean (SD). Test for significance was an unpaired Student *t* test.

Hgb, hemoglobin; PCV, packed cell volume.

Upadhyay. Effect of UCM in term infants. *Am J Obstet Gynecol* 2013.

Effect of umbilical cord milking in term and near term infants: randomized control trial

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TABLE 3
Hemodynamic parameters

Parameters	Overall infants		Term infants		Near term infants		P value for overall infants
	Intervention group (n = 100) ^a	Control group (n = 100) ^a	Intervention group (n = 74) ^a	Control group (n = 75) ^a	Intervention group (n = 26) ^a	Control group (n = 25) ^a	
MBP at 30 min	51.6 (11.3)	48.4 (10.7)	51.5 (11.3)	47.2 (10.9)	53.9 (9.7)	49.5 (9.1)	< .05
MBP at 12 h	50.6 (10.8)	47.3 (9.5)	50.4 (10.9)	46.0 (9.4)	55.7 (9.6)	50.5 (8.3)	< .05
MBP at 48 h	50.3 (11.0)	46.2 (9.2)	50.1 (10.9)	46.0 (9.4)	54.4 (9.2)	48.8 (7.2)	< .05
HR at 30 min	139.0 (10.0)	137.5 (8.2)	138.9 (11.1)	138.6 (7.5)	139.2 (6.3)	134.3(9.3)	> .05
HR at 12 h	138.3 (6.5)	133.5 (13.1)	138.2 (6.6)	134.4 (14.0)	138.8 (6.3)	173.9 (21)	< .005
HR at 48 h	135.3 (15.0)	134.4 (10.6)	134.5 (16.8)	135.7 (10.3)	135.0 (8.0)	131.9(9.8)	> .05
RR at 30 min	43.3 (6.2)	43.9 (7.9)	43.4 (5.9)	44.8 (8.04)	42.8 (7.1)	41.2 (6.8)	> .05
RR at 12 h	42.8 (5.6)	42.4 (6.9)	42.9 (5.2)	43.5 (7.1)	41.8 (5.6)	39.4 (5.6)	> .05
RR at 48 h	41.9 (6.1)	41.4 (6.6)	41.9 (5.9)	42.2 (6.0)	42.0 (6.7)	39.0 (7.6)	

Values are in mean (SD); the test for significance was an unpaired Student *t* test.

HR, heart rate per minute; MBP, mean blood pressure in millimeters of mercury; RR, respiratory rate per minute.

^a Number of subject at birth is mentioned in this table top and number of subjects at 6 weeks is mentioned in relevant boxes below.

Upadhyay. Effect of UCM in term infants. *Am J Obstet Gynecol* 2013.



- **Conclusion de l'étude:**

- Hb plus élevée
- Meilleur statut ferrique

A 6 semaines de vie pour les nouveau né à terme ou proche du terme.



Umbilical Cord Milking Stabilizes Cerebral Oxygenation and Perfusion in Infants Born before 29 Weeks of Gestation

**Takeshi Takami, MD, PhD¹, Yuusuke Suganami, MD, PhD¹, Daisuke Sunohara, MD, PhD¹, Atsushi Kondo, MD, PhD¹,
Norio Mizukaki, MD¹, Tao Fujioka, MD¹, Akinori Hoshika, MD, PhD¹, Osamu Akutagawa, MD, PhD²,
and Keiichi Isaka, MD, PhD²**

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Inclusion de 50 Nnés
2 groupes comparables
<29SA
<1250g
01/01/2006 au 31/12/2009

Table I. Characteristics of 50 subjects

	Control group (n = 24)	Milked group (n = 26)	<i>P</i> value
Gestational age (wk)	25.8 (1.6)*	25.1 (2.1)*	.45
Birth weight (g)	849 (218)*	851 (221)*	.98
Apgar score (1 min)	4.9 (1.9)*	5.4 (1.7)*	.12
Male, no. (%)	10 (42)	11 (42)	.96
Cesarean delivery, no. (%)	20 (83)	22 (85)	.93
Antenatal steroid, no. (%)	11 (46)	11 (42)	.78

