Prevention of post-term pregnancy in primary care obstetrics

Esteriek de Miranda

Prevention of post-term pregnancy in primary care obstetrics

The Sweeping study was funded by ZonMw “Netherlands Organisation for Health Research and Development” (grant application number: 22000036).

Prevention of post-term pregnancy in primary care obstetrics
Thesis, University of Amsterdam, The Netherlands

Cover: our daughter Merel

Lay-out and print: Pasmans Offsetdrukkerij BV, Den Haag

ISBN: 978-90-9022153-3

Prevention of post-term pregnancy in primary care obstetrics

ACADEMISCH PROEFSCHRIFT

ter verkrijging van de graad van doctor aan de Universiteit van Amsterdam
op het gezag van
de Rector Magnificus
prof. dr. D.C. van den Boom
ten overstaan van een door het college voor promoties ingestelde commissie,
in het openbaar te verdedigen in de Agnietenkapel
op vrijdag 26 oktober 2007, te 14.00 uur

door

Ester-Riek de Miranda

geboren te Amsterdam

Promotiecommissie

Promotores:	Prof. dr. O.P. Bleker
	Prof. dr. F.R. Rosendaal
Co-promotores:	Dr. J.G. van der Bom
	Prof. dr. G.J. Bonsel
Overige leden:	Dr. H.R. Iedema-Kuiper
	Prof. dr. J.H. Kok
	Prof. dr. J.M.W.M. Merkus
	Prof. dr. J.G. Nijhuis
	Prof. dr. E. Schadé
	Prof. dr. M. Vermeulen

Faculteit der Geneeskunde

ter herinnering aan onze dochter Merel

Contents

Chapter 1

Introduction

Post-term pregnancy

The duration of normal term pregnancy runs from 37 to 42 weeks; the definition of term pregnancy is based on statistical data derived from menstrual dates[1]. The mean duration of human pregnancy is approximately 281 days, calculated from the first day of a normal 28-day menstrual cycle; approximately 80% of pregnancies will end spontaneously between a gestational age of 37 (259 days) and 42 weeks (293 days) and about 90% of pregnancies will naturally end before day 294 (including preterm births). Post-term pregnancy is defined as a pregnancy with a gestational age of 294 days or more. In a survey of the natural duration of gestation in 4000 Dutch women with a reliable menstrual cycle, published in 1956, a Gaussian curve was found with the mean and maximum at 40 weeks of gestation and a symmetrical decline on both sides of the mean[2]. Approximately 10% of the pregnancies continued beyond 42 weeks, which was in concordance with the findings of a large Swedish population based study[3]. In those days labour induction was uncommon practice and pregnancies were allowed to continue until their natural end. Since the introduction of first-trimester ultrasound for determination of the gestational age the incidence of post-term pregnancy is reduced varying from 2% to approximately 7%[4-7] depending on the algorithm used for combining menstrual and ultrasound estimates[8]. First trimester ultrasound is more accurate in the calculation of the estimated date of delivery than the use of the last menstrual period because of wide variations in the length of the follicular phase. A first trimester ultrasound is now standard policy in midwifery practise.

Perinatal mortality in the post-term period

In the Dutch survey of Kloosterman [2], perinatal mortality and more explicit fetal mortality increased after 42 weeks and even more after 43 weeks pregnancy duration. Perinatal mortality was 1.0% in the term group, 3.6% in the 42½ - 43½ week group and 13.6% after 43½ weeks. Kloosterman showed that post-term fetal mortality was related to absolutely and relatively small placentas which resulted in lower birth weights than might be expected in prolonged pregnancies. These findings were in concordance with the observations of Clifford who introduced

the post-maturity syndrome in 1954[9]. This clinical syndrome, which is diagnosed after birth, is related to increased perinatal mortality and morbidity and includes loss of subcutaneous fat, dry and crackled skin often discoloured by meconium, and in more severe cases meconium aspiration syndrome. All symptoms are associated with placental insufficiency indicating that the fetal risks associated with the post-maturity syndrome are probably not a result of postmaturity per se, but of unrecognised placental failure at term[5].

Because of the increased risk of perinatal morbidity and mortality, post-term pregnancy is considered a high-risk circumstance [10-13] requiring specialist surveillance and termination of pregnancy[14;15] . However, it is mainly the increased risk of perinatal pathology caused by a small group of growth-restricted fetuses who are biologically post-term that account for obstetrical alertness[16;17;18]. Given the biological nature of pregnancy, most post-term pregnancies are not at a higher risk for perinatal morbidity and mortality[19;20;21;22], though macrosomia occurs more frequent due to continuing fetal growth[23]. Macrosomia is associated with maternal-fetal disproportion and shoulder dystocia and subsequently, in rare occasions, brachial palsy but not with an increased risk on perinatal mortality.

In order to differentiate between normal and pathological post-term pregnancies different policies on fetal testing, including cardiotocography and ultrasound, have been advocated to select the fetus at risk [4-26]. However, non-stress cardiotocography was not effective in the prevention of fetal death[27;28]. Ultrasound is frequently used for biophysical assessment, including the amount of amniotic fluid, doppler flow measurement and growth estimation. Studies on antepartum surveillance in post-term pregnancies showed an association between ultrasound detected oligohydramnios, meconium stained amniotic fluid and intrapartum fetal heart decelerations[29]. However, a decrease in adverse perinatal outcomes could not be established[30;31]. Doppler flow measurement beyond 41 weeks in otherwise low-risk pregnancies had no predictive value concerning the selection of the fetus at risk for perinatal morbidity or mortality in most studies on doppler flow measurement[32-36].

Growth retardation beyond term is associated with an increase in caesarean section for fetal distress[29;37]. Selection of growth retarded fetuses at term is therefore of major importance[37;38;39;40]. In various studies an increase in the caesarean section rate for fetal distress was noticed in pregnancies from 41 weeks onwards[41; 25; 42]. The largest trial on management of post-term pregnancy, the Canadian Multicen-

tre Postterm Pregnancy Trial[15], showed a lower rate of caesarean section for fetal distress when labour was induced at 41 weeks than in expectant management. Although differences in the rates of perinatal mortality and neonatal morbidity could not be established, the findings of the Canadian trial resulted in a tendency among obstetricians to adopt a policy of preventing post-term pregnancy by inducing all pregnancies at 41 weeks. However, serious criticism both on the design of the study and the interpretation of the results of the Canadian trial has probably prevented general introduction of this policy so far[22;43]. According to a recent Cochrane review[44] on induction of labour for improving birth outcome for women at or beyond term, a policy of labour induction after 41 completed weeks or later compared to awaiting spontaneous labour either indefinitely or at least one week, does not increase caesarean section rates and is associated with fewer perinatal deaths, though the absolute risk on perinatal death is extremely small.

Management of post-term pregnancy in the Netherlands

In the Netherlands, the guidelines on post-term pregnancy of the Dutch Society for Obstetrics and Gynaecology and the 'Obstetrical Manual' (Verloskundig Vademecum), which is endorsed by the professional associations of both obstetricians and midwives, considers post-term pregnancy as a pregnancy with a gestational age of ≥ 294 days (42 weeks), which requires specialist care. At present, post-term pregnancy occurs in 5.3% of all Dutch pregnancies[45]. "Impending" post-term pregnancy, defined as a gestation beyond 41 weeks and approaching 42 weeks in an otherwise low-risk pregnancy, was until recent not considered as an indication for labour induction. Labour induction from 42 weeks onwards is indicated, according to the guidelines, when additional risk factors as oligohydramnios or deviating foetal biometrics will appear[46]. In practice there exists a wide variation in obstetrical policy concerning low-risk pregnancies beyond 41 weeks, varying from referral at 42.0 weeks followed by expectant management until 43 weeks under CTG surveillance to twice a week CTG and ultrasound surveillance in secondary care commencing at 41 weeks and labour induction when post-term pregnancy is approaching. The latest update of the evidence based guideline of the Dutch Society for Obstetrics and Gynaecology on post-term

Table 1. Perinatal mortality in the Netherlands in 2003 according to three different definitions based on data from the Netherlands Perinatal Registry[45].

gestational age in weeks	total of all births (N)	fetal mortality (N)	perinatal mortality (N)	fetal mortality rate (%) WHO*	fetal mortality rate (%) Yudkin**	fetal mortality rate (%) Delft***	perinatal mortality rate (%) WHO*	perinatal mortality rate (%) Yudkin**	perinatal mortality rate (%) Delft***
37.0 – 40.6	130.903	295	439	0.23	0.17	0.22	0.34	0.25	0.33
41.0 – 41.6	33.078	69	103	0.21	0.16	0.20	0.31	0.24	0.30
>= 42	10.144	18	28	0.18	0.18	0.18	0.28	0.28	0.28

* Perinatal mortality rate according to the WHO definition: numerator is fetal mortality in a given week and first week mortality of live born infants delivered that week, denominator is the number of all babies delivered in the same week of gestational age

** Perinatal mortality according to the Yudkin definition[49]: numerator is the fetal and first week mortality related to a given week of gestational age, the denominator is the total number of fetuses undelivered at or beyond that week

*** Perinatal mortality according to the Delft definition[48]: numerator is the total of all fetal and first week mortality which still have to occur from the beginning of a given week of gestational age, denominator is the number of fetuses from the beginning of that week who are still undelivered and therefore at risk of fetal and neonatal death

pregnancy of June 2007 considers labour induction between 41 and 42 weeks in low-risk pregnancies on parent's request acceptable, this as a consequence of a current review on induction of labour for improving birth outcome for women at or beyond term[44].

Data obtained from The Netherlands Perinatal Registry (PRN-foundation)[45] showed that perinatal mortality in the Netherlands does not increase substantially when pregnancy continues beyond term (Table 1); the table shows the numbers and rates of perinatal mortality in the Netherlands according to the various definitions of fetal and perinatal mortality[47-49]. The figures are in concordance with previous studies on perinatal mortality in the post-term period[50;51;7]. However, other studies noticed an increase in perinatal mortality, mainly due to fetal death from 41 weeks onwards[38;52;53]. The determining factors contributing to perinatal mortality beyond term in the Netherlands are not systematically studied yet. A proposal for a nationwide perinatal audit system is waiting for regular funding.

Both in the Netherlands and abroad there is surprisingly little consensus about the appropriate management of pregnancies beyond term. Since the best policy beyond term for pregnancies that are considered as low-risk is still not clear, prevention of post-term pregnancy and consequently, spontaneous onset of labour at term seems to be the best option.

Aims of the study

This study has been set up to address the following issues:

1. Whether there are safe and effective non-pharmacological methods of labour induction in primary care obstetrics.

2. To study the opinion of Dutch midwives on safety and effectiveness of membrane sweeping for the prevention of post-term pregnancy in relation to the decisive factors of that opinion and the willingness to implement the results of a Dutch sweeping trial in midwifery practice.

3. To evaluate the safety and effectiveness of membrane sweeping at 41 weeks for the prevention of post-term pregnancy in low-risk pregnancies.

4. To determine the accuracy of the Bishop score at a gestational age of 41 weeks in predicting spontaneous onset of labour before 42 weeks of gestation after membrane sweeping.

5. To determine the accuracy of clinical estimation of fetal weight beyond term by midwives.

Outline of the thesis

This thesis is focused on effective midwifery care beyond term, in particular the prevention of post-term pregnancy by promoting spontaneous onset of labour.

Chapter 2 discusses the existing evidence for safety and effectiveness of non-pharmacological methods of labour induction used in primary care obstetrics. Pharmacological and mechanical induction of labour is not in use in a primary care setting because of the increased risk of fetal compromise and the subsequent need for urgent obstetrical intervention in a hospital setting[54;55-57]. Although various non-pharmacological methods of labour induction are regularly applied in midwifery practice, little is known about their safety and effectiveness. In this chapter origin, mechanism and (side-) effects of non-pharmacological methods of labour induction are described and relevant studies on safety and effectiveness of non-pharmacological methods of labour induction are discussed.

Chapter 3 shows the results of a study on the attitude of Dutch midwives regarding membrane sweeping for the prevention of post-term pregnancy. To sweep or not to sweep the membranes was subject of many debates amongst midwives, between midwives and obstetricians as well as amongst obstetricians. At time of the start of this survey there were conflicting results of studies on membrane sweeping. The opinion of practising primary care midwives on the effectiveness and side effects of membrane sweeping for the prevention of post-term pregnancy and the willingness to implement the results of the Dutch sweeping was requested in a nation-wide survey.

Chapter 4 presents the results of a randomised controlled trial on membrane sweeping at 41 weeks for the prevention of post-term pregnancy in low-risk pregnancies. Although various trials on the effectiveness of membrane sweeping have been accomplished, small sample sizes and heterogeneity of trial designs, including different endpoints, precludes generalisation of the trial results to a low-risk population; this explains the rationale of this study. Main outcome measures of the trial include post-term pregnancy and spontaneous onset of labour before 42 weeks. Secondary outcomes include adverse neonatal and maternal effects.

In ***Chapter 5*** the accuracy of the Bishop score at a gestational age of 41 weeks in predicting spontaneous onset of labour before 42 weeks of gestation after membrane sweeping is described. The Bishop score is frequently used to assess cervical ripeness and to predict the likelihood of success of labour induction. This study determines whether the Bishop score can be used as a predictor of successful membrane sweeping.

Chapter 6 shows the results of a study on the accuracy of clinical estimation of fetal weight beyond term by midwives. Growth retardation beyond term is a risk factor for perinatal morbidity and mortality when these infants are allowed to become post-term. The risk on perinatal morbidity due to macrosomia is also increased in the post-term period. Accurate fetal weight estimation is therefore of major importance. In this study estimation of fetal weight at 41 weeks of gestation is compared with actual birth weight.

Reference List

1. WHO. WHO, Recommended definitions , terminology and format for statistical tables related to the perinatal period and use of a new certificate for cause of perinatal deaths. Acta Obstet Gynecol Scand 1977; 56:247-253.
2. Kloosterman G.J. Prolonged pregnancy. International Monthly Review of Obstetrics and Gynecology 1956; 142(6):373-388.
3. Bergsjo P, Denman DW, III, Hoffman HJ, Meirik O. Duration of human singleton pregnancy. A population-based study. Acta Obstet Gynecol Scand 1990; 69(3):197-207.
4. Blondel B, Morin I, Platt RW, Kramer MS, Usher R, Breart G. Algorithms for combining menstrual and ultrasound estimates of gestational age: consequences for rates of preterm and post-term birth. BJOG 2002; 109(6):718-720.
5. Gardosi J, Geirsson RT. Routine ultrasound is the method of choice for dating pregnancy. Br J Obstet Gynaecol 1998; 105(9):933-936.
6. Gardosi J, Vanner T, Francis A. Gestational age and induction of labour for prolonged pregnancy. Br J Obstet Gynaecol 1997; 104(7):792-797.
7. Hovi M, Raatikainen K, Heiskanen N, Heinonen S. Obstetric outcome in post-term pregnancies: time for reappraisal in clinical management. Acta Obstet Gynecol Scand 2006; 85(7):805-809.
8. Savitz DA, Terry JW, Jr., Dole N, Thorp JM, Jr., Siega-Riz AM, Herring AH. Comparison of pregnancy dating by last menstrual period, ultrasound scanning, and their combination. Am J Obstet Gynecol 2002; 187(6):1660-1666.
9. Clifford S.H. Postmaturity with placental dysfunction. J Pediatr 1954; 44:1-13.
10. Kloosterman G.J. Epidemiology of postmaturity. In: Keirse M.J.N.C., Anderson A.B.M., Bennebroek Gravenhorst J., editors. Human Parturition. The Hague: Leiden University Press, 1979: 247-261.
11. Hilder L, Costeloe K, Thilaganathan B. Prolonged pregnancy: evaluating gestation-specific risks of fetal and infant mortality. Br J Obstet Gynaecol 1998; 105:169-173.
12. Nakling J., Backe B. Pregnancy risk increases from 41 weeks of gestation. Acta Obstet Gynecol Scand 2006; 85:663-668.
13. Ingemarsson I., Kallen K. Stillbirths and rate of neonatal deaths in 76761 post-term pregnancies in Sweden, 1982-1991: a register study. Acta Obstet Gynecol Scand 1997; 76:658-662.
14. Crowley P. Interventions for preventing or improving the outcome of delivery at or beyond term (Cochrane Review). The Cochrane Library, Issue 1 . 2001. Oxford: Update Software.
15. Hannah M.E., Hannah W.J., Hellmann J., Hewson S., Milner R., Willan A. Induction of labor as compared with serial antenatal monitoring in post-term pregnancy. N Engl J Med 2006; 326(24):1587-1592.

16. Divon M.Y., Haglund B., Nisell H., Olausson Otterblad P., Westgren M. Fetal and neonatal mortality in the postterm pregnancy: the impact of gestational age and fetal growth restriction. Am J Obstet Gynecol 1998; 178(4):726-729.

17. Clausson B, Cnattingius S, Axelsson O. Outcomes of post-term births: the role of fetal growth restriction and malformations. Obstet Gynecol 1999; 94:758-762.

18. Campbell MK, Ostbye T, Irgens LM. Post-term birth: risk factors and outcomes in a 10-year cohort of Norwegian births. Obstet Gynecol 1997; 89(4):543-548.

19. Usher R.H., Boyd M.E., McLean F.H., Kramer M.S. Assessment of fetal risk in postdate pregnancies. Am J Obstet Gynecol 1988; 158(2):259-264.

20. Carlomagno G., Candussi G., Zavino S., Primerano M.R. Postmaturity: how far is it a clinical entity in its own right? Clin Exp Obst Gyn 1996; 23(1):41-47.

21. Alexander J.M., McIntire D.D., Leveno K.J. Forty weeks and beyond: pregnancy outcomes by week of gestation. Obstet Gynecol 2000; 96(2):291-294.

22. Menticoglou S.M., Hall P.F. Routine induction of labour at 41 weeks gestation: nonsensus consensus. BJOG 2002; 109:485-491.

23. Fok W.Y, Chan L.Y., Tsui M.H.Y., Leung T.N., Lau T.K.Chung T.K.H. When to induce labor for post-term? A study of induction at 41 weeks versus 42 weeks. Eur J Obstet Gynecol Reprod Biol 2006; 125:206-210.

24. Guidetti DA, Divon MY, Langer O. Postdate fetal surveillance: is 41 weeks too early? Am J Obstet Gynecol 1989; 161(1):91-93.

25. Ohel G, Yaacobi N, Linder N, Younis J. Postdate antenatal testing. Int J Gynaecol Obstet 1995; 49(2):145-147.

26. O'Reilly-Green CP, Divon MY. Receiver operating characteristic curves of ultrasonographic estimates of fetal weight for prediction of fetal growth restriction in prolonged pregnancies. Am J Obstet Gynecol 1999; 181:1133-1138.

27. Li T, Rhoads GG, Demissie K, Smulian J. The efficacy of the non-stress test in preventing fetal death in post-term pregnancy. Paediatr Perinat Epidemiol 2001; 15(3):265-270.

28. Mohide P, Keirse MJNC. Biophysical assessment of fetal well-being . In: Chalmers I, Enkin M, Keirse MJNC, editors. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989: 477-492.

29. Alfirevic Z, Luckas M, Walkinshaw SA, McFarlane M, Curran R. A randomised comparison between amniotic fluid index and maximum pool depth in the monitoring of post-term pregnancy. Br J Obstet Gynaecol 1997; 104(2):207-211.

30. Bobby PD, Divon MY. Fetal testing in postdates. Curr Opin Obstet Gynecol 1997; 9(2):79-82.

31. Morris JM, Thompson K, Smithey J, Gaffney G, Cooke I, Chamberlain P et al. The usefulness of ultrasound assessment of amniotic fluid in predicting adverse outcome in prolonged pregnancy: a prospective blinded observational study. BJOG 2003; 110(11):989-994.

32. Farmakides G, Schulman H, Ducey J, Guzman E, Saladana L, Penny B et al. Uterine and umbilical artery Doppler velocimetry in postterm pregnancy. J Reprod Med 1988; 33(3):259-261.

33. Battaglia C, Larocca E, Lanzani A, Coukos G, Genazzani AR. Doppler velocimetry in prolonged pregnancy. Obstet Gynecol 1991; 77(2):213-216.

34. Malcus P, Marsal K, Persson PH. Fetal and uteroplacental blood flow in prolonged pregnancies. A clinical study. Ultrasound Obstet Gynecol 1991; 1(1):40-45.

35. Stokes HJ, Roberts RV, Newnham JP. Doppler flow velocity waveform analysis in postdate pregnancies. Aust N Z J Obstet Gynaecol 1991; 31(1):27-30.

36. Zimmermann P, Alback T, Koskinen J, Vaalamo P, Tuimala R, Ranta T. Doppler flow velocimetry of the umbilical artery, uteroplacental arteries and fetal middle cerebral artery in prolonged pregnancy. Ultrasound Obstet Gynecol 1995; 5(3):189-197.

37. Sylvestre G, Fisher M, Westgren M, Divon MY. Non-reassuring fetal status in the prolonged pregnancy: the impact of fetal weight. Ultrasound Obstet Gynecol 2001; 18(3):244-247.

38. Divon M.Y., Haglund B., Nisell H., Olausson Otterblad P., Westgren M. Fetal and neonatal mortality in the postterm pregnancy: the impact of gestational age and fetal growth restriction. Am J Obstet Gynecol 1998; 178(4):726-729.

39. Bais JM, Eskes M, Pel M, Bonsel GJ, Bleker OP. Effectiveness of detection of intrauterine growth retardation by abdominal palpation as screening test in a low risk population: an observational study. Eur J Obstet Gynecol Reprod Biol 2004; 116(2):164-169.

40. Lindqvist PG, Molin J. Does antenatal identification of small-for-gestational age fetuses significantly improve their outcome? Ultrasound Obstet Gynecol 2005; 25(3):258-264.

41. Treger M, Hallak M, Silberstein T, Friger M, Katz M, Mazor M. Post-term pregnancy: should induction of labor be considered before 42 weeks? J Matern Fetal Neonatal Med 2002; 11(1):50-53.

42. Sanchez-Ramos L, Olivier F, Delke I, Kaunitz AM. Labor induction versus expectant management for postterm pregnancies: a systematic review with meta-analysis. Obstet Gynecol 2003; 101(6):1312-1318.

43. Goer H. “Spin doctoring” the research. Birth 2003; 30(2):124-129.

44. Gulmezoglu AM, Crowther CA, Middleton P. Induction of labour for improving birth outcomes for women at or beyond term. Cochrane Database Syst Rev 2006;(4):CD004945.

45. The Netherlands Perinatal Registry. Perinatal care in the Netherlands 2003. van Huis AM, de Miranda E, Bruinse HW, Tamminga P, Brouwers HA, Ravelli AC et al., editors. 2006. Bilthoven, The Netherlands Perinatal Registry.

46. Post JA. Richtlijn serotiniteit NVOG. Commissie Richtlijnen NVOG, editor. 2007. Utrecht, Dutch Society of Obstetrics and Gynaecology.

47. WHO. WHO, Recommended definitions , terminology and format for statistical tables related to the perinatal period and use of a new certificate for cause of perinatal deaths. Acta Obstet Gynecol Scand 1977; 56:247-253.

48. Lim ML, Elferink-Stinkens PM, Wallenburg HC, van Hemel OJ. Estimate of perinatal mortality risk. Eur J Obstet Gynecol Reprod Biol 1993; 51(2):97-101.

49. Yudkin PL, Wood L, Redman CW. Risk of unexplained stillbirth at different gestational ages. Lancet 1987; 1(8543):1192-1194.

50. Menticoglou SM, Hall PF. Routine induction of labour at 41 weeks gestation: nonsensus consensus. BJOG 2002; 109(5):485-491.

51. Alexander J.M., McIntire D.D., Leveno K.J. Forty weeks and beyond: pregnancy outcomes by week of gestation. Obstet Gynecol 2000; 96(2):291-294.

52. Hilder L, Costeloe K, Thilaganathan B. Prolonged pregnancy: evaluating gestation-specific risks of fetal and infant mortality. Br J Obstet Gynaecol 1998; 105(2):169-173.

53. Ingemarsson I., Kallen K. Stillbirths and rate of neonatal deaths in 76761 post-term pregnancies in Sweden, 1982-1991: a register study. Acta Obstet Gynecol Scand 1997; 76:658-662.

54. van Gemund N, Hardeman A, Scherjon SA, Kanhai HHH. Intervention Rates after Elective Induction of Labor Compared to Labor with a Spontaneous Onset.

55. Vrouenraets FP, Roumen FJ, Dehing CJ, van den Akker ES, Aarts MJ, Scheve EJ. Bishop score and risk of cesarean delivery after induction of labor in nulliparous women. Obstet Gynecol 2005; 105(4):690-697.

56. Yudkin P, Frumar AM, Anderson AB, Turnbull AC. A retrospective study of induction of labour. Br J Obstet Gynaecol 1979; 86(4):257-265.

57. Dublin S, Lydon-Rochelle M, Kaplan RC, Watts DH, Critchlow CW. Maternal and neonatal outcomes after induction of labor without an identified indication. Am J Obstet Gynecol 2000; 183(4):986-994.

Chapter 2

Non-pharmacological methods of labour induction in primary care obstetrics: an overview

Esteriek de Miranda

Adapted from: Niet medicamenteus inleiden in de eerste lijn: van amniotomie tot wonderolie. In: Scherjon S.A., Beekhuizen W., Kanhai H.H.H., editors. Beëindiging van de zwangerschap: abortus, inductie en bijstimulatie. Leiden: Boerhaave Commissie, 2003: 179-201

Introduction

Elective termination of pregnancy by induction of labour is a deliberate intervention in pregnancy. It is intended to be beneficial but may harm both the mother and the child. Therefore it is of paramount interest to balance the benefits and risks of each indication.

At present, various effective drugs are available when induction of labour is required. In the literature all methods to hasten cervical ripening and onset of labour are classified as "induction of labour". This concept originates from the observation that a substantial proportion of cervical ripening procedures with prostaglandins ended with initiating of the process of labour.

Depending on the biological ripeness of the uterus and cervix, oxytocin or prostaglandins are the most frequently used drugs in secondary care obstetrics in the western world. Clinical surveillance is required in general both as a consequence of the indications for labour induction and because of potential side effects of the medication.

Induction of labour in primary care obstetrics is attempted in order to prevent labour induction in a secondary care setting. Indications for induction of labour in primary care are in particular prevention of post-term pregnancy and psychosocial conditions (e.g. failure to cope with prolonged pregnancy, home situation.)

The aim of this chapter is to review the literature on effectiveness and safety of induction methods used in primary care settings and to discuss the (assumed) mechanisms of these methods.

Methods

Medline was searched for publications with combinations of the following terms: “female”, “humans”, “pregnancy”, “cervical ripening”, “labor, induced/*methods” or “labour, induced/*methods” or “complementary therapies/*methods”, focused on primary care obstetrics. When available, papers in the English language were reviewed. If not, data are presented from review articles that summarize the paper in another language. A preference was made to present results from randomised trials. If a Cochrane review was available the results of the review were discussed. Levels of evidence have not been assigned because of the ranking problems which can occur when multiple dimensions of a study must be combined into a single grade[1]. The suggestion of Glasziou, Vandenbroucke and Chalmers[1] was followed to present a brief summary of the central evidence followed by a short assessment of the distinctive features of the studies involved.

Results

Acupuncture

The term “acupuncture” has its origins in the Latin words *acus* (needle) and *punctura,* (pricking) and refers to the method of stimulation of specific points, meridians, on the body surface. Acupuncture was developed in China were it is in use for more than 2000 years for the removal of blockades in the so-called “Chi-flow”. According to Chinese medicine[2], blockades in this “Chi-flow” are the cause of illness and pain. The supposed mechanism of acupuncture cannot be explained by the present knowledge of anatomy, physiology and pathology[3].

Acupuncture is regularly applied in western medicine too[4,5;6]. In obstetrics acupuncture is most frequently applied for pain control and cervical ripening but also for induction of labour. Acupuncture is said to stimulate the hypophysis; animal studies suggested an increase of the secretion of oxytocin after electrical stimulation of the neurohypophysical system[7]. According to Dunn[8], electrical stimulation through acupuncture on afferent nerve fibres can initiate various physiological mechanisms such as hormonal changes influenced through the ascending neu-

ronal pathways to the hypothalamus, or reflex activation of autonomic efferent nerves to the uterus.

In observational studies[9;10]acupuncture has been reported to be an effective and safe method for induction of labour. However, the small sample sizes and the absence of controls in these studies preclude any conclusions on the effectiveness of acupuncture for induction of labour.

In a study on the potential of electro-acupuncture to initiate contractions, 35 term pregnant women without labour pain were compared to 35 women who acted as controls (no sham acupuncture)[11]. Thirty-one of the women who received the intervention had a significant increase of frequency and intensity of uterine contractions while no increase was observed in women of the control group.

Theobald and Lundborg[12] evaluated the effect of acupuncture on labour onset in the term period. In the intervention group 27 women received acupuncture and 102 women acted as control, again without sham acupuncture. More women in the intervention group had deliveries ≤ 4 days before the estimated date of delivery comparing to the women in the control group (20/27 *vs* 47/102; OR 3.3, 95% Confidence Interval 1.3 – 8.4). However, there was no randomised allocation, which may have led to confounding by indication. Dunn [8] randomised 20 post-date pregnant women to transcutaneous electrical nerve stimulation at acupuncture points or a placebo treatment in which the electrodes were not activated. Frequency and strength of uterine contractions were monitored one hour before the start of the electrical nerve stimulation and the last two hours of a 4 hours test period. Dunn found a significant increase in frequency and strength of uterine contractions in the study group. However, it is not clear if delivery can be achieved with electrical nerve stimulation since the study period was limited to a 4 hours test period. In the only reported randomised controlled trial on acupuncture for cervical ripening and induction of labour[13], 56 low-risk women were randomised on their estimated date of delivery to acupuncture or no intervention. Women were examined thereafter at 2-day intervals. Trial outcomes included cervical length, Bishop score, time from date of study entry to delivery and number of postdate inductions. Data of 45 women (80%) were analysed, 11 women (20%) were excluded after randomisation. Cervical length was shortened at a faster rate in the acupuncture group though there was no difference in Bishop score. Time interval to delivery was significantly smaller in the acupuncture group (5 and 8

days respectively). There was no difference in labour inductions or in duration of labour. In this trial, 20% of the women were excluded from analysis, there were no intention to treat analyses.

Acupuncture has been reported to have an effect on the initiation of uterine contractions though there is lack of evidence on the safety and effectiveness of acupuncture for labour induction.

Amniotomy

Artificial rupture of membranes is perhaps the oldest method for labour induction. Amniotomy is associated with an increase in prostaglandin metabolism both in the amniotic fluid and in maternal plasma. An increase of prostaglandins in plasma is associated with a decrease of the induction-expulsion interval[14]. In contrast the oxytocin concentration is not influenced[15].

At present, amniotomy is predominantly applied in hospital settings and is followed by oxytocin administration when contractions are insufficient. In rare occasions agreements have been made on artificial rupture of membranes in a primary care setting for women who are scheduled for induction of labour the other day because of post-term pregnancy, to give them the opportunity to get into labour in the home situation. In a Cochrane review[16], two trials on the effect of amniotomy on the initiation of labour were included. One trial compared amniotomy for induction of labour to a single dose of prostaglandin E2 by vaginal gel[17]. Two hundred and sixty women with term pregnancies and a Bishop score of ≤ 6 (110 nulliparous- and 150 multiparous women) were randomised. There was a trend towards a shorter intervention-expulsion interval in the prostaglandin group, independent of parity. Augmentation was increased in the amniotomy only group compared to the prostaglandin group, both in nulliparous- and multiparous women, but the increase was larger for multiparous women(RR 2.33, 95% CI 1.33-4.10 and RR 3.63, 95% CI 1.77-7.41). Caesarean section percentages were similar in both groups. A small (n=50) randomised trial[18] evaluated whether change of the unfavourable cervix affects the ability to induce labour. Five different methods were evaluated in five subgroups, ten women in each group. The subgroups consisted of term women with a Bishop score of ≤ 4 who were allocated according to chart number to one of the five groups. In each group a different method was applied: controls (no intervention), laminaria, foley cath-

eter, oxytocin with intact membranes, and amniotomy. All interventions altered the cervix but only oxytocin affected the induction – expulsion time interval. No data were reported on time to labour onset or the proportion of women who went into labour or not. Considering the inadequate randomisation procedure[16] and the wide confidence intervals of the results, conclusions on the effectiveness of amniotomy for labour induction cannot be drawn.

Moldin et al[19] compared the effectiveness of amniotomy versus amniotomy with oxytocin infusion for labour induction in a randomised trial. One hundred and ninety-six term pregnant women with an indication for labour induction and a Bishop score of ≥ 6 were allocated to amniotomy followed by oxytocin infusion after 1 hour (n=98) or amniotomy alone (n=98). When labour did not occur after 24 hours in the latter group, oxytocin was applied finally. The induction-expulsion interval was shorter in the oxytocin group due to a shorter latent period in this group. The first stage in the active phase and the duration of the second stage were comparable in both groups. In the amniotomy group 32% (31/98) received oxytocin and in the oxytocin group 87% (85/98; RR 0.37 CI 0.30 – 0.47). This means that 68% of the woman in the amniotomy group delivered within 24 hours without additional oxytocics. Maternal and fetal results were similar. Data, originating from randomised trials on the value of amniotomy alone for induction of labour in a low-risk population in a low-risk setting, are lacking[16]. Risks of early amniotomy include prolapse of the umbilical cord when the presenting part is ill fitting, maternal and fetal infection, slow progression of labour, fetal blood loss due to vasa previa, and in occasional situations, fetal laceration[20,21].

Up to now, there is insufficient evidence on the efficacy and safety of amniotomy alone for induction of labour in a low-risk setting. More research on this field is needed in which assessment of the proper time-interval between amniotomy and secondary intervention needs attention.

Breast and nipple stimulation

Every breastfeeding mother knows that nursing the baby leads to contractions of the uterus. Therefore, this phenomenon was applied in many cultures for induction of labour or augmentation of labour[22]. It was assumed that stimulation of the breast would result in endogenous oxytocin release but this could not be con-

firmed experimentally [23]. Advantage of breast- or nipple stimulation is, that it can be applied by the expecting women herself. However, stimulation of nipples may result in hyper stimulation[24] and fetal bradycardia[25,26]. In a Cochrane review six randomised trials on unilateral breast massage and nipple stimulation for cervical ripening and labour induction were included with a total of 719 women[27]. This meta-analysis summarizes studies comparing breast stimulation with no intervention or another method of labour induction. In women with a favourable cervix, nipple stimulation led to a significant reduction in the proportion of undelivered women after 72 hours (62.7% *vs* 93.6%; RR 0.67, 95% CI 0.60-0.74). There were no cases of uterine hyperstimulation . One of the included trials concerned a three-armed trial in which breast stimulation was compared with oxytocin and with no intervention [28]. This trial was stopped untimely because of the occurrence of four perinatal deaths of whom three in the breast stimulation group. The researchers concluded that breast stimulation was effective for cervical ripening but should be applied only in case of fetal death because of the increased risk of adverse fetal outcome. One must take into account that this trial took place in a high-risk population, using an unclear allocation method and that the trial was stopped untimely. In the meta analysis, three trials with term low-risk women were included[29;30;31]. These three trials showed an increase of the mean Bishop score in the intervention group and more spontaneous onset of labour (RR 2.94, 95% CI 2.10 – 4.11). There were no fetal or maternal complications due to breast stimulation. One of these trials[29] evaluated the effect of breast self-stimulation on the incidence of post-term pregnancy. Two hundred low-risk women were randomly assigned to breast stimulation or control at 39 weeks. In the breast stimulation group spontaneous onset of labour before 42 weeks occurred more frequent (92/100 comparing to 79/100 in the control group; RR 1.17, 95% CI 1.04 – 1.27, number needed to treat = 8). When labour inductions before 42 weeks were included (6 in both groups), post-term pregnancy was still reduced in the breast stimulation group (5/100 *vs* 17/100; RR 0.29 CI 0.12 – 0.73).

Breast and (or) nipple stimulation seems to be an effective method for cervical ripening and initiating of uterine contractions, which can lead to spontaneous onset of labour. However, the risk on hyperstimulation of the uterus and subsequently (temporary) fetal bradycardia must be taken into account. Application of breast stimulation in a high-risk population is therefore discouraged until the safety of the method is sufficiently studied[27]. According to Summers[32], advice has

to be limited to the low-risk population and should imply carefully stimulating of alternate breasts, and to stop the breast stimulation during contractions.

In conclusion: since it is not clear whether breast- and nipple stimulation is associated with actual risks for the fetus, use of these methods in primary care obstetrics is questionable.

Castor oil

Castor oil is a known laxative that stimulates intestinal peristalsis by inhibiting electrolyte absorption. It is an extract from the seeds of Ricinus communis, consisting mainly of crude ricinoleic acid. The beans of the Ricinis communis are poisonous; one bean can kill a child, while two can be lethal for an adult. However, the toxins do not pass into the extracted oil. Castor oil can lead to uterine contraction[33], the ricinoleic acid in castor oil might be the active component that is responsible for the initiation of labour. Orally intake of castor oil leads to an increase of synthesis of PGE2 in the intrauterine tissues in pregnant rats[34].

There are only few studies known on the efficacy of castor oil for labour induction, of which only one randomised trial [35]. In this trial, 103 women with a gestational age of 40 – 42 weeks and a Bishop score of ≤ 4 were randomised to castor oil (single dose of 60 ml) or no treatment. Outcome measure was spontaneous onset of labour within 24 hour after intake. In the castor oil group, 58% (30/52 women) had spontaneous onset of labour compared to 4% (2/48) of the women in the control group (RR 31.36, 95% CI 7.51 – 128.08). There were no differences in other maternal and perinatal outcomes, besides that all women in the castor oil group reported nausea. The quality of this trial was criticised because of the alternating randomisation method, which can cause incomparability of groups, and the limited sample size[36]. A larger sample size is required to detect small but real differences in maternal and perinatal outcomes. According to a survey on obstetric and social factors prior to artificial rupture of membranes, intake of castor oil was associated with more meconium stained fluid and, subsequently, more Caesarean sections and low Apgar scores[37].

In view of the known side effects and the lack of reliable evidence on both the efficacy and safety of castor oil, castor oil should not be used for induction of labour.

Herbs and homeopathy

Herbs

Herbal preparations for induction of labour, seems to be widely used in primary care obstetrics. Surveys among nurse-midwives and expecting women on the use of herbal therapy during pregnancy, delivery preparation or the post-partum period revealed that a substantial proportion of the respondents respectively advise or have used herbal therapy for labour induction or delivery preparation[6;36;38-40]. Herbal preparations are considered as "natural" and therefore "safe"[39]. There are no Dutch data on the use of herbal preparations during pregnancy. Herbal preparations that are used for cervical ripening or labour induction are evening primrose (oil), blue cohosh and black cohosh (caulophyllum and cimicifuga), which are in use also in homeopathy, and red raspberry leaf (in tablets, tea, capsules). Evening primrose oil contains polyunsaturated omega-6 fatty acids, which are prostaglandin precursors, and isoflavones, which are phyto (plant-derived) estrogens. It may influence cervical ripening, 3 – 4 hours after ingestion. Studies on the effects of evening primrose on labour stimulation are rare[41] and there are no clinical studies on the safety or effects of evening primrose in human pregnancy.

Caulophyllum thalictroides also known as blue cohosh or squaw root, is a small forest plant of which the root was already used by native Americans to smooth the progress of childbirth. The active components of blue cohosh are the glycosides caulosaponin and caulophylosaponin, which have an oxytocic effect and the alkaloid methylcysteine (nicotine-like compound). Side effects from blue cohosh, are elevated blood pressure and blood sugar levels (caulophylline), nausea, severe stomach pain, and toxicity[39]. The glycosides caulosaponin and caulophyllosaponin are known to have a toxic effect on cardiac muscle probably due to the vasoconstrictor features. There are conflicting data from in vitro and in vivo studies in animals on the uterine stimulant effects of blue cohosh extracts[42] but there are no clinical studies supporting efficacy or safety of blue cohosh in women. In view of this information, the use of blue cohosh should be advised against.

The root of black cohosh (Cimicifuga racemosa) contains triterpene glycosides and quinolizidine-type alkaloids, which has an uterotonic effect and is used in combination with blue cohosh during pregnancy. Thus far, no clinical studies

are available on the effect and safety of black cohosh for labour induction.

Raspberry leaf (tea, tincture, tablets) is used for centuries for pregnancy related infirmities like nausea and vomiting but also to make delivery easier. Raspberry leaf is thought to have a relaxant effect on the uterus resulting in more efficient end better coordinated uterine contractions, thus shortening the length of labour. There is limited phytochemical information available for raspberry leaf, but the constituents including flavonoids and high doses of tannins. The effects of raspberry leaf (tablets) on delivery were studied in a double blind randomized placebo controlled trial[43]. In this trial 240 low-risk nulliparous women were randomized at a gestational age of 32 weeks to have a daily intake of 2 tablets containing 1.2 gram of the active ingredient or placebo tablets until delivery. The aim of the study was to evaluate whether raspberry leaf had an effect on duration of labour and course of labour. There was no difference in spontaneous onset of labour or differences in other outcomes. Negative side effects were not reported. Analysis was not performed according to the intention to treat principle.

Thus far, there is no scientific proof for a beneficial effect of herbal treatments for induction of labour. The use of these products in pregnancy may cause harm both the mother and her child.

Homeopathy is frequently used in primary care obstetrics for various indications[6]. Homeopathic medicines are extracted from natural resources like plants, animals and minerals and then diluted and shaken many times. According to the homeopathic "law of infinitesimals", the more dilute a solution is, the stronger its effect. The claim that an active ingredient pass on its healing capacity to the water or alcohol used for the dilution of the medicine is known as the 'memory' of the water (or alcohol)[44]. Extensive experiments however, failed to show such a memory [45]. The clinical effects resulting from homeopathic remedies are therefore attributed to the placebo effect[46] or to various sources of bias[47].

In a recent Cochrane review on the effectiveness of homeopathy for induction of labour[48], two studies were included. Beer et al.[49] assessed the efficacy of caulophyllum D4 in 40 women at term with prelabour rupture of membranes (PROM) and not in labour in a placebo double blind controlled trial. Primary outcome concerned the effect of caulophyllum on the time interval from study entry to the onset of regular uterine contractions. Women were allocated to take caulophyllum or a placebo every hour for seven hours. Each active tablet consisted

of 250 mg caulophyllum trituration D4, a mixture of magnesium stearate and a wheat starch mixture. The placebo contained no active ingredients but only the magnesium stearate and a wheat starch mixture. Basic characteristics were similar between study groups. There was no difference in primary outcome measure or secondary outcomes (augmentation, instrumental delivery, Apgar score). This trial was criticised for the poor methodological quality[48]. Furthermore, the sample size was too small to distinguish between both groups. The final conclusion of the Cochrane review was: "there is insufficient evidence to recommend the use of any homoeopathic therapies as a method of induction of labour."

Sexual intercourse

Unprotected intercourse to cause labour onset, is regularly advised in primary care obstetrics, pregnancy magazines and pregnancy books[50]. It is shown in various studies that components of sexual intercourse such as orgasm and prostaglandins in sperm and mechanical contact with the cervix are associated with cervical ripening and uterine contractions[51-54]. An association between coitus and preterm labour could not be established[55], although carriership of micro archaisms such as Trichomonas and Mycoplasma hominis may be associated with preterm labour or prelabour rupture of the membranes[56;57], a positive association was also found between coitus (once or more per week during the month before delivery) and amniotic fluid infection[58]. In a Cochrane review on sexual intercourse for cervical ripening and induction of labour, Kavanagh et al[59] included only one trial[60]. Twenty-eight women were randomised to intervention (sexual intercourse with compulsory ejaculation of the partner) or control with no sexual intercourse during 3 subsequent nights. Because of shortcomings in study design, the reviewers could not evaluate the role of sexual intercourse as a method of induction of labour.

In conclusion, sexual intercourse can lead to an increase of uterine activity but there is insufficient evidence on the effectiveness and safety of sexual intercourse for the initiation of labour.

Membrane sweeping

Sweeping of the intact membranes to induce labour is an old method, docu-

mented by Hamilton in 1810. The mechanism of sweeping is based on a local increase of prostaglandins due to sweeping of the membranes and mechanical stimulation of the cervix. In 1940 Ferguson discovered that stretching of the cervix augments uterine activity, since then known as "the Ferguson reflex"[61]. Mitchell[62] evaluated plasma concentrations of 13,14-dihydro-15-keto-prostaglandin-F2a (PGFM) in three groups of women with a gestational age of > 37 weeks. Samples ware taken 5 minutes before and 5 minutes after amniotomy, vaginal examination and membrane sweeping or only vaginal examination for assessment of cervical status. The concentration of PGFM increased after each intervention but increased significantly after amniotomy and vaginal examination combined with sweeping. In laboratory experiments with human myometrium tissue, obtained after Caesarean section or hysterectomy, Kloeck and Jung found an increase of PGE2 production when the myometrium was stretched in vitro[63]. Hillier did the same with human cervical tissue obtained from non-pregnant pre-menopausal women who had hysterectomy because of benign gynecological problems[64]. He also found a limited increase of the production of prostaglandins.