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- Critères d'exclusion
 - RCIU
 - Malformations
 - Troubles électrolytiques

- Comparaison
 - Bras milking
 - CP

low birth weight infants in our previous study⁷ were included in the controls (n = 24) for study. Infants who had cord milking were placed at or below the level of the placenta, and approximately 20 cm of the umbilical cord was vigorously milked towards the umbilicus 2 to 3 times before clamping the cord.¹⁰ The milking rate was approximately 20 cm/s. The umbilical cord of the control group infants was clamped immediately after birth. The present study was ap-

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● Résultats:

- Taux d'Hb initiale, diurèse des 24 premières heures plus élevés dans le groupe milking
- Moins de remplissages nécessaires
- Meilleure perfusion et oxygénation cérébrale

PPROM, no. (%)	8 (33)	11 (42)	.52
Hemoglobin value on admission (g/dL)	14.1 (1.6)*	16.8 (1.6)*	<.01 [‡]
MABP on admission (mm Hg)	28 (3.2)*	35 (4.3)*	<.05 [‡]
Urine output within 24 h (mL/kg)	1.1 (1.1)*	1.9 (1.3)*	<.05 [‡]
Volume expansion, no. (%)	14 (58)	5 (19)	<.05 [‡]
Inotropes, no. (%)	9 (38)	9 (35)	.86

PPROM, premature rupture of membranes.
*Values are presented as the mean (SD) number of cases.
†P < .05.
‡P < .01.

Notre étude



**Intérêt de la traite du cordon
chez les nouveau-nés prématurés
($<30SA$)**

Notre étude



- Type d'étude
 - Etude prospective cas-témoin
 - Essai contrôlé randomisé
 - En simple aveugle
 - Monocentrique (CHU de Nice services de réanimation néonatale/ Néonatalogie)

Notre étude



- **Population étudiée**

- 2 groupes parallèles
- Bras A: milking (50 Nnés)
- Bras B : clampage précoce (technique habituelle) (50 Nnés)

- **Critères d'inclusion**

- Nouveau né prématuré <30SA
- Nés entre le 01/06/2014 et le 01/12/2014 au CHU de Nice.

Notre étude



- Critères d'exclusion
 - Malformations congénitales
 - Les grossesses multiples
 - Les maladies maternelles
 - Les anomalies placentaires
 - Les prématurés hypotrophes
 - Mère rhésus négatif
 - Anomalie du cordon (cordon court)

Notre étude



- Critère de jugement principal:
 - Démontrer que la traite du cordon (versus clampage précoce du cordon) réduit le nombre de transfusions sanguines néonatales (critère : transfusion oui ou non dans les 28 premiers jours de vie)

Notre étude



- Critères de jugement secondaires:
 - Effets de la traite du cordon versus clampage précoce sur le taux d'hémoglobine (critère : Taux d'Hb au cordon et entre J-21 et J-28)
 - ✦ Résultat attendu : Δ Hb au cordon : 2.4 g/dl ($p < 0.01$)
 - ✦ Δ Hb entre J21 et J28 : 1,1g/dl ($p < 0.05$)
 - -Effets de la traite du cordon versus clampage précoce sur la pression artérielle moyenne à 30min , 12h et 48h de vie .
 - ✦ Resultats attendus respectivement :
 - ✦ A 30min Δ PAM : 3.2mmHG ($p < 0.05$) , à 12h Δ PAM : 3.3mmhg ($p < 0.05$) , à 48h Δ PAM : 4.1mmhg ($p < 0.05$)

Le consentement



Notice d'information et formulaire de consentement dans le cadre de l'étude prospective sur l'intérêt de la traite du cordon en salle de naissance chez le nouveau-né prématuré (<30SA)



Informations complémentaires

Lieu de naissance :

Grossesse gémellaire :

si oui préciser monoC/monoA monoC/biA biC/biA

Groupe et rhésus maternel :

Nouveau-né :

Antécédents maternels :

Pathologie de la grossesse :

Pathologies fœtale :

Corticothérapie anténatale :

Canal artériel :

Type et nombre de jour de ventilation :

Anomalies à l'ETF :

Références



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Effect of gravity on volume of placental transfusion: a multicentre, randomised, non-inferiority trial

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Summary

Background Delayed cord clamping allows for the passage of blood from the placenta to the baby and reduces the risk of iron deficiency in infancy. To hold the infant for more than 1 min at the level of the vagina (as is presently recommended), on the assumption that gravity affects the volume of placental transfusion, is cumbersome, might result in low compliance, and interferes with immediate contact of the infant with the mother. We aimed to assess whether gravity affects the volume of placental transfusion.