In a Cochrane review, Boulvain and Stan[65] included 22 randomised trials on membrane sweeping compared to no intervention or to the administration of prostaglandins or oxytocin as method of labour induction. The trials were very heterogenous in study design, which hampers pooled analyses and interpretation. Given these limitations the review concluded that sweeping of the membranes as a general policy in women at term, was associated with reduced duration of pregnancy and reduced frequency of pregnancy continuing beyond 41 weeks (RR 0.59, 95% CI 0.46 to 0.74) and 42 weeks (RR 0.28, 95% CI 0.15 to 0.50). To prevent one post-term pregnancy, the membranes of 11 women must be swept. There was no difference in risk on Caesarean section, meconium stained amniotic fluid and maternal or neonatal infection. The reviewers concluded that sweeping of the membranes reduces the risk of post-term pregnancy and reduces the use of other methods of induction of labour but membrane sweeping in low-risk women near term (37 – 40 weeks) does not seem to produce clinical important benefits. These results are not applicable for the Dutch situation. According to the World Health Organisation (WHO) and the International Federation of Gynecology and Obstetrics (FIGO) post-term pregnancy in the Netherlands is defined as a gestational age of 294 days or more (≥ 42 weeks). In 6 studies reviewed by Boulvain

and Stan[65], a gestational age of 287 days or more (≥ 41 weeks) was considered as "post-term", "prolonged", "postmature" or "postdate" necessitating induction of labour. In addition, most trials were conducted at a gestational age between 38 and 40 weeks of which one in a high-risk population, one in a mixed population and of three trials the population under study is not clear; the other trials were done in a low-risk population. Only three trials[66] included in the review[67;68] were conducted in a low-risk population with a gestational age of ≥ 41 weeks and one trial [69] started at a gestational age of 40+4. The population under study in the three trials and probably also in the fourth trial, is comparable with the Dutch low-risk population. However, all studies were done in a secondary care setting. Doany and McCarty evaluated the safety and efficacy of vaginal prostaglandin gel (PGE2) compared to sweeping for induction of labour[66] in a double-blind placebo controlled trial. Hundred and fifty low-risk expectant women were randomised at a gestational age of 41 weeks to four groups: no intervention and placebo gel (n=28), no sweeping and PGE2 gel (n=37), membrane sweeping and placebo gel (n=50), and membrane sweeping and PGE2 gel (n=28). The assigned treatment was administered at each subsequent visit, which was scheduled at 294 days of gestation (42 weeks) and every 3-4 days thereafter, to a maximum of 307 days. Patient characteristics were comparable. Indications for labour induction were comparable in the various groups. There was a trend towards shortening of the gestational age when the membranes were swept compared to placebo gel administration. Analysis according to compliance with the study protocol (no missing of scheduled appointment) showed a significant decrease in gestational age at delivery for membrane sweeping comparing to placebo gel administration. Limitations of this study are the small sample size of the subgroups making it difficult to distinguish between groups, furthermore, the number of women per subgroup is very unequal for which the reasons are not given in the paper. El-Torkey and Grant[67] evaluated the effectiveness of membrane sweeping for induction of labour in prolonged pregnancy (gestational age ≥ 41 weeks). Women at a gestational age of 41 weeks were offered the choice between induction of labour or surveillance. Women who opted for induction were randomised to sweeping or control. No vaginal examination was done in the control group. Eventually, 65 women were randomised. Patient characteristics were comparable. More women in the sweeping group had spontaneous onset of labour compared to controls (25/33 (76%) *vs* 12/32 (37%); OR 4.65, 95% BI 1.75-12.31). A greater proportion of

women in the sweeping group were in the active phase of the first stage of labour (cervical dilatation of 4 cm or more) at the first vaginal examination in the labour ward comparing to the women in the control group (16/33 (49%) vs 5/32 (16%); OR 4.39, 95% CI 1.56-12.32). Because the proportion of women with spontaneous onset of labour differed so much in favour of the sweeping group, the trial was stopped before the intended 110 women were included. There were no infections in the sweeping group; in the control group 4 women had an infection. There were no other differences in maternal or neonatal outcomes. Limitation of this trial is again the small sample size; to assess potential differences in maternal and fetal outcomes, a larger sample size is required.

Magann et al.[68] aimed to determine the optimal management of pregnancies beyond 41 weeks' gestation with an unfavourable cervix. He evaluated the risk of labour induction at 42 weeks in three groups. All low-risk pregnancies that reached 41 weeks' gestation with a Bishop score of < or = 4 were randomly assigned to one of three groups: (1) daily cervical examinations, (2) daily membrane stripping, or (3) daily placement of prostaglandin gel until 42 weeks; 105 women were included, 35 in each group. Patient characteristics were comparable in the three groups. The gestational age in both intervention groups was similar. Induction of labour at 42 weeks was more frequent in the control group comparing to the sweeping group or the PGE2 group (22/35 (63%) *versus* 6/35 (17%); RR 3.67, CI 1.84 – 7.80 and (22/35 (63%) *versus* 7/35 (20%); RR 3.14, CI 1.65 – 6.27). However, this comparison is not straightforward; in all groups induction of labour was performed before 42 weeks when a Bishop score of ≥ 8 was found (controls 9, sweeping group 5 and PGE2 group 6, indicating the remaining difference between the control group and intervention groups). Maternal and neonatal outcomes were comparable. Hill [64] criticised the post hoc sample size analysis of this study, challenging the validity of the sample size calculation. Conclusions are based on only 35 participating women in each group, which makes it difficult to assess differences in maternal and neonatal outcomes. Wong et al.[69] evaluated the efficacy of sweeping beyond 40 weeks of gestation in reducing formal induction of labour at 42 weeks. Sixty women were randomly allocated to sweeping and 60 women were allocated to control. The intervention was performed between 40+4 and 41+3 weeks in a probably low-risk population. Main outcome measures were incidence of formal induction of labour and complications of sweeping. Maternal en perinatal outcomes were assessed too. Sweeping shortened the time interval

from recruitment to delivery with one day (3.2 *vs* 4.2 days, mean difference: –0.9; CI –1.86 - –0.005). There was no difference in the occurrence of spontaneous onset of labour, induction of labour or other maternal and perinatal outcomes. The incidence of post-term pregnancy was decreased (14/60 (23%) *vs* 18/60 (30%) RR 0.78; CI 0.43 – 1.42) but the sample size is too small to assign this difference to the intervention.

The reviewed studies here, which are applicable to the Dutch situation, are inconsistent in their results and the sample sizes are too small to jump into conclusions on midwifery policy concerning prevention of post-term pregnancy by membrane sweeping. Membrane sweeping beyond 41 weeks appears to increase spontaneous onset of labour before 42 weeks in the absence of serious side effects. Thus far, evidence is lacking to assign any effect of parity or Bishop score on the pass rate of membrane sweeping. In the Netherlands, sweeping is regularly applied by midwives to prevent post-term pregnancy[70], though the effectiveness of the intervention for the prevention of post-term pregnancy in a population with specifically Dutch features had to be established.

Conclusion

In this chapter non-pharmacological methods, used in midwifery care, are reviewed. Methods such as intra-cervical application of catheters (e.g. Foley® catheter) are not discussed here because they are not in use in primary care obstetrics.

Midwives should be aware that substantial evidence is lacking on efficacy and safety of most non-pharmacological methods of labour induction in primary care obstetrics. To evaluate methods of labour induction in primary care obstetrics controlled trials with an adequate sample size are necessary. Fetal monitoring should be considered as part of these trials.

Reference List

1. Glasziou P, Vandenbroucke JP, Chalmers I. Assessing the quality of research. BMJ 2004; 328(7430):39-41.
2. Ewies AA, Olah KS. The sharp end of medical practice: the use of acupuncture in obstetrics and gynaecology. BJOG 2002; 109(1):1-4.
3. Renckens CN. The sharp end of medical practice: the use of acupuncture in obstetrics and gynaecology. BJOG 2002; 109(12):1418-1419.
4. Beal MW. Acupuncture and acupressure. Applications to women's reproductive health care. J Nurse Midwifery 1999; 44(3):217-230.
5. Smith CA, Crowther CA. Acupuncture for induction of labour. Cochrane Database Syst Rev 2004;(1):CD002962.
6. Allaire AD, Moos MK, Wells SR. Complementary and alternative medicine in pregnancy: a survey of North Carolina certified nurse-midwives. Obstet Gynecol 2000; 95(1):19-23.
7. Boer K, Lincoln DW, Swaab DF. Effects of electrical stimulation of the neurohypophysis on labour in the rat. J Endocrinol 1975; 65(2):163-176.
8. Dunn PA, Rogers D, Halford K. Transcutaneous electrical nerve stimulation at acupuncture points in the induction of uterine contractions. Obstet Gynecol 1989; 73(2):286-290.
9. Tsuei JJ, Lai Y, Sharma SD. The influence of acupuncture stimulation during pregnancy: the induction and inhibition of labor. Obstet Gynecol 1977; 50(4):479-8.
10. Yip SK, Pang JC, Sung ML. Induction of labor by acupuncture electro-stimulation. Am J Chin Med (Gard City N Y) 1976; 4(3):257-265.
11. Kubista E, Kucera H, Muller-Tyl E. Initiating contractions of the gravid uterus through electro-acupuncture. Am J Chin Med (Gard City N Y) 1975; 3(4):343-346.
12. Theobald, Lundborg RA. The electrical induction of labour with the transistor pulse generator and pulse current measuring device. J Obstet Gynaecol Br Emp 1962; 69:434-42.
13. Rabl M, Ahner R, Bitschnau M, Zeisler H, Husslein P. Acupuncture for cervical ripening and induction of labor at term--a randomized controlled trial. Wien Klin Wochenschr 2001; 113(23-24):942-946.
14. Husslein P, Kofler E, Rasmussen AB, Sumulong L, Fuchs AR, Fuchs F. Oxytocin and the initiation of human parturition. IV. Plasma concentrations of oxytocin and 13,14-dihydro-15-keto-prostaglandin F2 alpha during induction of labor by artificial rupture of the membranes. Am J Obstet Gynecol 1983; 147(5):503-507.
15. Thornton S, Davison JM, Baylis PH. Amniotomy-induced labour is not mediated by endogenous oxytocin. Br J Obstet Gynaecol 1989; 96(8):945-948.
16. Bricker L, Luckas M. Amniotomy alone for induction of labour. Cochrane Database Syst Rev 2000;(4):CD002862.

17. Mahmood TA, Rayner A, Smith NC, Beat I. A randomized prospective trial comparing single dose prostaglandin E2 vaginal gel with forewater amniotomy for induction of labour. Eur J Obstet Gynecol Reprod Biol 1995; 58(2):111-117.

18. Jagani N, Schulman H, Fleischer A, Mitchell J, Randolph G. Role of the cervix in the induction of labor. Obstet Gynecol 1982; 59(1):21-26.

19. Moldin PG, Sundell G. Induction of labour: a randomised clinical trial of amniotomy versus amniotomy with oxytocin infusion. Br J Obstet Gynaecol 1996; 103(4):306-312.

20. Satin AJ, Hankins GD. Induction of labor in the postdate fetus. Clin Obstet Gynecol 1989; 32(2):269-277.

21. Smith MA, Ruffin MT, Green LA. The rational management of labor. Am Fam Physician 1993; 47(6):1471-1481.

22. Curtis P, Evens S, Resnick J. Uterine hyperstimulation. The need for standard terminology. J Reprod Med 1987; 32(2):91-95.

23. Seoud MA, Sayigh R, Khayat H, Abou AL, Azoury RS. Electrical breast stimulation. Oxytocin, prolactin and uterine response. J Reprod Med 1993; 38(6):438-442.

24. Lenke RR, Nemes JM. Use of nipple stimulation to obtain contraction stress test. Obstet Gynecol 1984; 63(3):345-348.

25. Viegas OA, Arulkumaran S, Gibb DM, Ratnam SS. Nipple stimulation in late pregnancy causing uterine hyperstimulation and profound fetal bradycardia. Br J Obstet Gynaecol 1984; 91(4):364-366.

26. Schellpfeffer MA, Hoyle D, Johnson JW. Antepartal uterine hypercontractility secondary to nipple stimulation. Obstet Gynecol 1985; 65(4):588-591.

27. Kavanagh J, Kelly AJ, Thomas J. Breast stimulation for cervical ripening and induction of labour. Cochrane Database Syst Rev 2005;%20;(3):CD003392.

28. Damania KK, Natu U, Mhatre PN, Mataliya M, Mehta AC, Daftary SN. Evaluation of two methods employed for cervical ripening. J Postgrad Med 1992; 38(2):58-59.

29. Elliott JP, Flaherty JF. The use of breast stimulation to prevent postdate pregnancy. Am J Obstet Gynecol 1984; 149(6):628-632.

30. Salmon YM, Kee WH, Tan SL, Jen SW. Cervical ripening by breast stimulation. Obstet Gynecol 1986; 67(1):21-24.

31. Adewole IF, Franklin O, Matiluko AA. Cervical ripening and induction of labour by breast stimulation. Afr J Med Med Sci 1993; 22(4):81-85.

32. Summers L. Methods of cervical ripening and labor induction. J Nurse Midwifery 1997; 42(2):71-85.

33. Stewart JJ, Gaginella TS, Olsen WA, Bass P. Inhibitory actions of laxatives on motility and water and electrolyte transport in the gastrointestinal tract. J Pharmacol Exp Ther 1975; 192(2):458-467.

34. Gao J, Sun N, Wang F. [Effects of castor oil-diet on the synthesis of prostaglandin E2 in pregnant rats]. Zhonghua Fu Chan Ke Za Zhi 1999; 34(3):147-149.

35. Garry D, Figueroa R, Guillaume J, Cucco V. Use of castor oil in pregnancies at term. Altern Ther Health Med 2000; 6(1):77-79.

36. Kelly AJ, Kavanagh J, Thomas J. Castor oil, bath and/or enema for cervical priming and induction of labour. Cochrane Database Syst Rev 2001;(2):CD003099.

37. Mitri F, Hofmeyr GJ, van Gelderen CJ. Meconium during labour--self-medication and other associations. S Afr Med J 1987; 71(7):431-433.

38. Hepner DL, Harnett M, Segal S, Camann W, Bader AM, Tsen LC. Herbal medicine use in parturients. Anesth Analg 2002; 94(3):690-693.

39. McFarlin BL, Gibson MH, O'Rear J, Harman P. A national survey of herbal preparation use by nurse-midwives for labor stimulation. Review of the literature and recommendations for practice. J Nurse Midwifery 1999; 44(3):205-216.

40. Pinn G, Pallett L. Herbal medicine in pregnancy. Complement Ther Nurs Midwifery 2002; 8(2):77-80.

41. Dove D, Johnson P. Oral evening primrose oil: its effect on length of pregnancy and selected intrapartum outcomes in low-risk nulliparous women. J Nurse Midwifery 1999; 44(3):320-324.

42. Barnes J. Pharmacovigilance of herbal medicines: a UK perspective. Drug Saf 2003; 26(12):829-851.

43. Simpson M, Parsons M, Greenwood J, Wade K. Raspberry leaf in pregnancy: its safety and efficacy in labor. J Midwifery Womens Health 2001; 46(2):51-59.

44. Davenas E, Beauvais F, Amara J, Oberbaum M, Robinzon B, Miadonna A et al. Human basophil degranulation triggered by very dilute antiserum against IgE. Nature 1988; 333(6176):816-818.

45. Hirst SJ, Hayes NA, Burridge J, Pearce FL, Foreman JC. Human basophil degranulation is not triggered by very dilute antiserum against human IgE. Nature 1993; 366(6455):525-527.

46. Vandenbroucke JP. Homoeopathy trials: going nowhere. Lancet 1997;20;350(9081):824.

47. Sterne JA, Egger M, Smith GD. Systematic reviews in health care: Investigating and dealing with publication and other biases in meta-analysis. BMJ 2001; 323(7304):101-105.

48. Smith CA. Homoeopathy for induction of labour. Cochrane Database Syst Rev 2003;(4): CD003399.

49. Beer AM, Heiliger F. Randomized, double blind trial of Caulophyllum D4 for induction of labour after premature rupture of membranes at term. Geburtshilfe und Frauenheilkunde 1999; 59:431-435.

50. Smulders B, Croon M. Wat te doen als...? Veilig bevallen. Utrecht/Antwerpen: Kosmos - Z & K Publishers, 1996.

51. Toth M, Rehnstrom J, Fuchs AR. Prostaglandins E and F in cervical mucus of pregnant women. Am J Perinatol 1989; 6(2):142-144.

52. Platz-Christensen JJ, Pernevi P, Bokstrom H, Wiqvist N. Prostaglandin E and F2 alpha concentration in the cervical mucus and mechanism of cervical ripening. Prostaglandins 1997; 53(4):253-261.

53. Chayen B, Tejani N, Verma UL, Gordon G. Fetal heart rate changes and uterine activity during coitus. Acta Obstet Gynecol Scand 1986; 65(8):853-855.

54. Brustman LE, Raptoulis M, Langer O, Anyaegbunam A, Merkatz IR. Changes in the pattern of uterine contractility in relationship to coitus during pregnancies at low and high risk for preterm labor. Obstet Gynecol 1989; 73(2):166-168.

55. Georgakopoulos PA, Dodos D, Mechleris D. Sexuality in pregnancy and premature labour. Br J Obstet Gynaecol 1984; 91(9):891-893.

56. Read JS, Klebanoff MA. Sexual intercourse during pregnancy and preterm delivery: effects of vaginal microorganisms. The Vaginal Infections and Prematurity Study Group. Am J Obstet Gynecol 1993; 168(2):514-519.

57. Rayburn WF, Wilson EA. Coital activity and premature delivery. Am J Obstet Gynecol 1980; 137(8):972-974.

58. Naeye RL. Coitus and associated amniotic-fluid infections. N Engl J Med 1979; 301(22):1198-1200.

59. Kavanagh J, Kelly AJ, Thomas J. Sexual intercourse for cervical ripening and induction of labour. Cochrane Database Syst Rev 2001;(2):CD003093.

60. Benvold E. Coitus and induction of labour. Tidsskr for Jormodre 1996; 96:6-8.

61. Ferguson J. A study of the motility of the intact uterus at term. Surg Gynecol Obstet 1941; 73:359-366.

62. Mitchell MD, Flint AP, Bibby J, Brunt J, Arnold JM, Anderson AB et al. Rapid increases in plasma prostaglandin concentrations after vaginal examination and amniotomy. Br Med J 1977; 2(6096):1183-1185.

63. Kloeck FK, Jung H. In vitro release of prostaglandins from the human myometrium under the influence of stretching. Am J Obstet Gynecol 1973; 115(8):1066-1069.

64. Hillier K, Coad N. Synthesis of prostaglandins by the human uterine cervix in vitro during passive mechanical stretch. J Pharm Pharmacol 1982; 34(4):262-263.

65. Boulvain M, Stan C, Irion O. Membrane sweeping for induction of labour. Cochrane Database Syst Rev 2005;(1):CD000451.

66. Doany W, McCarty J. Outpatient management of the uncomplicated postdate pregnancy with intravaginal prostaglandin E2 gel and membrane stripping. J Matern Fetal Med 1997; 6(2):71-78.

67. el Torkey M, Grant JM. Sweeping of the membranes is an effective method of induction of labour in prolonged pregnancy: a report of a randomized trial. Br J Obstet Gynaecol 1992; 99(6):455-458.

68. Magann EF, Chauhan SP, Nevils BG, McNamara MF, Kinsella MJ, Morrison JC. Management of pregnancies beyond forty-one weeks' gestation with an unfavorable cervix. Am J Obstet Gynecol 1998; 178(6):1279-1287.

69. Wong SF, Hui SK, Choi H, Ho LC. Does sweeping of membranes beyond 40 weeks reduce the need for formal induction of labour? BJOG 2002; 109(6):632-636.

70. de Miranda E, Bonsel GJ, Eskes M, Birnie E, Bleker OP. A survey of membrane sweeping in low-risk pregnancies between 41 and 42 weeks of gestation to prevent post-term pregnancy. Midwifery: accepted.

Chapter 3

A survey of membrane sweeping in low-risk pregnancies between 41 and 42 weeks of gestation to prevent post-term pregnancy

Esteriek de Miranda
Gouke J. Bonsel
Martine Eskes
Erwin Birnie
Otto P. Bleker

Accepted in Midwifery

Abstract

Objective The objective of this study was twofold.
To explore the attitude of qualified practising midwives in the Netherlands to membrane sweeping in low-risk pregnancies beyond 41 weeks to prevent post-term pregnancy.
To determine the willingness of midwives to adjust obstetrical policy to the results of an future randomised trial on sweeping.

Study design A semi-structured questionnaire was sent to all 1288 currently practising members of the Royal Netherlands Organisation of Midwives, which accounts for 85% of all then practising midwives in the Netherlands (N = 1515). The response was 76.3 %, n = 983. The χ^2- test was used for statistical analysis.

Results A majority (64 %) were convinced of the effectiveness of sweeping the membranes to prevent post-term pregnancy, 17% was neutral, 18% were not convinced and 1% was strongly opposed to sweeping. The effectiveness of membrane sweeping was judged to be higher with multiparous than nulliparous women. The benefits of membrane sweeping outweigh the side effects according to the majority of the midwives (65 %). More then 90 % stated that they would be prepared to adjust their policy on sweeping based on the results of a randomised controlled trial on sweeping in the Netherlands.

Conclusion A majority of midwives were convinced of the effectiveness of membrane sweeping beyond 41 weeks while nearly all midwives were prepared to adjust their policy on sweeping when reliable data will become available.

Introduction

Post-term pregnancy, defined as a gestational age of 294 days (42 weeks) or more (WHO 1977, FIGO 1986), is associated with increased perinatal morbidity and mortality. The reported incidence of post-term pregnancy ranges from 4% to 18%, depending on the method of calculation of the gestational age[1]. Despite the official definition, several authors already refer to post-term pregnancy after 287 days (41 weeks) of gestation[2;3-7]

Midwives and obstetricians often perform sweeping or stripping of the membranes to initiate labour in order to prevent post-term pregnancies. Routine use of membrane sweeping between 38 and 40 weeks does not produce clinically important benefits[8]. The benefits in initiating labour may be limited to pregnant women with a gestational age of more than 41 weeks.[6;8-10].

In the Netherlands pregnancies of 42 weeks of gestation or more are considered as post-term, following international guidelines. The gestational age is determined by early ultrasound in all instances of uncertain gestational age and often also in women who are certain of their last menstrual period. The Dutch obstetrical system is based on a continuous risk selection during pregnancy and labour. In general, independent midwives take care of low-risk pregnancies; only a few general practitioners are involved in low-risk obstetrical care. Since most pregnancies start as low-risk, midwives are primarily responsible for the risk-selection. Accordingly, pregnant women are assigned to either primary or secondary referred care, each with its own caregivers. Referred care is administered by obstetricians. After 41 weeks, sweeping of the membranes in low-risk pregnancies is a widely accepted intervention, as many assume sweeping reduces the risk of post term pregnancy and carries little risk. It is one of the few therapeutic interventions available to midwives during the prenatal period of otherwise low-risk pregnancies. However, there is a wide range of variation in actually practice. Pregnancies of 42 weeks are referred to the obstetrician, usually for labour induction, although expectant management of post-term pregnancy under fetal surveillance is still possible in a few hospitals.

In view of the variation in practice regarding sweeping and because of the inconclusive evidence on its effectiveness in a low-risk population with a pregnancy beyond 41 weeks, we designed a randomised-controlled trial. This trial was preceded by a nationwide survey to examine the attitude of midwives towards

membrane sweeping and their willingness to adjust their policy according to the outcome of the scheduled sweeping trial. As evidence-based midwifery was only introduced a few years ago, we expected that the more experienced midwives would be less prepared to change their policy. The less experienced midwives were expected to be more open to the results of the trial.

Materials and methods

A semi-structured questionnaire with a pre-paid response envelope was sent in 2000 to all practising members of the Royal Dutch Organisation of Midwives (n = 1288), which accounts for 85% of all practising midwives in the Netherlands (n = 1515). No reminder was sent.

The questionnaire consisted of 11 short questions with predetermined response categories and two open answer questions. The questions covered the opinion on sweeping and its side effects, the origin of that opinion, and some general and specific background items such as years of experience, practice setting and educational background. We did not asked for detailed self-reported data on sweeping but asked the midwives to roughly indicate if and how often they apply sweeping for the prevention of post-term pregnancy. The willingness to change the sweeping policy according to the outcome of the trial was recorded as primary outcome.

The χ^2- test was used to determine the effects of specified factors on the results of the questionnaire.

Results

The response was 76.3 % (n = 983). Two questionnaires from midwives with no practical experience were excluded. The questionnaires of respondents who had stopped practising very recently (n = 4) were included; all of them had at least 6-10 years experience. A total of 981 questionnaires were suitable for analysis. The characteristics of the respondents are shown in Table 1.

Half of the respondents had been working 10 years or less (51.2 %). Most midwives (90.2 %) worked in a primary care midwifery practice. About 10 percent

Table 1. Characteristics of respondents (n = 981)

Characteristics	Number*	Percentage
Years in practice		
0 – 5	269	27.7
6 – 10	228	23.5
11 – 15	168	17.3
16 – 20	92	9.5
> 20	213	22.0
Practice setting		
single	78	8.0
team	734	75.4
hospital	79	8.1
stand-in	66	6.8
other	16	1.6
Midwifery school		
Amsterdam	284	29.3
Heerlen / Kerkrade	286	29.5
Rotterdam	287	29.6
Abroad	113	11.6

* Numbers do not add up to 981 due to missing information on questionnaires

worked in a health centre, a hospital or in another institutional setting. The midwives with the longest experience (≥ 16 years) more often worked in a solo practice ($P < 0.001$). The three existing midwifery schools in the Netherlands were equally represented as education institute among the respondents to the survey.

A majority of respondents (63.7 %) were convinced that sweeping the membranes beyond 41 weeks was an effective method to prevent post term pregnancy. (Table 2)

Only 1.3 % categorically opposed sweeping while 18.1 % felt uncertain about the effectiveness of sweeping. Most midwives distinguished between nulliparous and multiparous women, and generally they judged the procedure to be more effective in multiparous than in nulliparous women. The general opinion on sweeping was unrelated to the number of year's experience ($P = 0.22$). There was no association between the opinion on effectiveness in general and the setting in which the midwives worked ($P = 0.93$), but those working in a primary care prac-

Table 2. Attitude of Dutch midwives towards sweeping (n = 981)

Opinion on...	Number*	Percentage
Effectiveness of sweeping in general		
Highly convinced of effectiveness	79	8.1
Convinced	539	55.6
Neutral	163	16.8
Not convinced	176	18.1
Absolutely opposed	13	1.3
Effectiveness of sweeping in nulliparous		
Always effective	2	0.2
Often	98	10.1
Sometimes	823	84.9
Never	47	4.9
Effectiveness of sweeping in multiparous		
Always effective	14	1.4
Often	603	62.1
Sometimes	345	35.6
Never	9	0.9
Side effects of sweeping		
Often	184	19.2
Sometimes	715	74.5
Never	61	6.4
Importance of side effects		
Less important than advantages	608	64.6
As important as advantages	234	24.9
More important than advantages	99	10.5

* Numbers do not add up to 981 due to missing information on questionnaires

tice (single, team, stand-in) judge the effectiveness of sweeping in multiparous women higher than those working in a hospital ($P < 0.01$). There was no difference in opinion between the midwives trained in the three schools regarding the effectiveness of sweeping ($P = 0.92$).

Table 2 also displays the midwives' opinion on the side effects of sweeping. The main side effects mentioned were irregular contractions (54.2 %), early labour (18.8 %), false labour (10.5 %), bleeding (15.4 %), psychological distress / wrong expectations (6.7 %), prolonged labour (4.5%), rupture of membranes (3.5

%) and pain (2.1 %). Of the 61 (6.4 %) of respondents who had never observed any side effects, 80 % were convinced of the effectiveness of sweeping. A majority of all respondents (64.6 %) believed that the benefits of sweeping outweighed the side effects while 25% felt that the pros and cons were in balance.

Figure 1 shows current practice of sweeping according to parity, which shows that most midwives adapted their policy according to parity. The midwife's own experience, according to this self-reported questionnaire, was the most important factor determining the stated policy on sweeping (94 %). The experience of associates was mentioned by 40.5 % of respondents, while theoretical knowledge appeared to be less important, with only 25.6 % referring to the midwifery school. Obstetrical literature was mentioned as a determining factor by 15.4 % of respondents.

In view of the potential to implement, we evaluated the willingness of the midwives to adjust their policy on the results of the parallel-randomised controlled trial on sweeping in the low-risk population (Table 3). The majority (70.2 %) declared to be prepared to adjust their policy in either direction, and another 20.6 % stated to be conditionally prepared (e.g., "if the study was done properly", "if the associates approve" or "if the outcome fits in the practice"). Only 3.5%

Figure 1. Current practice of sweeping: How often do midwives sweep the membranes between 41 - 42 weeks according to parity?

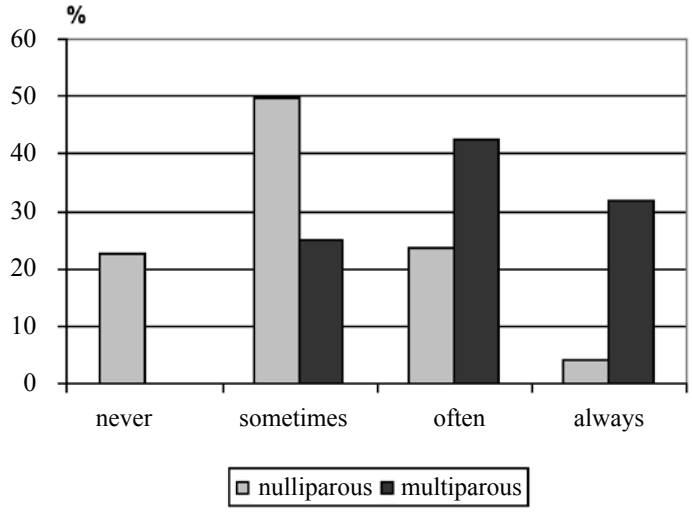


Table 3. Willingness to adjust current policy according to results of Dutch sweeping trial.

Willing to adjust current policy	Number*	Percentage
Yes	669	70.2
Yes, under certain conditions	197	20.7
No	33	3.5
No, only unless specific necessary conditions are fulfilled	54	5.7

* Numbers do not add up to 981 due to missing information on questionnaires

was not prepared to adjust the policy on sweeping and 5.7% was not prepared to do so unless the results are undoubtedly clear (in either direction) or the results of the trial must be in correspondence with the conviction of the midwive in question. This means that 90.8 % of midwives might be willing to adjust their policy (Table 3). However, the willingness to adjust policy towards membrane sweeping depended on the years of practice, ranging from 95.1 % for those with less than 5 years (n = 269) to 81.6 % for those with more than 20 years of practise (n = 214).

Discussion

The majority of midwives had a positive opinion on the effectiveness of sweeping the membranes beyond 41 weeks to prevent post-term pregnancy. More than 90 % of the midwives was prepared to adjust their policy on sweeping, in either direction if the results of the ongoing sweeping trial in the Netherlands indicated a need for a change of policy.

The response on the questionnaire was high, 76.3 % (n = 983); this concerns 65% of all Dutch practising midwives (n = 1515). In order to determine how representative the survey was, we compared the group of respondents with data of all Dutch midwives. Every year, the Netherlands Institute of Primary Healthcare (NIVEL) collects data of all registered midwives[11]. Except for stand-ins and midwives working in a hospital, who are underrepresented in our survey, it seems

representative for the Dutch midwives. Because most clinical midwives work in secondary care obstetrics and as the number of stand-in midwives is relatively small, this under representation is of minor importance.

Although the majority of the midwives had a positive attitude towards membrane sweeping, there was insufficient evidence for efficacy of this procedure in the literature at the time of the survey. In a Cochrane Review on sweeping, Boulvain et al.[8] concluded that routine use of membrane sweeping does not produce clinically important benefits. This gap between the opinion of the Dutch midwives and the lack of evidence in the literature may have several reasons, such as the timing of sweeping. In most trials sweeping was conducted between 38 and 40 weeks, whereas in the Netherlands it is mostly performed after 41 weeks. The small number of women in some trials that have been conducted makes it difficult to generalise, as does the heterogeneity of both trial designs and trials' results.

The results of this survey show that midwives at least differentiate between sweeping in nulliparous and multiparous women. At the time of the survey however, there was little evidence whether sweeping of the membranes is more effective if parity and cervical status are taken into account[8].

A remarkable finding is the minor importance of midwifery training in forming an opinion. This is in contrast with the OBINT study[12], in which the factors that influence provider-associated differences were assessed, in particular the obstetrician's attitude towards obstetrical interventions. According to that study, the way the obstetrician was trained has a lifelong determining effect on their attitude towards obstetric interventions. We do not know whether the different result we found in our study among midwives is related to differences between professional groups, or the issue at hand.

The side effects that have been reported to occur in clinical trials were also mentioned in the survey. The majority of the midwives consider the advantages of sweeping to outweigh the disadvantages. The Cochrane review[8] reported no major side effects such as maternal or neonatal infection, but acknowledges significant discomfort during the intervention and some 'minor' side effects (bleeding, irregular contractions), as reported in the survey.

We did not ask detailed self-report data on membrane sweeping. The finding that 64 % of the respondents were convinced of its effectiveness however, suggests that the majority of Dutch midwives regularly employs this procedure.

Because of the importance of personal experience in forming an opinion on sweeping, we had some concerns whether midwives would be prepared to change their policy on sweeping when reliable data from a clinical trial would become available. A large majority (91%) declared to be prepared to adjust their policy. As expected, the highest percentage of midwives willing to adjust their policy were those who had practised less than 5 years (95.1%) and the lowest percentages, which were still high, were those who have practised more than 20 years (81.6%). This general positive attitude can be caused by the strong emphasis on evidence-based midwifery the last few years, while on the other hand some midwives who have been practising longer may be more satisfied with the results of their own experience gained during many years of practice.

Even though we used an anonymous self-reporting questionnaire, we cannot exclude the presence of socially desirable answers, in particular with regard to the willingness to change policies. This willingness was present, but it may be difficult to turn into action once new evidence favours a change of what is felt as practice 'style'.

Reference List

1. Bakketeig L, Bergsjo P. Post-term pregnancy: magnitude of the problem. In: Chalmers I, Enkin M, Keirse MJNC, editors. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 2007: 765-775.
2. Boulvain M, Fraser WD, Marcoux S, Fontaine JY, Bazin S, Pinault JJ et al. Does sweeping of the membranes reduce the need for formal induction of labour? A randomised controlled trial. Br J Obstet Gynaecol 1998; 105(1):34-40.
3. Cammu H, Haitsma V. Sweeping of the membranes at 39 weeks in nulliparous women: a randomised controlled trial. Br J Obstet Gynaecol 1998; 105(1):41-44.
4. Berghella V, Rogers RA, Lescale K. Stripping of membranes as a safe method to reduce prolonged pregnancies. Obstet Gynecol 1996; 87(6):927-931.
5. Doany W, McCarty J. Outpatient management of the uncomplicated postdate pregnancy with intravaginal prostaglandin E2 gel and membrane stripping. J Matern Fetal Med 1997; 6(2):71-78.
6. el Torkey M, Grant JM. Sweeping of the membranes is an effective method of induction of labour in prolonged pregnancy: a report of a randomized trial. Br J Obstet Gynaecol 1992; 99(6):455-458.
7. Magann EF, Chauhan SP, Nevils BG, McNamara MF, Kinsella MJ, Morrison JC. Management of pregnancies beyond forty-one weeks' gestation with an unfavorable cervix. Am J Obstet Gynecol 1998; 178(6):1279-1287.
8. Boulvain M, Stan C, Irion O. Membrane sweeping for induction of labour. Cochrane Database Syst Rev 2005;(1):CD000451.
9. Goldenberg M, Dulitzky M, Feldman B, Zolti M, Bider D. Stretching of the cervix and stripping of the membranes at term: a randomised controlled study. Eur J Obstet Gynecol Reprod Biol 1996; 66(2):129-132.
10. McColgin SW, Hampton HL, McCaul JF, Howard PR, Andrew ME, Morrison JC. Stripping membranes at term: can it safely reduce the incidence of post-term pregnancies? Obstet Gynecol 1990; 76(4):678-680.
11. Hingstman L, Wiegers T. Cijfers uit de registratie van verloskundigen: peiling 1998. 1998. Utrecht, NIVEL.
12. Pel M, Heres MH, Hart AA, van d, V, Treffers PE. Provider-associated factors in obstetric interventions. Eur J Obstet Gynecol Reprod Biol 1995; 61(2):129-134.

Chapter 4

Membrane sweeping and prevention of post-term pregnancy in low-risk pregnancies: a randomised controlled trial

Esteriek de Miranda
Johanna G. van der Bom
Gouke J. Bonsel
Otto P. Bleker
Frits R. Rosendaal

Adapted from: Membrane sweeping and prevention of post-term pregnancy in low-risk pregnancies: a randomised controlled trial. BJOG 2006; 113(4):402-408.

Abstract

Objective To evaluate the effectiveness of membrane sweeping at 41 weeks for the prevention of post-term pregnancy.

Design A multicenter individually randomised controlled trial.

Setting Fifty-one primary care midwifery practices in the Netherlands.

Population A total of 742 low-risk pregnant women at 41 weeks of gestation.

Methods Participants were randomly assigned to serial sweeping of the membranes (every 48 hours until labour commenced up to 42 weeks of gestation) or no intervention.

Main outcome measures Post-term pregnancy (≥42 weeks). Subgroup analyses were performed on nulliparous and parous women. Secondary outcomes included adverse effects.

Results Sweeping of the membranes at 41 weeks decreased the risk of post-term pregnancy (87/375 (23%) versus 149/367 (41%); relative risk (RR) 0.57, 95% confidence interval (CI) 0.46 – 0.71; number needed to treat (NNT) 6, CI 4 - 9). Benefits were also seen in both subgroups (nulliparous 57/198 (29%) versus 89/192 (46%); RR 0.62, 95% CI 0.48 – 0.81; NNT 6, 95% CI 4 – 12 and parous: 30/177 (17%) versus 60/175 (34%); RR 0.49, 95% CI 0.34 – 0.73; NNT 6, 95% CI 4 – 6). Spontaneous onset of labour < 42 weeks was increased (253/375 (68%) versus 198/367 (54%); RR 1.25, 95% CI 1.11-1.41). Adverse effects were similar in both groups except for uncomplicated bleeding which was reported more frequently in the sweeping group (111/364 (31%) versus 16/345 (5%); RR 6.58, 95% CI 3.98 – 10.87). Other obstetric outcomes and indicators of neonatal morbidity were similar in both groups. There were two perinatal deaths in each group.

Conclusion Membrane sweeping at 41 weeks can substantially reduce the proportion of women with post-term pregnancy.

Introduction

Post-term pregnancy (gestational age of ≥ 294 days (≥ 42 weeks)[1]), is associated with increased perinatal morbidity and mortality[2]. The incidence of post-term pregnancy ranges from 4% to 18%[3], depending on the method of determination of the gestational age, the subject population and the local practice patterns. Sweeping the membranes (digital separation of the membranes from the lower uterine segment) is an old and simple method[4] to promote spontaneous onset of labour, which is regularly applied to prevent post-term pregnancy, although its effectiveness in relation to the optimal timing of the procedure is still unclear. Membrane sweeping causes an increase of prostaglandin metabolites in the maternal circulation and in local prostaglandin production[5;6]. Both are associated with ripening of the cervix and, ultimately, with spontaneous onset of labour.

The results of trials on the effectiveness of membrane sweeping have been inconsistent[7-25], possibly due to methodological differences between studies[7]. Routine use of membrane sweeping between 38 and 40 weeks does not seem to produce clinically important benefits according to a recent Cochrane review[7]; yet it might be beneficial in women with a gestational age of 41 weeks[15;16]. Our aim was to assess the effectiveness of membrane sweeping starting at 41 weeks for the prevention of post-term pregnancy among a low-risk population in a primary care setting.

Methods

A multicenter individually randomised trial was conducted in 51 midwifery practices throughout the Netherlands between June 2000 and March 2003. Pregnant women were eligible for inclusion in the trial when they were low-risk at presentation (single fetus in cephalic presentation, no pregnancy complications or risk factors and no obstacles for normal vaginal delivery) with a reliable gestational age of 41 weeks (range 40+6 - 41+3) and no history of blood loss after the first trimester or suspicion of loss of amnion fluid during pregnancy. The primary outcome was post-term pregnancy which was defined as a gestational age of 294 days or more. A referral to the local obstetrician for surveillance or induction of

labour was programmed at 42 weeks. Induction of labour was scheduled by the obstetricians according to local hospital protocols and varied from induction at 42+0 to expectant management until 43+0 weeks. For this reason formal induction of labour was not suitable as primary outcome measure.

At a gestational age of 39 weeks all eligible women received written information on the trial and at 40 weeks they were invited to participate. A written informed consent was obtained at the antenatal visit of 41 weeks, after which the participating woman opened the next successive randomisation envelope.

Randomisation in this open trial was accomplished by blocked randomisation using 30 odd blocks of 25[26], with a variable allocation ratio of 12:13 or 13:12. The allocations were placed within consecutively numbered, opaque, sealed envelopes. A box containing the agreed number of randomisations (variable for each centre) was sent to the midwifery practices where they were kept. The participating midwives were unaware of the randomisation method. Stratification by centre was performed in order to reveal any differences according to midwifery practice.

After every randomisation the numbered envelope with the allocation card was posted the same day to the trial coordinator together with a randomisation form with date of randomisation, allocation group and patient characteristics.

Women allocated to the control group received routine monitoring. To prevent prostaglandin release, vaginal examination was not performed in the control group until the onset of labour. In addition we asked the midwives to refrain from advice regarding sexual intercourse as a way of stimulating labour onset, regardless of the allocation. Women allocated to sweeping received routine monitoring as well, followed by a vaginal examination for assessment of the cervical ripeness (Bishop score)[27] and immediate sweeping. The midwives did not calculate the Bishop score themselves but ticked off the appropriate category on the various items of the Bishop score (dilatation 0-3 points, effacement 0-3, station 0-3, consistency 0-2 and cervical position 0-2). Sweeping was performed by separating the lower membranes as much as possible from its cervical attachment, with three circumferential passes of the examining fingers. When sweeping was not possible because the cervix was closed, cervical massage was performed[15]. Massage of the cervical surface was performed with circular pushing and massaging movements of the fore- and middle finger for approximately 15 seconds. Sweeping was repeated every 48 hours, with a maximum of three times, until labour

commenced or 42 weeks of gestation was reached. The midwives explained to the women who had been swept that bloodstained mucus or painful contractions could occur.

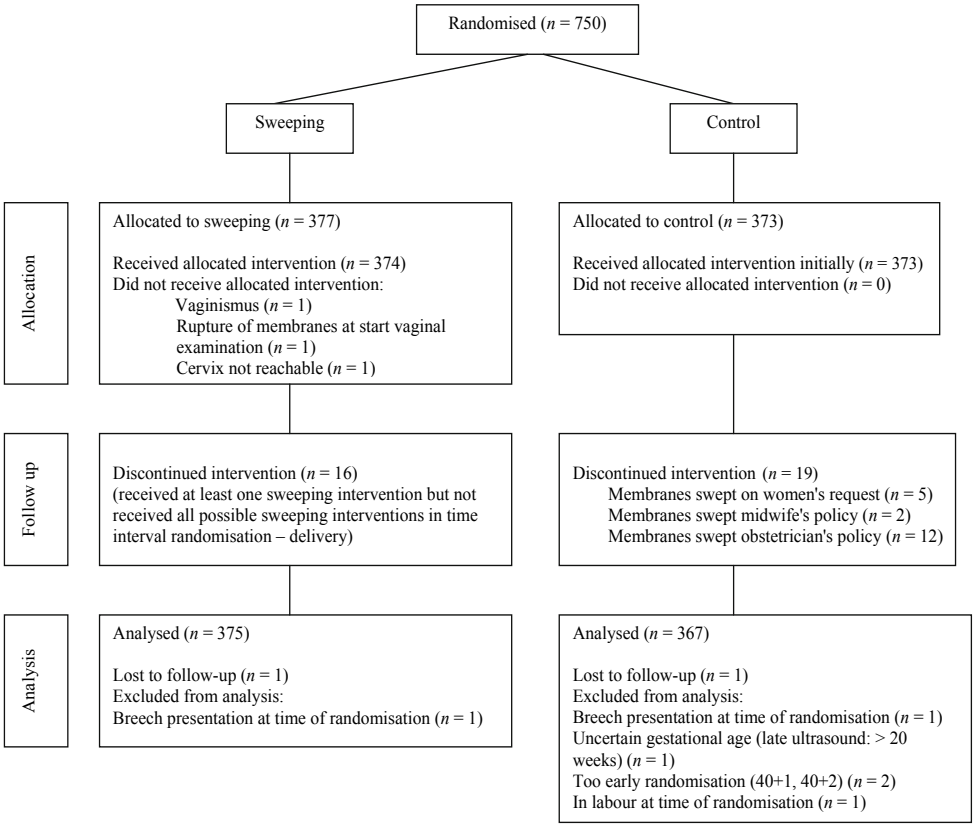
The ethics committee of the Academic Medical Center of Amsterdam approved the trial.

Data concerning prenatal care, obstetrical intervention, delivery and child condition were recorded on a case report form (CRF). We also collected data on the adverse effects and the woman's satisfaction by self-reported questionnaires. If labour did not start within 48 hours, a questionnaire assessing possible side effects such as contractions, nature of the contractions and vaginal bleeding was completed. The midwives asked all women to complete the questionnaires.
The primary endpoint of the trial was delivery at or beyond 42 weeks. The sample size was calculated based on estimations contained in previous reports on the future of Dutch obstetrical practice[28] and based on data of the The Netherlands Perinatal Registry (LVR)[29]. Both the reports are based on detailed data regarding pregnancy, birth and child condition from 95% of Dutch midwives and obstetricians. For an expected difference favouring sweeping of 10%, i.e. 30% instead of 40% post-term deliveries, with an alpha of 0.05 and a beta of 0.20, two groups of 375 women were required. Analysis was based on intention to treat. We computed relative risks (RR) to compare crude and stratified proportions and calculated the 'number needed to treat (NNT)' with 95% confidence limits. Kaplan-Meier analysis was used to describe postponement ('survival') from randomisation to post-term pregnancy, and additional logistic regression analysis was performed to adjust the comparison of proportions for centre effects. Data analysis was performed using SPSS software (SPSS, Chicago, Il, USA).

Results

From June 2000 to March 2003, 141 midwives from 51 midwifery practices randomised 750 women. Allocation was balanced (difference ≤ 2) within 44 practices and unbalanced (difference 3 - 6) in 7 practices. Eight women were excluded from analysis because they did not meet the inclusion criteria (five controls, one sweeping) or were lost to follow up (one in each group; Figure 1). We included two women allocated to control and one woman allocated to sweeping who were

Figure 1. Flow diagram of participants through each stage of the sweeping trial.



unintentionally randomised at a gestational age of 40+5 and one woman allocated to sweeping who was randomised at a gestational age of 41+5.

Primary analysis was by intention to treat, i.e. three women allocated to sweeping, who did not received the intervention, and 19 women randomised to the control group, who were nevertheless swept, were analysed according to the allocated group. This left 742 women to be analysed, 375 in the sweeping group and 367 in the control group (Figure 1).