Methods We did a multicentre non-inferiority trial at three university-affiliated hospitals in Argentina. We obtained informed consent from healthy mothers with normal term pregnancies admitted early in labour. Vigorous babies born vaginally were randomly assigned in a 1:1 ratio by computer-generated blocks and sequentially numbered sealed opaque envelopes to be held for 2 min before clamping the umbilical cord, at the level of the vagina (introitus group) or on the mother's abdomen or chest (abdomen group). Newborn babies were weighed immediately after birth and after cord clamping. The primary outcome was the difference in weight (as a proxy of placental transfusion volume). The prespecified non-inferiority margin was 18 g (20%). We used t test and χ^2 test for group comparison, and used a multivariable linear regression analysis to control for covariables. This trial is registered with ClinicalTrials.gov, number NCT01497353.

Findings Between Aug 1, 2011, and Aug 31, 2012, we allocated 274 newborn babies to the introitus group and 272 to the abdomen group. 77 newborn babies in the introitus group and 78 in the abdomen group were ineligible after randomisation (eg, caesarean section, forceps delivery, short umbilical cord or nuchal cord). Mean weight change was 56 g (SD 47, 95% CI 50–63) for 197 babies in the introitus group compared with 53 g (45, 46–59) for 194 babies in the abdomen group, supporting non-inferiority of the two approaches (difference 3 g, 95% CI –5.8 to 12.8; $p=0.45$). We did not note any serious adverse events during the study.

Interpretation Position of the newborn baby before cord clamping does not seem to affect volume of placental transfusion. Mothers could safely be allowed to hold their baby on their abdomen or chest. This change in practice might increase obstetric compliance with the procedure, enhance maternal-infant bonding, and decrease from deficiency in infancy.

Funding Foundation for Maternal and Child Health (FUNDASAMIN).

Introduction

The ideal timing for umbilical cord clamping is controversial.¹ Delayed cord clamping allows for passage of blood from the placenta to the baby (known as placental transfusion).^{2,3} When cord clamping is done after 60 s, newborn babies have a median birthweight 101 g higher than those born after early clamping (before 60 s),³ probably representing an average placental transfusion of 96 mL [1 mL of blood=1.05 g].⁴

Delayed cord clamping increases haemoglobin in the neonatal period and decreases the risk of iron deficiency in infancy,^{5,6} a serious public health problem in low-income^{7,8} and high-income countries.^{9,10} The procedure is included in the guidelines for delivery room management of newborn babies from several professional organisations,^{11–16} but compliance with the recommendation is low.^{17,18} This low compliance could be related to some published studies suggesting that delayed cord clamping is associated with maternal complications.¹ However, results of a Cochrane meta-analysis¹ clearly

show no increase in maternal haemorrhage, the use of uterotonics, or duration of the third stage of labour.

On the assumption that gravity affects the volume of placental transfusion, recommendations suggest that newborn babies be held at or below the level of the vagina.^{19,20} This procedure is cumbersome, interferes with immediate contact with the mother, and might therefore contribute to low compliance. The effect of gravity on the volume of transfusion is based on the studies by Gardner and by Yao.^{19,20} Although those studies were not randomised trials and were done 35 years ago, they had rigorous methods.

If gravity plays a small or negligible part in placental transfusion, then most infants born after vaginal delivery could be placed immediately on the mother's abdomen or chest before clamping the umbilical cord. Depending on the position of the mother (lying down, semi-sitting, or sitting), the newborn baby would be above the vaginal level by about 30 cm. In view of the scarce evidence of the effect of gravity,¹⁹ we aimed to assess whether, provided



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