Questionnaires from the participants were available in 687 cases (93%). The CRFs of 22 women allocated to control and 11 women allocated to sweeping

were lost, mainly during hospitalisation. Data on the main outcomes for these 33 women could be collected in all cases from the midwifery dossiers and the hospital files, but information on Bishop score, adverse effects and subject's satisfaction was missing.

The baseline characteristics of the groups were similar (Table 1). Both the groups contained slightly more nulliparous women than parous women. The median Bishop score (BS) at baseline in the sweeping group was 4 (inter quartile range [IQR] 2 – 5). Bishop scores of nulliparous and parous women were similar at baseline (median BS among nulliparous women 4 [IQR 2 – 5] and among parous women 4 as well [IQR 3 – 5]). There were 283 women with a BS < 6 at baseline and 81 women with a BS of ≥ 6.

Gestational age was determined by ultrasound before 18 weeks in 595 (80%) women or by certain last menstrual period corresponding with initial examination in 147 women (20%).

Sweeping significantly reduced the proportion of post-term pregnancies, which occurred in 23% of the women allocated to sweeping and in 41% of the controls (Table 2). The effect was observed both in nulliparous and parous women. Adjustment for centre revealed no difference with the crude estimate (results not shown). When the analysis was restricted to women who had a first trimester ultrasound, the effect on post-term pregnancy was similar (66/299 (22%) versus 121/296 (41%); RR 0.54, 95% CI 0.42 – 0.70). Re-analysis with all the excluded women included did not affect the overall Relative Risk.

In the intervention group, 76 of 283 (27%) women with a BS < 6 at baseline

Table 1. Characteristics of study participants, according to group.
Values are given as median, inter quartile range (IQR) or numbers (n) / percentage (%).

	Sweeping (n = 375)		**Control (n = 367)**	
	Median	**IQR**	**Median**	**IQR**
Maternal age (years)	31	28 – 33	31	28 – 34
Gestational age (days) at recruitment	288	287 – 289	288	287 – 289
Parity				
Nulliparous	198 (53)		192 (52)	
Parous	177 (47)		175 (48)	

Table 2. Frequencies and relative risks of post-term pregnancy (≥ 294 days) and mode of labour onset.
Values are given as numbers (n) / total / percentage (%), relative risk (RR) and number needed to treat (NNT).

	Sweeping (*n* = 375)	**Controls (*n* = 367)**	**RR (95% CI)**	**NNT (95% CI)**
Post-term pregnancy	87 (23)	149 (41)	0.57 (0.46 – 0.71)	6 (4 – 9)
Nulliparous	57 / 198 (29)	89 / 192 (46)	0.62 (0.48 – 0.81)	6 (4 – 12)
Parous	30 / 177 (17)	60 / 175 (34)	0.49 (0.34 – 0.73)	6 (4 – 6)
Spontaneous onset of labour < 42 weeks	253 (68)	198 (54)	1.25 (1.11 – 1.41)	
Nulliparous	119/198 (60)	94/192 (49)	1.23 (1.02 – 1.48)	
Parous	134/177 (76)	104/175 (59)	1.27 (1.10 – 1.48)	
Spontaneous onset of labour ≥ 42 weeks	32 (9)	53 (14)	0.59 (0.39 – 0.89)	
Labour induction	90 (24)	115 (31)	0.77 (0.61 – 0.97)	
< 42 weeks	35 (9)	19 (5)	1.80 (1.06 – 3.08)	
Impending post-term pregnancy	8	4		
24 hours rupture of membranes	11	4		
On request	4	1		
Other*	12	10		
≥ 42 weeks	55 (15)	96 (26)	0.56 (0.42 – 0.75)	
Post-term pregnancy	51	92		
> 24 hours rupture of membranes	2	1		
Other	2	3		
Mode of labour induction				
Only with oxytocine	51 (14)	56 (15)	0.89 (0.63 – 1.26)	
Start with prostaglandins	33 (9)	51 (14)	0.63 (0.42 – 0.96)	
Start with AROM** (performed by the midwife)	6 (2)	8 (2)	0.73 (0.27 – 2.01)	
Prelabour Caesarean section < 42 weeks***	0	1		

* Other = mixed indications (such as suboptimal CTG, decreased amniotic fluid, decreased fetal movements or combinations of these indications)
** AROM = Artificial Rupture Of Membranes; performed by the midwife
*** There were no elective Caesarean sections ≥ 42 weeks

and 7 of 81 (9%) women with a BS of ≥ 6 had a post-term pregnancy. Of the 375 women allocated to sweeping, 103 received cervix massage initially because of the impossibility of sweeping (nulliparous 67 and parous 36) and 65 women had massage of the cervix at all examinations. Of these 65 women 34 (52%) had a post-term pregnancy compared to 30/242 (12%) in the sweeping only group (RR 4.22, 95% CI 2.83 – 6.16). In the control group, 19 women were swept, mainly after referral because of (impending) post-term pregnancy. Of these 19 women, 13 continued to post-term pregnancy.

Sweeping reduced the time between randomisation and delivery by 1 day (3.50 versus 4.47 days, mean difference 0.97 days, 95% CI 0.60 –1.35). Survival curves describing the cumulative probability of delivery before 42 weeks are shown in Figure 2. Sweeping significantly increased spontaneous onset of labour before 42 weeks (Table 2), mainly during the first 2 days (Figure 3). Induction of labour before 42 weeks was significantly increased in the sweeping group, mainly as a consequence of non medical indications for labour induction ("impending post-term pregnancy"and "on request"). Labour induction ≥ 42 weeks was significantly decreased in the sweeping group, the need for labour induction with prostaglandins was reduced as well in the sweeping group.

The positive effect of sweeping on spontaneous onset of labour was seen in nulliparous as well as in parous women. Sweeping significantly increased the likelihood of delivery in a primary care setting but stratification according to parity showed that a substantial positive effect was restricted to parous women (Table 3).

Other obstetric and neonatal outcomes are summarised in Table 4. There were no differences in other obstetric outcomes such as rupture of membranes before onset of labour, > 24 hours ruptured membranes, augmentation of labour, false labour, fever during labour, analgesia during labour and mode of delivery. Adverse neonatal outcomes were similarly frequent in both groups with no difference in Apgar score <7 at 5 minutes or admission the neonatal care unit (or in the indications for admission there). There were four perinatal deaths, two in each group. In the sweeping group, one fetal death occurred at a gestational age of 41+6; the umbilical cord was looped around the baby's neck six times. The second perinatal death in the sweeping group occurred 36 hours after an uncomplicated term delivery (41+3). A respiratory arrest took place 33 hours after delivery, immediate resuscitation failed and the infant died 3 hours later. Post mortem and bacterial cultures revealed that the probable course of death was group

Figure 2. Survival curve of time from randomisation to post-term pregnancy.

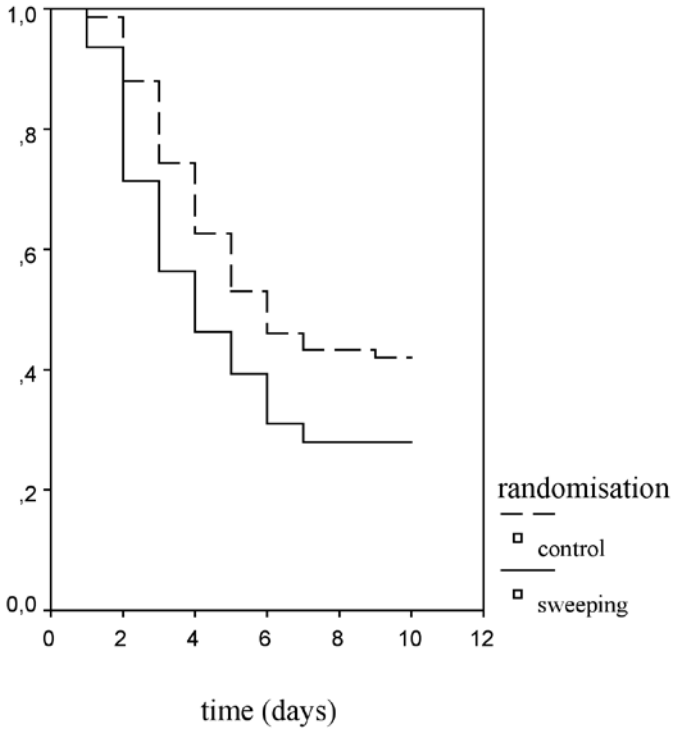


Figure 3. Number of women with spontaneous onset of labour before 42 weeks according to number of days after randomisation.

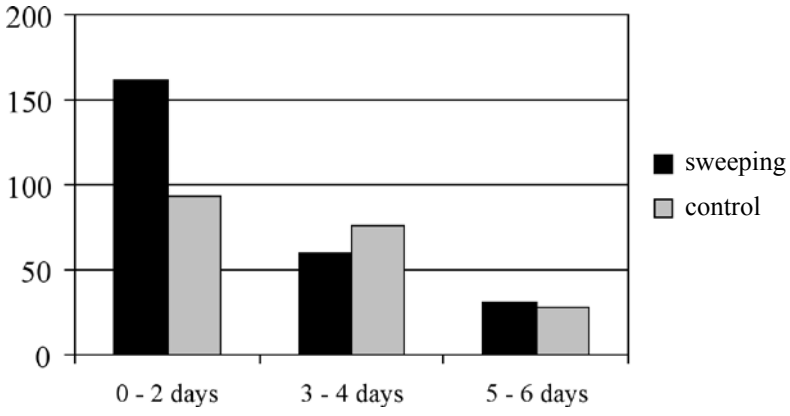


Table 3. Mode of delivery before 42 weeks according to allocation to sweeping or control.
Values are given as numbers (n) / total / percentage (%), relative risk (RR) and number needed to treat (NNT).

	Sweeping (n = 375)	**Controls (n = 367)**	**RR (95% CI)**	**NNT (95% CI)**
Spontaneous vaginal delivery	216 (58)	168 (46)	1.26 (1.09 – 1.45)	8 (5 – 21)
nulliparous	90/198 (46)	73/192 (38)	1.20 (0.94 – 1.51)	13 (6 - ∞)
parous	126/177 (71)	95/175 (54)	1.31 (1.11 – 1.55)	6 (4 – 14)
Parturition without interventions (primary care parturition)	188 (50)	150 (41)	1.23 (1.05 – 1.44)	11 (6 – 48)
nulliparous	69/198 (35)	61/192 (32)	1.10 (0.83 – 1.45)	33 (8 - ∞)
parous	119/177 (67)	89/175 (51)	1.32 (1.11 – 1.58)	6 (4 – 16)

B streptococcal disease (GBS). There were no risk factors for GBS disease during pregnancy or delivery. In the control group, there was one unexplained death at 42 weeks after a failed vacuum extraction, followed by caesarean section, and one perinatal death because of lung and kidney hypoplasia.

Adverse effects of sweeping reported until 48 hours after randomisation were similar in both the groups (Table 6), except for bleeding which was reported more frequently in the sweeping group. The frequency and character of contractions before onset of labour was similar in both groups but the duration of the contractions tended to be longer in the sweeping group. Membrane sweeping was 'not painful' according to 111 women (31%) and 179 (51%) judged sweeping to be 'somewhat painful' while 60 (17%) women experienced sweeping as 'painful or very painful'. In no instance the procedure had to be stopped because of pain. After delivery, 88% (312/353) indicated that they would choose for membrane sweeping in a next pregnancy. Even among the 239 women who experienced sweeping as more or less painful, 210 (88%) reported that they would prefer membrane sweeping again in the next pregnancy. In the control group 266 women (79%) would choose for membrane sweeping in a next pregnancy. The reasons for choosing membrane sweeping in a next pregnancy were similar in both groups. Main reasons were the wish to deliver at home (41%), the conviction that sweeping will advance birth (23%), the wish to deliver as natural as possible (16%), to take every opportunity to earlier delivery (15%) and the wish to deliver with the support of the midwife (3%); 2% indicated other reasons.

Table 4. Other obstetric outcomes, according to sweeping or control. Values are given as numbers (n) / percentage (%) and relative risk (RR).

	Sweeping n = 375 / %	**Control n = 367 / %**	**RR**	**(95% CI)**
Prelabour rupture of membranes* #	57 (19)	50 (19)	1.03	(0.73 – 1.44)
> 24 hours ruptured membranes	16 (4)	12 (3)	1.31	(0.63 – 2.72)
Augmentation of labour	47 (13)	40 (11)	1.15	(0.76 – 1.75)
False labour	21 (6)	15 (4)	1.37	(0.72 – 2.62)
Fever during labour	7 (2)	4 (1)	1.71	(0.51 – 5.80)
Fever: 38° C	7	3		
Fever: > 38° C	0	1		
Meconium stained amniotic fluid	88 (24)	87 (24)	0.99	(0.76 – 1.28)
Analgesia during labour (not for caesarean section)				
Pethidine	47 (13)	45 (12)	1.02	(0.70 – 1.50)
Epidural	17 (5)	14 (4)	1.19	(0.60 – 2.38)
Mode of delivery				
Spontaneous	283 (76)	279 (76)	0.99	(0.92 – 1.08)
Forceps	6 (2)	4 (1)	1.47	(0.42 – 5.16)
Vacuum	49 (13)	49 (13)	0.98	(0.68 – 1.42)
Caesarean section	37 (10)	35 (10)	1.04	(0.67 – 1.61)
Adverse neonatal outcomes	30 (8)	29 (8)	1.01	(0.60 – 1.70)

* = Prelabour rupture of membranes, defined as spontaneous rupture of membranes before onset of labour.
# = calculated on *n* sweeping: 296 and *n* control: 267 due to later introduction of this subject in the CRF files.

Discussion

We performed a randomised trial to compare the effects of sweeping, with routine monitoring among low-risk pregnant women at a gestational age of 41 weeks. Membrane sweeping substantially reduced the number of post-term pregnancies and increased spontaneous onset of labour before 42 weeks.

Our study design tried to build on problems that are discussed in the Cochrane review on sweeping and on suggestions for future study made there and in previous trials. A major limitation of the systematic review concerned the relatively small sizes of the included studies; a large scale trial on membrane sweeping was

lacking. Because efficacy was expected to be low at an earlier gestational age and because the major concern is delivery beyond 42 weeks, we started the intervention at 41 weeks. In addition, to avoid interference with obstetrical indications for induction of labour before 42 weeks, we evaluated sweeping in a low-risk population in a primary care setting. A major difference with most trials, in which sweeping was performed by one or two obstetricians, was the participation of many different midwives[30], implying that our results reflect real practice. We also followed the suggestion of a strategy of multiple successive sweeping[10;18] rather then a single intervention.

Two characteristics of our trial merit discussion. First, we contrasted a strategy of serial sweeping to no sweeping. Our design does not, therefore, permit any conclusion as to whether serial sweeping is superior to single sweeping. Second, we did not determine Bishop scores in the control group, to avoid an effect of this procedure. Given the size of the groups and the randomisation process, it is unlikely that the initial Bishop scores differed between the two groups. Since we did not measure Bishop scores in the control group, it was not possible to show the effect of sweeping or massage on the ripening of the cervix, or the effect of sweeping for various Bishop scores. Indirectly the effect from sweeping on the ripening of the cervix can be inferred from the reduced need for prostaglandins for induction of labour in the intervention group. At baseline, Bishop scores, as determined in the group randomised to sweeping, were low and not different between parous and nulliparous women, which supports the observations of Harris et al.[31].

It has been argued on theoretical grounds that sweeping should be more beneficial in parous women. Previous trials, however, did not confirm this. Although in our trial the relative risk reduction was larger in parous women than in nulliparous women, sweeping was effective in both groups, and the absolute risk difference (NNT) was the same. Nevertheless, a substantial positive effect of sweeping on the occurrence of 'spontaneous onset of labour followed by vaginal delivery' and 'delivery in a primary care setting' could only be observed for parous women. Al these outcomes relate to subgroup analyses, and the power of these to detect real but small differences is low.

Sweeping reduced the time between randomisation and delivery with 1 day. This shift in time is reflected in the occurrence of spontaneous onset of labour and of labour induction in both groups. Spontaneous onset of labour before 42

weeks was increased in the sweeping group while spontaneous onset of labour ≥ 42 weeks was increased in the control group. Labour induction before 42 weeks on the other hand, was increased in the sweeping group while induction ≥ 42 weeks was increased in the control group. Women in both groups had labour induction < 42 weeks for non medical reasons like 'impending post-term pregnancy' and 'on request'. For logistic reasons (office closure over the weekend), referral to the obstetrician occurred in some occasions 1 or 2 days before 42 weeks of gestation. The increase in labour induction < 42 weeks in the sweeping group disappears if analysis is repeated without these non medical inductions. More labour inductions < 42 weeks will result in an artificial decrease of post-term pregnancy. However, if labour inductions < 42 weeks are included within the number of post-term pregnancies, the absolute risk reduction in favour of membrane sweeping remains. Though it concerns small absolute numbers, an increase was seen in the intervention group in labour induction before 42 weeks because of > 24 hours rupture of membranes. However, there was no difference seen in the total frequency of > 24 hours rupture of membranes between the groups. Induction policy differs widely between hospitals especially on two of the main indications of labour induction in an otherwise low-risk population, post-term pregnancy and > 24 hours broken membranes. Since a fixed date for labour induction could not be given prior to randomisation, labour induction was not suitable as a reliable primary outcome measure.

Some previous trials have raised a concern about an increase in prelabour rupture of membranes with sweeping[10;16]. Although one accidental rupture of membranes occurred at the start of the sweeping procedure, we observed no difference in the frequency of prelabour rupture of membranes between the sweeping and the control group, which is in agreement with most other trials on sweeping[7;9;11;12;17;25].

We excluded eight women because they were incorrectly included (n=6) or were lost to follow up (n=2). This number is too small (1%) to have caused bias.

An important limitation of randomised trials such as ours is that they are seldom large enough to study rare adverse effects. In previous studies no harmful adverse effects of sweeping were reported[7]. In the study of Allott and Palmer[8], there was one case of group B streptococcal disease (GBS) in the control group. In our study, one perinatal death, probably because of early onset of GBS, occurred in the sweeping group. It concerned an uncomplicated parturition of a nullipa-

rous woman without risk factors for GBS disease at a gestational age of 41+3. Thus far, membrane sweeping has not been associated with group B streptococcal disease[32-36]. Consequently, the revised guidelines from Centers for Disease Controls and Prevention for the prevention of perinatal GBS did not recommend avoiding of membrane sweeping in GBS-colonised wome [37]. However, as this disease occurs so rarely, a relation with sweeping is difficult to establish in a randomised trial. Future studies, preferably case-control studies, need to address the effect of sweeping on perinatal GBS disease.

In our study, 17% of the women experienced sweeping as painful, which is roughly the same as reported previously[30], when 22% of women experienced the procedure as painful. In concordance with these results, women allocated to sweeping had a positive judgement on the intervention.

Conclusions

Even assuming the lowest incidence of post-term pregnancy of 4%, membrane sweeping at 41 weeks will substantially reduce the proportion of women with post-term pregnancy. It is a simple and effective method that can be applied in out of hospital settings worldwide.

Reference List

1. WHO. WHO, Recommended definitions , terminology and format for statistical tables related to the perinatal period and use of a new certificate for cause of perinatal deaths. Acta Obstet Gynecol Scand. 1977; 56:247-253.
2. Hilder L, Costeloe K, Thilaganathan B. Prolonged pregnancy: evaluating gestation-specific risks of fetal and infant mortality. Br J Obstet Gynaecol. 1998; 105:169-173.
3. Bakketeig L, Bergsjø P. Post-term pregnancy: magnitude of the problem. In: Chalmers I, Enkin MW, Keirse MJNC, editors. Effective care in pregnancy and childbirth. Oxford: Oxford University Press, 1989:765-775.
4. Munro KJ, Johnson RW, Philips MH. Historical review of British obstetrics and gynaecology, 1800-1950. Edinburgh: Livingstone; 1954.
5. Mitchell MD, Flint AP, Bibby J, Brunt J, Arnold JM, Anderson AB et al. Rapid increases in plasma prostaglandin concentrations after vaginal examination and amniotomy. Br Med J. 1977; 2: 1183-1185.
6. Keirse MJ, Thiery M, Parewijck W, Mitchell MD. Chronic stimulation of uterine prostaglandin synthesis during cervical ripening before the onset of labor. Prostaglandins. 1983; 25:671-682.
7. Boulvain M, Irion O. Membrane sweeping for induction of labour (Cochrane Review). The Cochrane Library.Issue 1. 2004. Chichester, UK: John Wiley & Sons, Ltd.
8. Allott HA, Palmer CR. Sweeping the membranes: a valid procedure in stimulating the onset of labour? BJOG. 1993; 100:898-903.
9. Berghella V, Rogers RA, Lescale K. Stripping of membranes as a safe method to reduce prolonged pregnancies. Obstet Gynecol. 1996; 87:927-931.
10. Cammu H, Haitsma V. Sweeping of the membranes at 39 weeks in nulliparous women: a randomised controlled trial. BJOG. 1998; 105:41-44.
11. McColgin SW, Hampton HL, McCaul JF, Howard PR, Andrew ME, Morrison JC. Stripping membranes at term: can it safely reduce the incidence of post-term pregnancies? Obstet Gynecol. 1990; 76: 678-680.
12. Crane J, Bennett K, Young D, Windrim R, Kravitz H. The effectiveness of sweeping membranes at term: a randomized trial. Obstet Gynecol. 1997; 89:586-590.
13. Dare FO, Oboro VO. The role of membrane stripping in prevention of post-term pregnancy: a randomised clinical trial in Ile-lfe, Nigeria. J Obstet Gynaecol. 2002; 22:283-286.
14. Doany W, McCarty J. Outpatient management of the uncomplicated postdate pregnancy with intravaginal prostaglandin E2 gel and membrane stripping. J Matern Fetal Med. 1997; 6: 71-78.
15. el Torkey M, Grant JM. Sweeping of the membranes is an effective method of induction of labour in prolonged pregnancy: a report of a randomized trial. BJOG. 1992; 99:455-458.

16. Goldenberg M, Dulitzky M, Feldman B, Zolti M, Bider D. Stretching of the cervix and stripping of the membranes at term: a randomised controlled study. Eur J Obstet Gynecol Reprod Biol. 1996; 66:129-132.

17. Gupta R, Vasishta K, Sawhney H, Ray P. Safety and efficacy of stripping of membranes at term. Int J Gynaecol Obstet. 1998; 60:115-121.

18. Magann EF, McNamara MF, Whitworth NS, Chauhan SP, Thorpe RA, Morrison JC. Can we decrease postdatism in women with an unfavorable cervix and a negative fetal fibronectin test result at term by serial membrane sweeping? Am J Obstet Gynecol. 1998; 179:890-894.

19. Magann EF, Chauhan SP, McNamara MF, Bass JD, Estes CM, Morrison JC. Membrane sweeping versus dinoprostone vaginal insert in the management of pregnancies beyond 41 weeks with an unfavorable cervix. J Perinatol. 1999; 19:88-91.

20. Salamalekis E, Vitoratos N, Kassanos D, Loghis C, Batalias L, Panayotopoulos N et al. Sweeping of the membranes versus uterine stimulation by oxytocin in nulliparous women. A randomized controlled trial. Gynecol Obstet Invest. 2000; 49:240-243.

21. Swann O. Induction of labor by stripping membranes. Obstet Gynecol. 1958; 11:74-78.

22. Tannirandorn Y, Jumrustanasan T. A comparative study of membrane stripping and nonstripping for induction of labor in uncomplicated term pregnancy. J Med Assoc Thai . 1999; 82:229-233.

23. Weissberg SM, Spellacy WN. Membrane stripping to induce labor. J Reprod Med. 1977; 19: 125-127.

24. Wiriyasirivaj B, Vutyavanich T, Ruangsri RA. A randomized controlled trial of membrane stripping at term to promote labor. Obstet Gynecol. 1996; 87:767-770.

25. Wong SF, Hui SK, Choi H, Ho LC. Does sweeping of membranes beyond 40 weeks reduce the need for formal induction of labour? BJOG. 2002; 109:632-636.

26. Schulz KF, Grimes DA. Unequal group sizes in randomised trials: guarding against guessing. Lancet. 2002; 359:966-970.

27. Bishop EH. Pelvic scoring for elective induction. Obstet Gynecol. 1964; 24:266-268.

28. Bonsel GJ, van der Maas PJ. Aan de wieg van de toekomst. Scenario's voor de zorg rond de menselijke voortplanting 1995-2010. STG Stichting Toekomstscenario's Gezondheidszorg. Houten/Diegem: Bohn Stafleu Van Loghum; 1994.

29. Elferink-Stinkens PM, van Hemel OJ, Brand R, Merkus JM. The Perinatal Database of the Netherlands. Eur J Obstet Gynecol Reprod Biol. 2001; 94:125-138.

30. Boulvain M, Fraser WD, Marcoux S, Fontaine JY, Bazin S, Pinault JJ et al. Does sweeping of the membranes reduce the need for formal induction of labour? A randomised controlled trial. BJOG. 1998; 105:34-40.

31. Harris BA, Jr., Huddleston JF, Sutliff G, Perlis HW. The unfavorable cervix in prolonged pregnancy. Obstet Gynecol. 1983; 62:171-174.

32. Adair CE, Kowalsky L, Quon H, Ma D, Stoffman J, McGeer A et al. Risk factors for early-onset group B streptococcal disease in neonates: a population-based case-control study. CMAJ. 2003; 169:198-203.

33. Lyytikainen O, Nuorti JP, Halmesmaki E, Carlson P, Uotila J, Vuento R et al. Invasive group B streptococcal infections in Finland: a population-based study. Emerg Infect Dis. 2003; 9:469-473.

34. Schuchat A. Group B streptococcus. Lancet. 1999; 353:51-56.

35. Levine EM, Strom CM, Ghai V, Barton JJ. Intrapartum management relating to the risk of perinatal transmission of group B streptococcus. Infect Dis Obstet Gynecol. 1998; 6:25-29.

36. Lieu TA, Mohle-Boetani JC, Ray GT, Ackerson LM, Walton DL. Neonatal group B streptococcal infection in a managed care population. Perinatal Group B Streptococcal Infection Study Group. Obstet Gynecol. 1998; 92:21-27.

37. Schrag S, Gorwitz R, Fultz-Butts K, Schuchat A. Prevention of perinatal group B streptococcal disease. Revised guidelines from CDC. MMWR Recomm Rep. 2002; 51:1-22.

Chapter 5

Cervical score and prediction of successful sweeping

Esteriek de Miranda
Johanna G. van der Bom
Gouke J. Bonsel
Otto P. Bleker
Frits R. Rosendaal

Submitted

Abstract

Objective To determine the accuracy of the Bishop score at a gestational age of 41 weeks in predicting spontaneous onset of labour before 42 weeks of gestation after membrane sweeping.

Design A prospective observational study.

Setting 51 primary care midwifery practices in the Netherlands.

Population 364 low-risk pregnant women with a gestational age of 41 weeks.

Methods A secondary analysis of a trial comparing membrane sweeping with no intervention. All participants allocated to membrane sweeping were submitted to digital examination to assess the Bishop score. A logistic regression model was used to assess the predictive ability of the Bishop score and its separate components on spontaneous onset of labour before 42 weeks. We compared area under the receiver operating curves (AUC) to select the optimal model for the prediction of spontaneous onset of labour before 42 weeks.

Main outcome measures The performance of the Bishop score in predicting spontaneous onset of labour before 42 weeks.

Results The Bishop score was a moderate predictor of spontaneous onset of labour before 42 weeks after membrane sweeping or cervical massage (AUC 0.67, 95% confidence interval (CI) 0.61 – 0.73). The predictive ability of cervical dilatation alone was equivalent to that of the Bishop score (AUC 0.68, 95% CI 0.62 – 0.74). Cervical dilatation combined with cervical consistency was the best predictor (AUC 0.71, 95% CI 0.56 – 0.68). When analysis was restricted to actual sweeping at first examination, cervical dilatation combined with cervical consistency remained the best predictor.

Conclusion The predictive ability of the Bishop score is moderate and almost completely explained by cervical dilatation, which is one of its five components. Restriction to actual sweeping showed that cervical dilatation combined with cervical consistency predicted best, though the predictive ability remains moderate.

Introduction

Digital examination of the cervix is commonly used to assess cervical ripeness when considering induction of labour beyond term. Systematically quantified cervical assessment to select term parous women with a favourable cervix for labour induction was introduced by Bishop in 1964[1]. The Bishop score consists of five components each with various scoring options (dilatation 0-3 points, effacement 0-3, station 0-3, consistency 0-2 and cervical position 0-2); the sum of all points is the Bishop score. The Bishop score has been criticised because of its low predictive value for successful induction of labour[2;3-5] but it is still one of the most frequently applied methods to determine cervical ripeness in parous as well as in nulliparous women[6].

Membrane sweeping can be considered as a non-pharmacological method of cervical ripening or labour induction and is frequently used to prevent post-term pregnancy[7]. To select women for membrane sweeping, it is important to distinguish women who are likely to have spontaneous onset of labour before 42 weeks after membrane sweeping from those women who most likely will not. The present analysis was performed to determine the accuracy of the Bishop score in predicting spontaneous onset of labour before 42 weeks of gestation after membrane sweeping in nulliparous and parous women.

Methods

Three-hundred-sixty-four women undergoing membrane sweeping in a randomised trial on membrane sweeping for prevention of post-term pregnancy were studied prospectively. The multicentre individually randomised trial was conducted in 51 midwifery practices throughout the Netherlands between June 2000 and March 2003. Details and results have been described previously[1]. In short, pregnant women were eligible for inclusion in the trial when they were low-risk at presentation (single fetus in cephalic presentation, no pregnancy complications or risk factors and no obstacles for normal vaginal delivery) with a reliable gestational age of 41 weeks (range 40+6 - 41+3), and no history of blood loss after the first trimester or loss of amnion fluid during pregnancy. Gestational age was determined by ultrasound before 18 weeks, exact date of last menstrual period or both. Written informed consent was obtained from all participants.

Women allocated to sweeping received routine monitoring, followed by a vaginal examination for assessment of the cervical ripeness (Bishop score) and immediate sweeping. The midwives did not calculate the Bishop score themselves but ticked off the appropriate category on the various items of the Bishop score. Sweeping was performed by separating the lower membranes as much as possible from its cervical attachment with three circumferential passes of the examining fingers. When sweeping was not possible because of closure of the cervix, massage of the cervix was performed. Sweeping was repeated every second day unless labour had started, with a maximum of three times until 42 weeks of gestation. Referral to the obstetrician for surveillance or induction of labour was scheduled at 42 weeks. The outcome of primary interest was spontaneous onset of labour before 42 weeks, which was defined as onset of labour without formal induction (spontaneous contractions leading to increasing dilatation or spontaneous rupture of membranes followed by contractions leading to increasing dilatation within 24 hours).

Data concerning prenatal care, obstetrical intervention, delivery and child condition were recorded in a case report form.

Multivariate logistic regression was used to identify predictive variables associated with spontaneous onset of labour before 42 weeks. Standard area under the curves (AUC) was used to select the optimal model for the prediction of spontaneous onset of labour before 42 weeks. Data analysis was performed using SPSS for Windows software (Release 11.0; SPSS Inc, Chicago, Il, USA).

Results

Prognosis after sweeping at 41 weeks

The Bishop score at study entry was completed for 364 women; 190 nulliparous and 174 parous women. The median gestational age was 288 days (inter quartile range (IQR) 287 – 289). Gestational age was determined by ultrasound before 18 weeks in 293 (80%) women and by reliable last menstrual period corresponding with initial examination in 71 women (20%). The median Bishop score was 4 points (IQR 2 – 5) with no difference according to parity. There was no difference in distribution of low (< 6) and high (≥ 6) Bishop scores between nulliparous and parous women (Table 1). However, a very low Bishop score (0 – 2) was more frequent among nulliparous than among parous women (61/190 (32%) versus 42/174 (24%)). The

Table 1. Maternal Characteristics and Bishop Score at first examination.

	All (n=364)	Nulliparous women (n=190)	Parous women (n=174)
Maternal age (median (IQR*))	31 (28 – 33)	30 (27 – 32)	32 (30 – 35)
Gestational age (days) at first examination (median (IQR))	288 (287 – 289)	288 (287 – 289)	288 (287 – 289)
Initial Bishop Score (median (IQR*))	4 (2 – 5)	4 (2 – 5)	4 (3 – 5)
Bishop Score 0 – 2 (n / (%))	103 (28)	61 (32)	42 (24)
Bishop Score 3 – 5 (n / (%))	180 (50)	89 (47)	91 (52)
Bishop Score 6 – 8 (n / (%))	70 (19)	35 (18)	35 (20)
Bishop Score 9 – 11** (n / (%))	11 (3)	5 (3)	6 (3)
Bishop Score < 6 (n / (%))	283 (78)	150 (79)	133 (76)
Bishop Score ≥ 6 (n / (%)	81 (22)	40 (21)	41 (24)

* IQR = Inter Quartile Range
** There were no Bishop scores > 11.

full distribution of Bishop scores according to parity is showed in Figure 1.

Time from study entry to delivery was 3.5 days (95% CI 3.2 – 3.8). (Table 2). Women with an unfavourable cervix (Bishop score < 6) delivered later after sweeping than women with a favourable cervix (Bishop score ≥ 6), 3.9 days (95% CI 3.6 – 4.2) and 2.1 days (95% CI 1.7 – 2.5), respectively.

Successful sweeping, defined as spontaneous onset of labour before 42 weeks, occurred in 248 cases (68%); 61% of the nulliparous women (116/190) and 76% (132/174) of the parous women (Table 3). Time to spontaneous onset of labour < 42 weeks was 2.2 days (95% CI 2.0 – 2.4); 2.5 days (CI 2.2 – 2.8) for nulliparous women and 2.0 days (95% CI 1.7 – 2.3) for parous women (Table 2). Figure 2 presents the Kaplan-Meier curves of time to spontaneous onset of labour before 42 weeks according to low or high Bishop scores. Parous women with a high Bishop score had the shortest time interval between study entry and spontaneous onset of labour before

Figure 1. Distribution of Bishop Scores.

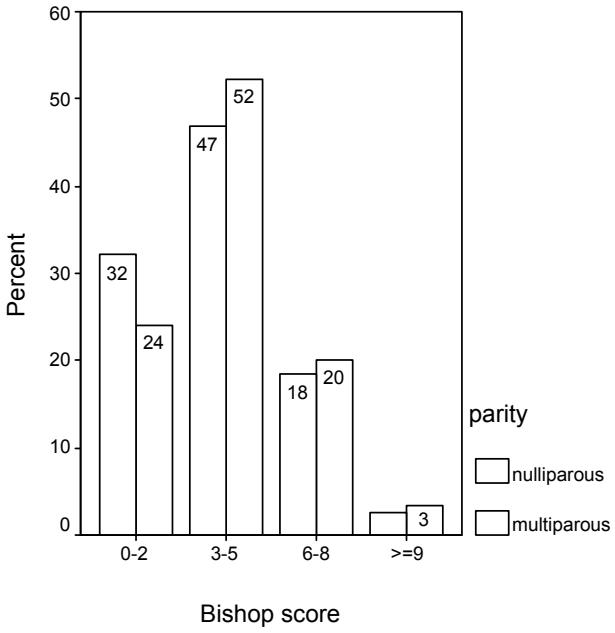
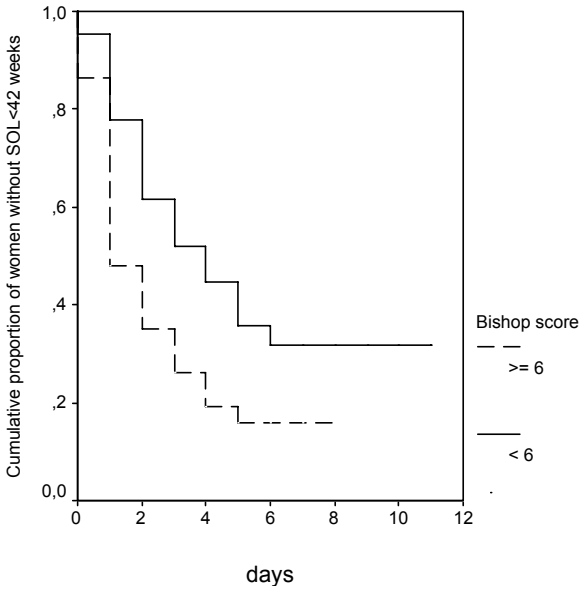


Table 2. Time to delivery and to spontaneous onset of labour before 42 weeks (days: mean; 95% Confidence Interval) according to parity and Bishop score at time of entering the study (41 weeks).

	All	**Bishop score < 6**	**Bishop score ≥ 6**
Days to delivery: mean (95% CI)	3.5 (3.2 – 3.8)	3.9 (3.6 – 4.2)	2.1 (1.7 – 2.5)
Nulliparous: mean (95% CI)	3.9 (3.5 – 4.3)	4.2 (3.8 – 4.6)	2.7 (2.0 – 3.4)
Parous: mean (95% CI)	3.1 (2.7 – 3.5)	3.5 (3.0 – 4.0)	1.7 (1.2 – 2.2)
Days to SOL < 42 wks*: mean (95% CI)	2.2 (2.0 – 2.4)	2.5 (2.3 – 2.7)	1.5 (1.2 – 1.8)
Nulliparous: mean (95% CI)	2.5 (2.2 – 2.8)	2.7 (2.4 – 3.0)	1.8 (1.3 – 2.3)
Parous: mean (95% CI)	2.0 (1.7 – 2.3)	2.2 (1.9 – 2.5)	1.4 (1.0 – 1.8)

* SOL < 42 wks: Spontaneous Onset of Labour before 42 weeks of gestation

Figure 2. Kaplan-Meier Curve of time interval (days) from study entry to spontaneous onset of labour before 42 weeks according to Bishop score.



42 weeks and nulliparous women with a low Bishop score the largest time interval (1.4 days; 95% CI 1.0 – 1.8 versus 2.7 days; 95% CI 2.4 – 3.0). Women with low Bishop scores had a lower risk of spontaneous onset of labour < 42 weeks compared to women with high Bishop scores (182/283 versus 66/81; RR 0.79, 95% CI 0.71 – 0.92). Nulliparous women had a decreased risk on spontaneous onset of labour < 42 weeks compared to parous women (116/190 *vs* 132/174; RR 0.81, 95% CI 0.71 – 0.93). Nulliparous women with low Bishop scores had a similar risk of spontaneous onset of labour < 42 weeks compared to nulliparous with high Bishop scores (88/150 *vs* 28/40; RR 0.84, 95% CI 0.69 – 1.10). Parous women with low Bishop scores had a decreased risk on spontaneous onset of labour < 42 weeks compared to parous women with high Bishop scores. (94/133 versus 38/41; RR 0.76, 95% CI 0.71 – 0.90).

Predictive ability of Bishop score and its separate components

Univariate and multivariate models were used to describe the associations between the various components of the Bishop score at study entry and spontaneous onset of labour before 42 weeks (Table 3). In the univariate models all items independently predicted spontaneous onset of labour before 42 weeks. In the multivariate model cervical dilatation (data analyses according to cervical dilatation in the Bishop score: closed, 1-2 cm and 3-4 cm; there was only one woman with dilatation ≥ 5 who was added to the 3-4 category) and cervical consistency remained as independent predictors (Table 3). Parity was added to the multivariate model but was not statistically significantly associated with spontaneous onset of labour <42 weeks (data not shown).

The discriminative ability of the Bishop score, cervical dilatation and cervical consistency in the prediction of spontaneous onset of labour before 42 weeks are presented in Table 4. The area under the curve was 0.67 for the total Bishop score (95% CI 0.61 – 0.73), 0.57 for low/high Bishop score (95% CI 0,51 – 0.63), 0.71 for the predictors dilatation & cervical consistency (95% CI 0.65 – 0.76) and 0.68 for dilatation alone (95% CI 0.62 – 0.74). When analysed according to actual sweeping at first examination (internal cervical os accessible), the combination of dilatation and consistency was the most predictive as well with an AUC of 0.61 (95% CI 0.52 – 0.70). Subgroup analysis according to cervical massage, when sweeping was not possible at first examination, showed that the Bishop score had no predictive ability for spontaneous onset of labour before 42 weeks.

In accordance with the multivariate analysis, a weighted score was assigned to the items of cervical consistency and dilatation (Table 5). Table 6 shows the observed frequencies of spontaneous onset of labour according to the score using consistency and dilatation. Finally, we assessed how well dilatation alone predicted spontaneous onset of labour < 42 weeks (Table 7). The frequencies of spontaneous onset of labour < 42 weeks according to cervical dilatation score indicate the strong association between increasing cervical dilatation and spontaneous onset of labour before 42 weeks.

Table 3. Results of univariate and multivariate logistic regression analysis of separate Bishop Score items on spontaneous onset of labour before 42 weeks.

	n /%	Univariate Odds Ratio (95% CI)	P value	Multivariate Odds Ratio (95% CI)	P value
Cervical Position categorical	364 / 100	1.9 (1.2 – 2.9)	< 0.01	1.1 (0.6 – 1.8)	0.8
posterior	188 / 52	1		1	
midposition	172 / 47	1.98 (1.3 – 3.1)	< 0.01	1.1 (0.7 – 1.9)	0.7
anterior	4 / 1	1.9 (0.2 – 18.7)	0.58	0.9 (0.1 – 10.1)	0.9
Cervical Consistency categorical	364 / 100	2.1 (1.5 – 2.9)	< 0.01	1.5 (1. – 2.2)	0.04
firm	71 / 19	1		1	
medium	196 / 54	2.3 (1.3 – 4.0)	< 0.01	1.4 (0.7 – 2.6)	0.3
soft	97 / 27	4.2 (2.1 – 8.4)	< 0.01	2.1 (0.9 – 4.6)	0.1
Cervical Effacement (%) categorical	364 / 100	1.3 (1.0 – 1.7)	0.04	0.9 (0.6 – 1.2)	0.4
0 – 30	174 / 48	1		1	
40 – 50	122 / 33	2.1 (1.3 – 3.5)	0.01	1.1 (0.6 – 2.0)	0.8
60 – 70	40 / 11	2.3 (1.0 – 5.1)	0.05	1.1 (0.4 – 2.6)	0.9
> 80	28 / 8	1.4 (0.6 – 3.2)	0.5	0.5 (0.2 – 1.4)	0.2
Cervical Dilatation categorical*	364 / 100	4.1 (2.6 – 6.5)	< 0.01	3.5 (2.1 – 5.9)	< 0.01
closed	121 / 33	1		1	
1 – 2 cm	225 / 62	4.3 (2.7 – 7.2)	< 0.01	3.77 (2.2 – 6.6)	< 0.01
>= 3 cm	18 / 5	9.6 (2.1 – 43.6)	< 0.01	7.7 (1.5 – 39.8)	0.02
Station of Head categorical	364 / 100	1.5 (1.1 – 2.1)	0.01	1.2 (0.9 – 1.8)	0.3
-3	113 / 31	1		1	
-2	186 / 51	2.1 (1.3 – 3.5)	< 0.01	1.9 (1.1 – 3.3)	0.02
-1	62 / 17	2.0 (1.0 – 4.0)	0.04	1.3 (0.6 – 2.7)	0.5
+1, +2	3 / 1	1.5 (0.1 – 17.4)	0.7	0.8 (0.1 – 9.8)	0.8

*There was only one dilatation in the original category > 5, this one was added to the 3-4 category which was renamed >= 3 category

Table 4. Area under the ROC of the Bishop score at 41 weeks, cervical dilatation, cervical consistency and parity on the prediction of spontaneous onset of labour (SOL) before 42 weeks of gestation.

	P - value	SOL < 42 weeks AUC (95% CI)
Bishop Score (total)	< 0.01	0.67 (0.61 – 0.73)
Bishop Score according to actual sweep	0.14	0.57 (0.47 – 0.66)
Bishop Score according to cervical massage	0.46	0.54 (0.43 – 0.65)
Cervical Dilatation	< 0.01	0.68 (0.62 – 0.74)
Cervical dilatation according to actual sweep	0.24	0.55 (0.46 – 0.64)
Cervical dilatation according to cervical massage	0.60	0.53 (0.42 – 0.64)
Cervical Consistency	< 0.01	0.62 (0.56 – 0.68)
Cervical consistency according to actual sweep	0.04	0.59 (0.51 – 0.68)
Cervical consistency according to cervical massage	0.49	0.54 (0.43 – 0.65)
Cervical dilatation & cervical consistency	< 0.01	0.71 (0.65 – 0.76)
Cervical dilatation & cervical consistency according to actual sweep	0.02	0.61 (0.52 – 0.70)
Cervical dilatation & cervical consistency according to cervical massage	0.19	0.58 (0.46 – 0.69)
Parity	< 0.01	0.58 (0.52 – 0.65)
Parity according to actual sweep	0.09	0.58 (0.49 – 0.67)
Parity according to cervical massage	0.51	0.54 (0.43 – 0.65)

Table 5. Results of multivariate logistic regression analysis of the indicator variables cervical consistency and cervical dilatation at 41 weeks on spontaneous onset of labour before 42 weeks and assigned weighted score for each category.

	β	Standard Error	P value	Weighted score
Cervical Consistency categorical				
firm	–	–	–	0
medium	0.41	0.31	0.19	1
soft	0.74	0.38	0.05	2
Cervical Dilatation categorical*				
closed	–	–	–	0
1 – 2 cm	1.32	0.26	<0.001	3
>= 3 cm	1.96	0.79	0.01	5

Figure 3. ROC curves of independent predictors of spontaneous onset of labour before 42 weeks.

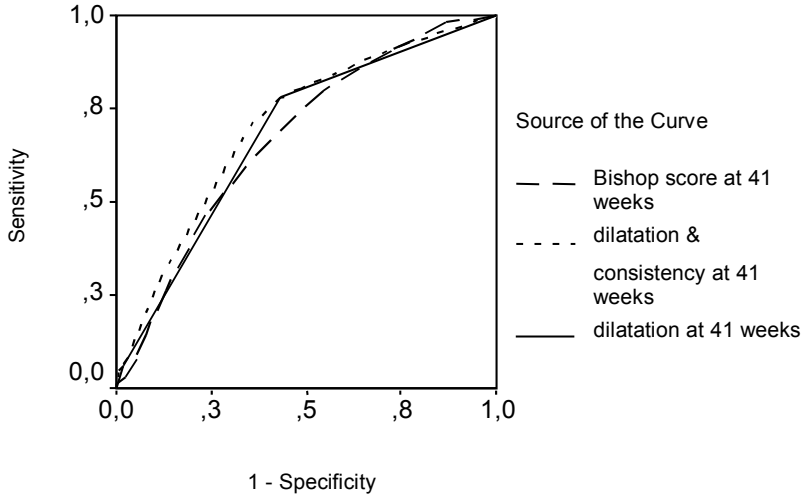


Table 6. Cumulative incidences of spontaneous onset of labour before 42 weeks according to weighted score (cervical dilatation and cervical consistency)

Dilatation / cervical consistency	**Weighted score**	**Spontaneous onset of labour < 42 weeks n / total (%)**
closed / firm	0	19 / 47 (47)
closed / medium	1	29 / 61 (48)
closed / soft	2	7 / 13 (54)
1-2 cm / firm	3	15 / 23 (65)
1-2 cm / medium	4	102 / 130 (79)
1-2 cm / soft	5	60 / 72 (83)
≥ 3 cm / firm	5	1 / 1 (100)
≥ 3 cm / medium	6	4 / 5 (80)
≥ 3 cm / soft	7	11 /12 (92)

Table 7. Cumulative incidences of spontaneous onset of labour before 42 weeks according to cervical dilatation at 41 weeks.

	Absolute number / total (%)
closed cervix	55 / 121 (46)
1-2 cm dilatation	177 / 225 (79)
≥ 3 cm dilatation	16 / 18 (89)

Discussion

The Bishop score was a moderate predictor of spontaneous onset of labour before 42 weeks after membrane sweeping (AUC 0.67; 95% CI 0.61 – 0.73). The predictive ability of cervical dilatation alone was equivalent to that of the Bishop score (AUC 0.68; 95% CI 0.62 – 0.74).

It was not possible to compare the predictive ability of the Bishop score after sweeping with the predictive ability of the Bishop score without sweeping because of the absence of a control group in which the women experienced formal Bishop scoring without membrane sweeping.

An advantage of this study is the participation of many different midwives, which indicates that our results reflect real practice.

At 41 weeks both nulli- and multiparous women had relatively low Bishop scores, which is in concordance with findings from other studies[8]. There was no difference in Bishop scores between women with and without first trimester ultrasound[9].

Though the accuracy of the Bishop score has been criticised because of its subjective character, imprecision and poor predictive value for successful induction[2-4;10-13], the Bishop score is still considered the best and simplest method for cervical assessment[6;14;15]. Cervical dilatation alone, however, may be a better predictor for successful induction than the Bishop score[3;16;17]. In addition, cervical diameter measurements dilatation simulator studies determined an accuracy in dilatation measurement of 90%, when an error of ± 1 cm was allowed for, and the reliability of the measurement seemed irrespective of examiners experience[18;19]. Some authors suggested to modify the Bishop score and assign more weight to cervical dilatation as this seemed to be the main predictor of successful induction of labour[16;17;20]. These modified scoring systems however, did not perform any better than the Bishop score[6]. Faltin-Traub et al suggested to use informal evaluation of the cervix (favourable/unfavourable) instead of the Bishop score and she found a fair to substantial agreement between observers (Kappa coefficients .64, .45 and .46 respectively) and concluded that informal evaluation of the cervix is as reliable as the Bishop score[21]. Williams et al suggested to use only cervical dilatation when assessing patients for cervical ripening and labour induction[3].

In our study the combination of cervical dilatation with cervical consistency was the best predictor of successful sweeping (spontaneous onset of labour < 42 weeks) in nulliparous- and parous women followed closely by cervical dilatation

alone, though the improvement as a predictive test comparing to the Bishop score was very small. Formal Bishop scoring though, including assessment of cervical consistency, appeared to be more sensitive to subjective judgement[10;12; 21] and has little added value[3;16;17] compared to the more simple and accurate determination of cervical dilatation alone[18]. However, both assessments have a moderate performance on the prediction of spontaneous onset of labour before 42 weeks, therefore the clinical relevance of these predictors is questionable.

Reference List

1. Bishop EH. Pelvic scoring for elective induction. Obstet Gynecol 1964; 24:266-8.:266-268.
2. Fuentes A, Williams M. Cervical assessment. Clin Obstet Gynecol 1995; 38(2):224-231.
3. Williams MC, Krammer J, O'Brien WF. The value of the cervical score in predicting successful outcome of labor induction. Obstet Gynecol 1997; 90(5):784-789.
4. Hughey MJ, McElin TW, Bird CC. An evaluation of preinduction scoring systems. Obstet Gynecol 1976; 48(6):635-641.
5. Dhall K, Mittal SC, Kumar A. Evaluation of preinduction scoring systems. Aust N Z J Obstet Gynaecol 1987; 27(4):309-311.
6. Edwards RK, Richards DS. Preinduction cervical assessment. Clin Obstet Gynecol 2000; 43(3):440-446.
7. Boulvain M, Stan C, Irion O. Membrane sweeping for induction of labour. Cochrane Database Syst Rev 2005;(1):CD000451.
8. Harris BA, Jr., Huddleston JF, Sutliff G, Perlis HW. The unfavorable cervix in prolonged pregnancy. Obstet Gynecol 1983; 62(2):171-174.
9. Ingemarsson I, Heden L. Cervical score and onset of spontaneous labor in prolonged pregnancy dated by second-trimester ultrasonic scan. Obstet Gynecol 1989; 74(1):102-105.
10. Holcomb WL, Jr., Smeltzer JS. Cervical effacement: variation in belief among clinicians. Obstet Gynecol 1991; 78(1):43-45.
11. Hendrix NW, Chauhan SP, Morrison JC, Magann EF, Martin JN, Jr., Devoe LD. Bishop score: a poor diagnostic test to predict failed induction versus vaginal delivery. South Med J 1998; 91(3):248-252.
12. Jackson GM, Ludmir J, Bader TJ. The accuracy of digital examination and ultrasound in the evaluation of cervical length. Obstet Gynecol 1992; 79(2):214-218.
13. Yang SH, Roh CR, Kim JH. Transvaginal ultrasonography for cervical assessment before induction of labor. J Ultrasound Med 2004; 23(3):375-82.
14. Gonen R, Degani S, Ron A. Prediction of successful induction of labor: comparison of transvaginal ultrasonography and the Bishop score. Eur J Ultrasound 1998; 7(3):183-187.
15. Rozenberg P, Chevret S, Chastang C, Ville Y. Comparison of digital and ultrasonographic examination of the cervix in predicting time interval from induction to delivery in women with a low Bishop score. BJOG 2005; 112(2):192-196.
16. Friedman EA, Niswander KR, Bayonet-Rivera NP, Sachtleben MR. Prelabor status evaluation. II. Weighted score. Obstet Gynecol 1967; 29(4):539-544.
17. Watson WJ, Stevens D, Welter S, Day D. Factors predicting successful labor induction. Obstet Gynecol 1996; 88(6):990-992.

18. Phelps JY, Higby K, Smyth MH, Ward JA, Arredondo F, Mayer AR. Accuracy and intraobserver variability of simulated cervical dilatation measurements. Am J Obstet Gynecol 1995; 173:942-945.

19. Tuffnell DJ, Bryce F, Johnson N, Lilford RJ. Simulation of cervical changes in labour: reproducibility of expert assessment. Lancet 1989; 2(8671):1089-1090.

20. Lyndrup J, Legarth J, Weber T, Nickelsen C, Guldbaek E. Predictive value of pelvic scores for induction of labor by local PGE2. Eur J Obstet Gynecol Reprod Biol 1992; 47(1):17-23.

21. Faltin-Traub EF, Boulvain M, Faltin DL, Extermann P, Irion O. Reliability of the Bishop score before labour induction at term. Eur J Obstet Gynecol Reprod Biol 2004; 112(2):178-181.

Chapter 6

The accuracy of clinical estimation of fetal weight beyond term in low-risk pregnancies

Esteriek de Miranda
Frits R. Rosendaal
Gouke J. Bonsel
Otto P. Bleker

Submitted

Abstract

Objectives To determine the accuracy of clinical estimation of fetal weight beyond term by midwives.

Design A prospective observational study.

Setting 51 primary care midwifery practices in The Netherlands.

Population 704 low-risk pregnant women with a gestational age of 41 weeks

Method Fetal weight was estimated clinically at 41 weeks of gestation and compared with actual birth weight.

Results In general, actual birth weight was underestimated (mean difference:(–) 81 g; 95% CI 52-110 g). Clinical estimation of fetal weight had a mean absolute error (standard deviation) of 317 grams (245) and a mean absolute percentage error of 8.4 (6.6); 67% of the estimations were within 10% of the actual birth weight. Birth weight was predicted most accurate within the category between 3000 – 4000 grams of actual birth weight (mean difference 30 g; 95% CI (1 – 59), mean absolute error 252 g (192). Three quarters of the estimations (75%) were within 10% of actual birth weight. Birth weight below 3000 g was systematically overestimated (mean difference 542 g; 95% CI 406-678), mean absolute error 572 g (289), sensitivity to detect birth weight < 3000 g 15%, positive likelihood ratio 25). Birth weight above 4000 g was systematically underestimated (mean difference: (-)399; 95% CI 356-441), mean absolute error 423 g (282), sensitivity to detect high birth weight 38%, positive likelihood ratio 4).

Conclusion Midwives are accurate in clinical estimation of fetal weight beyond term in the normal birth weight range, but they overestimate birth weight below 3000 g and underestimate birth weight above 4000 g.

Introduction

Estimation of fetal weight is a major element of pregnancy surveillance by midwives. Midwives primarily rely on their manual skills in the absence of more elaborate technical equipment, which is available in secondary care obstetrics. Since risk selection and obstetrical management depends to a relevant extent on the estimation of fetal weight, accuracy of clinical estimation of fetal weight has to be established and should be more than "guesswork"[1]. Apart from clinical estimation of fetal weight, ultrasound is frequently used in obstetrics for fetal weight estimation. Both techniques, ultrasound- and clinical estimation, have similar levels of accuracy during the term period[2-6] while in post-term pregnancies[7] and in the normal and high ranges of actual birth weight[6] clinical estimation of fetal weight is reported to be superior. All studies were accomplished in hospital settings, and the estimations were performed by residents or obstetricians.

The purpose of the present study was to determine the accuracy of birth weight estimation in low-risk pregnancies beyond term, as executed by independent midwives [8] in primary care midwifery practices.

Methods

Between June 2000 and March 2003, 704 low-risk women at 41 weeks of gestation underwent clinical assessment of fetal weight at 51 primary care midwifery practices throughout The Netherlands. Assessment involved abdominal palpation and fundal size; no standardized method was used. Gestational age was determined by reliable last menstrual period, ultrasound assessment within the first 20 weeks of gestation, or both.

The pregnant women participated in a multicenter individually randomised controlled trial evaluating membrane sweeping (versus not) in low-risk pregnancies at 41 weeks for the prevention of post-term pregnancy[9]. Pregnant women were eligible for inclusion in the trial when they were low-risk at presentation (single fetus in cephalic presentation, no pregnancy complications or risk factors, and no objections to normal vaginal delivery) with a reliable gestational age of 41 weeks (range 40+6 - 41+3).

Data concerning clinical assessment of fetal weight, prenatal care, obstetrical

intervention, delivery and child condition were recorded in a case report form. The weight estimates were obtained in grams and adjusted for growth during time to delivery[10]. Weight gain per day was calculated according to Mongelli as ([5*Estimated Fetal Weight]/100)/7. The adjusted fetal weight estimates were compared with the actual birth weight using mean error (estimation of fetal weight minus actual birth weight: a - b), mean absolute error (absolute value of estimation of fetal weight - actual birth weight: | a – b |), mean percentage error ([estimation of fetal weight – actual birth weight] x 100/ actual birth weight, by percentage: (a-b) / b x 100%), the mean absolute percentage error (absolute value [estimation of fetal weight – actual birth weight] x 100/ actual birth weight, by percentage: | a - b| / b x 100%) and percentage of estimates within 10% of actual birth weight for newborns in the entire study group (n | a- b | / b < 0.1) and in three strata of birth weights (< 3000 g, 3000 – 4000 g, and > 4000 grams). Test characteristics of fetal weight estimation were calculated according to actual birth weight stratum. Mode of delivery and adverse neonatal outcome in the actual birth weight strata was analysed according to the strata of fetal weight estimation.

Results

Seven-hundred and four women, mainly Caucasian (95%), were evaluated by 194 midwives in 51 midwifery practices. Maternal characteristics and mean actual birth weight are showed in table 1. Gestational age at recruitment was 41 weeks (median 288 days; Inter Quartile Range 287-289). Course of time between estimation and delivery was 4 days (median; IQR 2-6). Mean actual birth weight in grams was 3788 grams (standard deviation 446) and ranged from 2400 to 5070 g. The distribution of actual birth weight is depicted in Figure 1.

Clinical estimation of fetal weight ranged from 2500 to 4500 g with a mean (SD) of 3605 g (313). Adjusted for growth during time to delivery, estimation of fetal weight ranged from 2518 to 4660 g with a mean of 3707 g (330) (Figure 2). On average, actual birth weight was underestimated (mean difference: (-)81 g; 95% Confidence Interval (CI) 52-110) (Table 2). Low actual birth weight according to the International Classification of Diseases (ICD-9-CM: birth weight < 2500 g) occurred only twice (2400 g and 2495 g); both low birth weight cases were overestimated. Normal birth weight between 2500 and 4000 g was recorded on 488 occa-

Table 1. Maternal characteristics (n = 704)

Values are given as median /(IQR) or mean / (SD) or n (%)		
Maternal age, years (median/IQR)	31	(28 – 34)
Gestational age at recruitment, days (median/IQR)	288	(287 – 289)
Time from EFW to delivery, days (median/IQR)	4	(2 – 6)
Actual birth weight in grams (mean/SD)	3788	(± 446)
Parity		
Nulliparous (n (%))	366	(52)
Parous (n (%))	338	(48)

Figure 1. Actual birth weight distribution in grams.

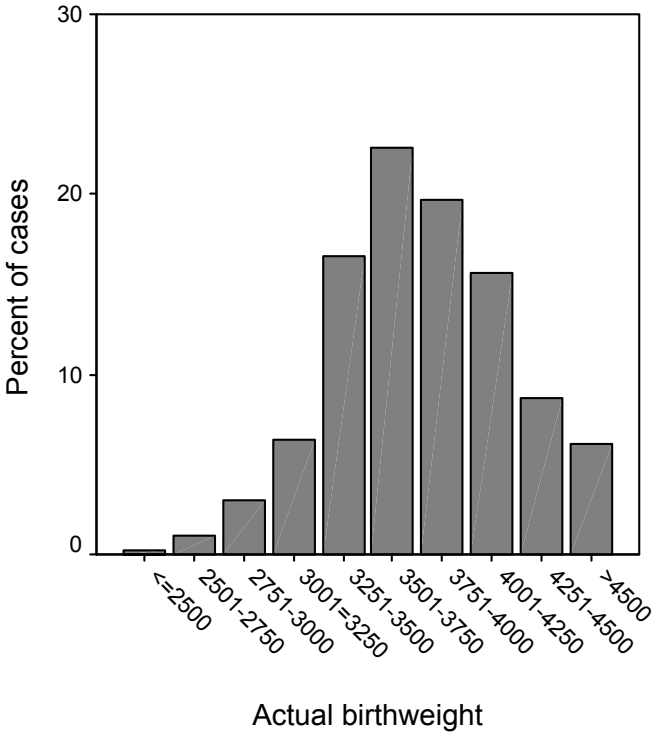


Table 2. Mean difference (mean error)* between adjusted estimated fetal weight (EFW) and actual birth weight (ABW) according to Actual Birth Weight Strata.

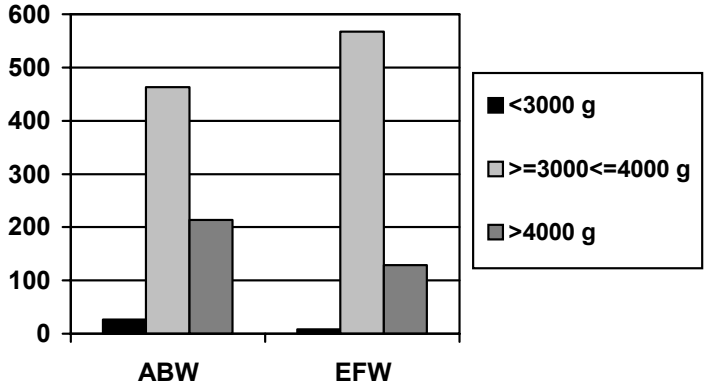
	EFW mean birth weight (g) / (SD)	**ABW mean birth weight (g) / (SD)**	**mean difference (95% CI)**
All	3707 (330)	3788 (446)	(-)81 (52-110)
< 3000 g (N=27)	3353 (331)	2811 (152)	542 (406 - 678)
< 2500 g (n=2)	*3139 (540)*	*2447 (61)*	*749 (458 – 1040)*
≥ 2500 - < 2750 g (n=6)	*3427 (269)*	*2678 (62)*	*672 (372 – 972)*
≥ 2750 - < 3000 g (n=19)	*3352 (339)*	*2891 (67)*	*461 (299 – 624)*
≥ 3000 - ≤ 4000 g (N = 463)	3636 (295)	3606 (247)	30 (1-59)
≥ 3000 - < 3250 g (n=44)	*3434 (274)*	*3135 (73)*	*299 (212 – 386)*
≥ 3250 - < 3500 g (n=100)	*3544 (262)*	*3387 (73)*	*158 (105 – 210)*
≥ 3500 - < 3750 g (n=161)	*3686 (301)*	*3612 (75)*	*75 (30 – 120)*
≥ 3750 - ≤ 4000 g (n =158)	*3697 (277)*	*3868 (85)*	*(-)171 (129 – 212)*
> 4000 g (N= 214)	3906 (301)	4305 (243)	(-)399 (356-441)
> 4000 - < 4250 g (n=105)	*3822 (248)*	*4110 (64)*	*(-)287 (238 – 336)*
≥ 4250 - < 4500 g (n =59)	*3929 (341)*	*4339 (70)*	*(-)410 (325 – 494)*
≥ 4500 g (n=50)	*4051 (298)*	*4671 (150)*	*(-)619 (530 – 708)*

* Paired Samples T-Test

sions (69%). The frequency of high birth weight (> 4000 g) was 30% (214/704) and of birth weight greater than 4500 g, 6% (43/704). Paired samples analysis showed consistency in the direction of the estimation errors, starting from the mean actual birth stratum with the smallest difference (≥ 3500 g - < 3750 g); the lower the birth weight the greater the overestimation and the higher the birth weight the greater the underestimation (Table 2).

Table 3 shows the measures of differences selected. In general, actual birth weight was underestimated with a mean absolute error of 317 g (SD 245) and a mean absolute percentage error of 8.4 (6.6). The percentage within 10% of the actual birth weight was 67%. The errors within the normal birth weight stratum (mean absolute error 252 g (192), mean absolute percentage error 7.1 (5.5)) were smaller compared to the low-normal birth weight stratum (mean absolute error 572 g (289), mean absolute percentage error 20.6 (10.8)) and the high birth weight stratum

Figure 2. Weight distribution (numbers) according to actual birth weight (ABW) and estimated fetal weight (EFW), adjusted for growth during time to delivery.



(mean absolute error 423 g (282), mean absolute percentage error 9.7 (6.2)), resulting in 75% of the fetal weight estimations within 10% of actual birth weight in the normal birth weight stratum.

Eighty nine percent (411/463) of the actual birth weight stratum of ≥ 3000 - ≤ 4000 g was estimated accurately (Table 4). Only 4 of the 27 (15%) low-normal actual birth weights were detected as such. Actual birth weight > 4000 g. was accurately estimated in 38% (81/214). Sensitivity, specificity, positive and nega-

Table 3. Relative accuracy of clinical estimated fetal weight (adjusted for growth during time to delivery) according to actual birth weight strata.

Birth Weight strata	Number n / (%)	Mean absolute error g / (SD)	Mean % error % / (SD)	Mean absolute % error % / (SD)	Percent of EFW within 10% (%)
All	704 / (100)	317 (245)	–1.3 (10.6)	8.4 (6.6)	67
< 3000 g	27 / (3.8)	572 (289)	19.6 (12.6)	20.6 (10.8)	15
3000 – 4000 g	463 / (65.8)	252 (192)	1.1 (8.9)	7.1 (5.5)	75
> 4000 g	214 / (30.4)	423 (282)	–9.1 (7.0)	9.7 (6.2)	57

Mean absolute error (absolute value of estimation of fetal weight minus actual birth weight), mean percentage error ([estimation of fetal weight – actual birth weight] x 100/ actual birth weight, by percentage), mean absolute percentage error (absolute value [estimation of fetal weight – actual birth weight] x 100/ actual birth weight, by percentage).

tive predictive values and likelihood ratio for detection of low-normal and high actual birth weight are shown in table 5. Sensitivity of estimation for detection of low-normal actual birth weight and high birth weight was low (only 15% and 38% respectively). However, the specificity for low-normal actual birth weight was high and the positive likelihood ratio to detect low-normal birth weight was 25. There was no difference in accuracy of estimation of fetal weight between nulliparous and parous pregnancies.

There were no differences in mode of delivery between the strata of estimated fetal weight and actual birth weight. Instrumental vaginal delivery and cesarean section in the stratum of actual birth weight > 4000 g did not increase when estimation of fetal weight exceeded 4000 g. (Table 6). Meconium-stained amniotic fluid,

Table 4. Number (percentage) of correct Estimated Fetal Weights (adjusted for growth) according to Actual Birth Weight Strata.

	EFW**		
	< 3000 g. n = 8	**≥ 3000 - ≤ 4000 g. n = 567**	**> 4000 g. n = 129**
ABW* < 3000 g. N = 27 (100%)	4 (15)	23 (85)	0
ABW ≥ 3000 - ≤ 4000 g. N = 463 (100%)	4 (1)	411 (89)	48 (10)
ABW > 4000 g. N = 214 (100%)	0	133 (62)	81 (38)

* ABW = Actual Birth Weight
** EFW = Estimated Fetal Weight (adjusted for growth during time from estimation to delivery)

Table 5. Accuracy of clinical estimation of fetal weight (adjusted for growth) to predict low-normal actual birth weight (< 3000 g) and high birth weight (> 4000 g).

	N / total	Sensitivity (%)	Specificity (%)	PPV (%)	NPV (%)	PLR	NLR
Actual birth weight < 3000 g	4 / 27	15	99	50	97	25.1	0.9
Actual birth weight > 4000 g	78 / 214	38	90	63	77	4.0	0.7

PPV = positive predictive value; NPV = negative predictive value; PLR = positive likelihood ratio; NLR = negative likelihood ratio

fetal distress during birth and adverse neonatal outcomes appeared more frequent in the actual birth weight stratum < 3000 g compared to the actual birth weight stratum ≥ 3000 g (Table 7). The frequency of adverse neonatal outcomes did not differ in the normal and the high actual birth weight strata (data not shown).

Table 6. Pregnancy outcome in deliveries of actual birth weight > 4000 g and according to clinical estimation of fetal weight (adjusted for growth during time to delivery).

	Actual Birth Weight (g) > 4000	**Clinical Estimation of Fetal Weight (g)**	
		> 4000	**≤ 4000**
Number of neonates n (%)	214 (100)	81 (100)	133 (100)
Mean birth weight (g (SD))	4305 (243)	4407 (261)	4242 (209)
Spontaneous vaginal delivery n (%)	161/214 (75)	65/81 (80)	96/133 (72)
Instrumental vaginal delivery n (%)	34/214 (16)	10/81 (12)	24/133 (18)
Cesarean section n (%)	19/214 (9)	6/81 (7)	13/133 (10)

Table 7. Adverse perinatal outcomes according to actual birth weight strata.

	Actual Birth Weight < 3000 g. n = 27 (100%)	**Actual Birth Weight ≥ 3000 g. n = 677 (100%)**	**Odds Ratio (95% Confidence Interval)**
Meconium stained amniotic fluid	12 (44)	161 (24)	2,56 (1.20 – 5.50)
Fetal distress during birth	10 (37)	131 (19)	2,45 (1.12 – 5.39)
Adverse neonatal outcomes*	5 (19)	50 (7)	2,85 (1.04 – 7.85)

* Adverse neonatal outcomes: Apgar score 5 min. < 7, N(I)CU admission or perinatal mortality (there were no perinatal deaths in the low-normal birth weight stratum)

Discussion

In the present study, clinical prediction of birth weight was most accurate in the normal birth weight range with 75% of the estimated fetal weights within 10% of actual birth weight. This is in accordance with previous reports on clinical estimation of fetal weight[3;6;11]. Accuracy of clinical estimation of fetal weight in our study was reduced in the low-normal and high birth weight strata. Observed low-normal birth weight was systematically overestimated, which is in accordance with other studies[11], high birth weight was systematically underestimated. In earlier studies, both clinical estimation and ultrasound estimation of fetal weight underestimated the actual birth weight in the high birth weight range[6;12]. The observed patterns of estimation bias suggests that most observers tend to estimate towards the mean birth weight[11].

Accuracy of clinical estimation was independent of parity in our study, the same results were shown in the study of Herrero[13]. Though we did not measure clinical experience, previous studies did not show an improvement in accuracy of clinical estimation of fetal weight with increasing clinical experience[12-14].

The present study included only women with low-risk pregnancies. Pregnancies with signs related to growth retardation like hypertension, pre-eclampsia, or other pregnancy complications, were already referred to the obstetrician in an earlier stage. Consequently, normal birth weights were far more present than low-normal birth weights. Clinical estimation of fetal weight in this low-risk group appeared to be not suitable as a diagnostic test for low-normal and high actual birth weight considering the low sensitivities (15% and 38% respectively). The sensitivity to predict high birth weight in our study was lower than in other studies (Chauhan 54%, Chauhan 50%, Weiner 68%)[3;7;15] while the positive predictive value (PPV) in the present study (63%) was similar with the study of Chauhan (60%) [3] and higher comparing with the study of Weiner (38%). These differences in predictive values could be caused by variations in the prevalence of macrosomia in the studied populations.

Post-term pregnancy is associated with more macrosomic fetus and more cesarean sections than term pregnancies[16-20]. Chauhan et al. in their study of estimation of birth weight among 84 post-term (defined as ≥ 41 weeks) women, observed an incidence of macrosomia (birth weight ≥ 4000 g) of 23.8% [7], Chervenak et al. similarly reported an incidence of 25.5%[20]. In our study population the incidence of

high birth weight (actual birth weight > 4000) was 30.4%; when recalculated to ≥ 4000 g the incidence was slightly increased to 32.2% (227/704). This discrepancy might be due to differences in ethnical origin of the studied populations or to our selected population in which only low-risk pregnancies were included at a gestational age of 41 weeks. Antenatal prediction of fetal macrosomia is associated with an increase in caesarean deliveries[15;20;21]. In our study there were no differences in mode of delivery between the three fetal weight strata and the actual birth weight strata , therefore no consequences for mode of delivery could be established as a result of estimation error. At the inclusion time of the present study all the participating women were low-risk, indicating a high percentage of deliveries starting low-risk (72%) under surveillance of the midwife, which can add to the explanation for the low caesarean section rate.

In this study various factors could have influenced the results. We did not obtain data on mothers' body mass index, which may effect the accuracy of the prediction. Another limitation could have been the lack of information on the type of scales which were used to weigh the babies (digital or other) or how many different scales were utilised. We did not ask the midwives to use a standardised method of clinical estimation of fetal weight. This could have caused systematic differences between the clinical estimations of the midwives. However, the participation of many different midwives will imply that our results reflect real practice. Since the aim of the study was not to compare various methods of estimation or weighing, all reasons for incorrect measurement are irrelevant. Another limitation of our study might be the still limited sample size with low absolute numbers of extreme values. Therefore it is possible to show excellent performance without fetal weight estimation by stating every pregnancy to be normal weight as there were only two cases of low birth weight (< 2500 grams) in our study. However, adverse perinatal outcomes were increased in the low-normal birth weight stratum which is in concordance with the results of other studies[22-25] and making it important to identify these fetus at risk of adverse perinatal outcomes. In a recent review on screening for growth restriction Chauhan concluded that sonographic assessment of birth weight at 30-32 weeks and at 36-37 weeks should be routine policy in all low-risk pregnancies in order to detect growth abnormality in time[25]. Ultrasound estimation beyond term has no better performance than clinical estimation of fetal weight [7], but serial ultrasound measurement could perhaps distinguish better between normal growth and restricted growth. In view of the low diagnostic performance of clinical estimation

of fetal weight, this recommendation should be evaluated in a larger study.

In conclusion, our data confirm the results of most other studies on clinical estimation of fetal weight; low-normal birth weight was overestimated and high birth weight was underestimated while estimation was more accurate in the normal birth weight range. We assume that the results give a good indication of the accuracy of fetal weight estimation beyond term by midwives, even if we take the low-risk population into account.

Reference List

1. Willocks J, Donald I, Duggan TC, Day N. Foetal cephalometry by ultrasound. J Obstet Gynaecol Br Commonw 1964; 71:11-20.:11-20.
2. Watson WJ, Soisson AP, Harlass FE. Estimated weight of the term fetus. Accuracy of ultrasound vs. clinical examination. J Reprod Med 1988; 33(4):369-371.
3. Chauhan SP, Hendrix NW, Magann EF, Morrison JC, Kenney SP, Devoe LD. Limitations of clinical and sonographic estimates of birth weight: experience with 1034 parturients. Obstet Gynecol 1998; 91(1):72-77.
4. Baum JD, Gussman D, Wirth JC, III. Clinical and patient estimation of fetal weight vs. ultrasound estimation. J Reprod Med 2002; 47(3):194-198.
5. Chauhan SP, Lutton PM, Bailey KJ, Guerrieri JP, Morrison JC. Intrapartum clinical, sonographic, and parous patients' estimates of newborn birth weight. Obstet Gynecol 1992; 79(6):956-958.
6. Sherman DJ, Arieli S, Tovbin J, Siegel G, Caspi E, Bukovsky I. A comparison of clinical and ultrasonic estimation of fetal weight. Obstet Gynecol 1998; 91(2):212-217.
7. Chauhan SP, Sullivan CA, Magann EF, Perry KG, Roberts WE, Morrison JC. Estimate of birthweight among post-term pregnancy: clinical versus sonographic. J Matern Fetal Med 1994; 3(208):208-211.
8. McKay S. Models of midwifery care. Denmark, Sweden, and The Netherlands. J Nurse Midwifery 1993; 38(2):114-120.
9. de Miranda E, van der Bom JG, Bonsel GJ, Bleker OP, Rosendaal FR. Membrane sweeping and prevention of post-term pregnancy in low-risk pregnancies: a randomised controlled trial. BJOG 2006; 113(4):402-408.
10. Mongelli M, Biswas A. A fetal growth standard derived from multiple modalities. Early Hum Dev 2001; 60(3):171-177.
11. Bossak WS, Spellacy WN. Accuracy of estimating fetal weight by abdominal palpation. J Reprod Med 1972; 9(2):58-60.
12. Ong HC, Sen DK. Clinical estimation of fetal weight. Am J Obstet Gynecol 1972; 112(7):877-880.
13. Herrero RL, Fitzsimmons J. Estimated fetal weight. Maternal vs. physician estimate. J Reprod Med 1999; 44(8):674-678.
14. Chauhan SP, Cowan BD, Magann EF, Bradford TH, Roberts WE, Morrison JC. Intrapartum detection of a macrosomic fetus: clinical versus 8 sonographic models. Aust N Z J Obstet Gynaecol 1995; 35(3):266-270.
15. Weiner Z, Ben Shlomo I, Beck-Fruchter R, Goldberg Y, Shalev E. Clinical and ultrasonographic weight estimation in large for gestational age fetus. Eur J Obstet Gynecol Reprod Biol 2002; 105(1):20-24.

16. Ecker JL. Cesarean delivery for suspected macrosomia: inefficient at best. Clin Obstet Gynecol 2004; 47(2):352-364.

17. Treger M, Hallak M, Silberstein T, Friger M, Katz M, Mazor M. Post-term pregnancy: should induction of labor be considered before 42 weeks? J Matern Fetal Neonatal Med 2002; 11(1):50-53.

18. Rouse DJ, Owen J, Goldenberg RL, Cliver SP. The effectiveness and costs of elective cesarean delivery for fetal macrosomia diagnosed by ultrasound. JAMA 1996; 276(18):1480-1486.

19. Rouse DJ, Owen J. Sonography, suspected macrosomia, and prophylactic cesarean: a limited partnership. Clin Obstet Gynecol 2000; 43(2):326-334.

20. Chervenak JL, Divon MY, Hirsch J, Girz BA, Langer O. Macrosomia in the postdate pregnancy: is routine ultrasonographic screening indicated? Am J Obstet Gynecol 1989; 161(3):753-756.

21. Weeks JW, Pitman T, Spinnato JA. Fetal macrosomia: does antenatal prediction affect delivery route and birth outcome? Am J Obstet Gynecol 1995; 173(4):1215-1219.

22. Bais JM, Eskes M, Pel M, Bonsel GJ, Bleker OP. Effectiveness of detection of intrauterine growth retardation by abdominal palpation as screening test in a low-risk population: an observational study. Eur J Obstet Gynecol Reprod Biol 2004; 116(2):164-169.

23. Clausson B, Cnattingius S, Axelsson O. Outcomes of post-term births: the role of fetal growth restriction and malformations. Obstet Gynecol 1999; 94:758-762.

24. Lindqvist PG, Molin J. Does antenatal identification of small-for-gestational age fetuses significantly improve their outcome? Ultrasound Obstet Gynecol 2005; 25(3):258-264.

25. Chauhan SP, Magann EF. Screening for fetal growth restriction. Clin Obstet Gynecol 2006; 49(2):284-294.

Chapter 7

General discussion

Prevention of post-term pregnancy was the main focus of this thesis. Midwives regularly try to prevent post-term pregnancy by stimulating spontaneous onset of labour beyond term in order to prevent a more medical approach of the process of childbirth in the post-term period. A review of the literature on the effectiveness and safety of non-pharmacological methods of labour induction in primary care obstetrics was therefore included.
Membrane sweeping is one of the most frequently used non-pharmacological methods for the prevention of post-term pregnancy in both primary and secondary care obstetrics. Because of the continuous debate in daily practice among supporters and opponents regarding the effectiveness and safety of membrane sweeping, we decided to design a randomised controlled trial on membrane sweeping for the prevention of post-term pregnancy. Before we started the trial, we collected data on the opinion of Dutch midwives on membrane sweeping in order to compare opinions with evidence-based results.

A Cochrane review on the effectiveness of membrane sweeping for induction of labour[1] published at the time of the design of our trial showed conflicting results. This was mainly due to the relatively small size of the studies and the heterogeneity between trials' results. To ensure that our study would be large enough we decided to calculate the sample size on the basis of reports on the future of Dutch obstetric practice[2] and on representative data of The Netherlands Perinatal Registry (PRN-foundation)[3]. In the latter registry more than 95% of Dutch midwives and obstetricians participated at that time. Because the study population was large, we took the opportunity to collect data prospectively which were not directly related to sweeping but could provide information on the accuracy of fetal weight estimation, an important aspect of midwifery risk selection.
The research questions as formulated in the introduction are answered and discussed in the previous chapters. In this chapter the individual studies will be combined and discussed as such.

We evaluated whether there are safe and effective non-pharmacological methods for induction of labour. There was a remarkable lack of comparative studies on effectiveness and safety of many non pharmacological methods of labour induction. The majority of the studies were observational, if there were studies at all. The comparative studies which were found had small sample sizes and often no randomised allocation or unclear allocation methods, which may have led to confounding by indication. Proper studies on alternative methods which are subject

to intensive debate between “believers” and “non-believers”, like herbal preparation and homeopathy, are rare. Consequently, many studies in the review turned out to have sample sizes that were too small to allow generalised conclusions. An important finding was that the Dutch expression “if it doesn’t work, it doesn’t harm” appeared to be not general applicable on all non-pharmacological methods of labour induction; some remedies like castor oil, various herbs in their natural form and breast and nipple stimulation may harm the unborn.

One of the most popular non-pharmacological methods for the prevention of post-term pregnancy in primary and secondary care obstetrics is sweeping of the membranes. Preceding a trial on membrane sweeping for the prevention of post-term pregnancy, a semi-structured questionnaire was sent to all practising members of the Royal Netherlands Organisation of Midwives. The objective of this study was to explore the attitude of qualified practicing midwives to membrane sweeping in low-risk pregnancies beyond 41 weeks to prevent post-term pregnancy in relation to the decisive factors of that opinion and the willingness to implement the results of a forthcoming Dutch sweeping trial in midwifery practice. A majority of the midwives were convinced of the effectiveness of membrane sweeping beyond 41 weeks while more than 90% of the midwives was prepared to adjust their policy on sweeping when the results of the sweeping trial in the Netherlands would give reason for a change of policy in either direction. Only a small percentage of the midwives still preferred a policy in line with the own experience or conviction. Midwives distinguish between nulliparous and multiparous women when judging effectiveness of membrane sweeping, though at the time of the survey little evidence existed on the effectiveness of sweeping when parity is taken into account. We did not ask for detailed information on the sweeping practice of midwives because that implies the availability of detailed registration on actual sweeping. Instead of detailed data we asked the midwives to evaluate their own sweeping practice. Subsequently we evaluated the safety and effectiveness of membrane sweeping at 41 weeks for the prevention of post-term pregnancy in low-risk pregnancies. A multicentre randomised controlled trial was conducted in 51 midwifery practices throughout the Netherlands. Sweeping reduced the proportion of post-term pregnancies by 17 %. A slightly better result was seen for multiparous women but a positive effect was seen in both groups and the number needed to treat was equal. Sweeping increased spontaneous onset of labour before 42 weeks both in nulliparous and parous women. There were no differences in other obstetrics outcomes in both groups and

adverse neonatal outcomes were similar in both groups. It can be concluded from the results of our trial that sweeping is effective in the prevention of post-term pregnancy. Since it shortens gestation on average with only one day the advantage is limited. There were more labour inductions before 42 weeks in the intervention group, which may have led to an artificial reduction of the primary outcome "post-term pregnancy" in the sweeping group. However, if inductions before 42 weeks are added up to the proportion of post-term pregnancies, the absolute risk reduction in favour of sweeping endures. Notwithstanding the increase in spontaneous onset of labour before 42 weeks, sweeping had no effect on the course of delivery. Nulliparous women encountered the same delivery problems as usual. One of the main reasons to prevent post-term pregnancy by stimulating spontaneous onset of labour is to prevent pharmacological induction of labour. Since a fixed date for labour induction could not be given prior to randomisation, labour induction was not suitable as a reliable outcome measure. Policy on when to induce labour differs widely between hospitals especially on two of the main indications of labour induction in an otherwise low-risk population, post-term pregnancy and > 24 hours broken membranes. Therefore we focussed on another reliable primary outcome measure: "post-term pregnancy" followed by "spontaneous onset of labour" as a major secondary outcome. We included both nulliparous and multiparous women in our study but the randomisation procedure was not pre-stratified and the sample size was not calculated according to parity. We could distinguish according to parity for the primary outcome, but to detect small differences in other outcome measures, a pre-stratified design on parity would be desirable.

We also evaluated if the Bishop score at 41 weeks can be used as a predictor of spontaneous onset of labour before 42 weeks after membrane sweeping or cervical massage. The Bishop score is frequently used to distinguish between women with a favourable cervix for labour induction and those who should have cervical ripening with prostaglandins first. All participants allocated to membrane sweeping were submitted to digital examination to assess the Bishop score before sweeping or cervical massage. We assessed the predictive ability of the Bishop score and its separate components on spontaneous onset of labour before 42 weeks and selected the optimal model for the prediction of spontaneous onset of labour before 42 weeks. The Bishop score was a moderate predictor of spontaneous onset of labour before 42 weeks after membrane sweeping. The predictive ability of cervical dilatation alone was equivalent to that of the Bishop score, which is self-evident because if

the cervix is open it is possible to sweep. Sub-analysis of the group of women who had a real sweep (no massage) at first examination showed that cervical consistency in combination with dilatation was a better predictor than dilatation alone. In the subgroup with cervical massage and no sweep at first examination, the Bishop score had no predictive ability. Because almost 50% of the women with the most unripe cervix still had spontaneous onset of labour before 42 weeks comparing to more than 80% of the women with a favourable cervix, clinical utility of cervical assessment before sweeping appears to be low. A limitation of our study is the absence of a control group with cervical scoring without sweeping. Therefore it is not possible to evaluate the benefits of sweeping in women with a ripe cervix comparing to those with an unripe cervix. Indirectly an effect of sweeping on cervical ripening could be noticed because of a decreased use of prostaglandins for cervical ripening in the intervention group of the sweeping study. This could be related to the sweeping intervention.

Assessment of fetal growth is a major element of midwifery prenatal care; it is part of the process of continuous risk selection. Since fetal growth retardation is associated with adverse perinatal outcome, prenatal detection of fetal growth retardation is of major importance. For detection of isolated fetal growth retardation, unrelated with factors such as hypertension, preëclampsia, oligohydramnios or declined fetal movements, accurate fetal weight assessment is essential in primary care obstetrics. We therefore determined the accuracy of clinical estimation of fetal weight by midwives. Fetal weight was estimated at 41 weeks of gestation and compared with actual birth weight because the time interval between estimation at 41 weeks and assessment of actual birth weight was expected to be short. The weight estimates were adjusted for growth during time to delivery. In general, actual birth weight was underestimated. Birth weight was predicted most accurate within the category between 3000 – 4000 grams of actual birth weight. Three quarters of the estimations in this category were within 10% of actual birth weight. Birth weight below 3000 g was systematically overestimated and birth weight above 4000 g was systematically underestimated. Our data confirm the results of most other studies on clinical estimation of fetal weight. Normal birth weight is predicted rather accurate but high birth weight and low-normal birth weight are difficult to determine. An arbitrary distinction in three birth weight categories can introduce errors due to the size of the chosen categories. On average it would require a larger error for the babies in the 3000 – 4000 g range to be regarded as misclassified than for the babies

< 3000 g and the babies > 4000 g, were a small underestimate could led to misclassification. For this reason paired samples analyses of "estimation of fetal weight" and "actual birth weight" in 10 weight categories of 250 grams each was added to the three actual birth weight strata. According to this subgroup analysis, the lower the actual birth weight the greater the overestimation error; the higher the actual birth weight the greater the underestimation error. We made the distinction in three actual birth weight categories for two reasons. First, previous studies made a similar distinction, which simplifies comparison of results. Second, the focus of our study was on birth weight categories that are involved in risk selection. According to earlier studies, normal birth weight is estimated rather well in contrast to low and high birth weight. Identification of high actual birth weight is important to assess the best place of birth. Although not all small babies are growth retarded, detection of low actual birth weight is important because of the increase of perinatal problems when it concerns real growth retardation. A limitation of our study is the low absolute numbers of extreme values. A larger study on clinical estimation at term would probably have the same limitations; most women with a growth-retarded fetus will have earlier signs of fetal compromise or earlier maternal complications of pregnancy, which are related to growth retardation. Serial ultrasound measurement in low risk pregnancies is suggested to detect growth abnormality in time [5], though the accuracy of this policy should be assessed in larger studies.

Until more accurate methods for the detection of growth-retarded fetus at term are found, alertness of the midwife on the accuracy of her own clinical estimation of fetal weight is of major importance.

The studies described in this thesis are all related to daily midwifery practice. There is a commonly felt need by Dutch midwives for evidence-based midwifery. Recently, training of research-midwives has come into existence, and so in the near future we can expect more research into aspects of midwifery practice.

Reference List

1. Boulvain M, Irion O. Stripping/sweeping the membranes for inducing labour or preventing post-term pregnancy. Cochrane Database Syst Rev 2000;(2):CD000451.

2. Bonsel GJ, van der Maas PJ. Aan de wieg van de toekomst: scenario's voor de zorg rond de menselijke voortplanting, 1995-2010. STG Stichting Toekomstscenario's Gezondheidszorg. Houten/Diegem: Bohn Stafleu Van Loghum, 1994.

3 . The Netherlands Perinatal Registry. 1999. Utrecht.

4. Weatherley-Jones E, Thompson EA, Thomas KJ. The placebo-controlled tr.ial as a test of complementary and alternative medicine: observations from research experience of individualised homeopathic treatment. Homeopathy 2004; 93:186-189.

5. Chauhan SP, Magann EF. Screening for fetal growth restriction. Clin Obstet Gynecol 2006; 49:284-294.

Chapter 8

Implications for midwifery practice and recommendations for future research

Implications for midwifery practice based on our findings

- Serial sweeping of the membranes should be offered to women with low-risk pregnancies at a gestational age of 41 weeks in order to reduce the risk on post-term pregnancy and to increase the probability of spontaneous onset of labour.
- Sweeping can be offered to both primiparous and parous women.
- Other methods of labour induction in primary care obstetrics should not be offered until efficacy and safety of these methods are established.
- The Bishop score, prior to membrane sweeping, is of limited value for the prediction of spontaneous onset of labour before 42 weeks.
- Fetal weight estimation is of limited value regarding detection of low- and high birth weight. Alertness is required in case of fetal weight estimation in the lower range of normal birth weight; there is a considerable risk on overestimation.

Recommendations for future research

- More research is needed to identify effective and safe methods for stimulation of spontaneous onset of labour in primary care obstetrics.
- More studies are needed to answer the question whether single sweeping at a gestational age of 41 weeks is just as effective as serial sweeping for the prevention of post-term pregnancy.
- More research is needed to answer the question if there is a relation between sweeping and the risk of GBS disease.
- More studies are needed to determine if an informal cervical score (ripe/unripe) corresponds with the formal Bishop in assessing the degree of ripeness of the cervix.
- More research is needed to the determining factors of women's opinion regarding either expectant management or induction of labour at 41 and 42 weeks of gestation.
- A randomised controlled trial with adequate power to detect a relevant effect size is needed to evaluate the efficacy of ultrasound surveillance of fetal growth at 30-

32 and at 36-37 weeks of gestation for the identification of growth restriction in otherwise low-risk pregnancies.

- A randomised controlled trial with adequate power, comparing cardiotocography + ultrasound at 41 weeks versus expectant management is necessary to answer the question if extra surveillance in low-risk pregnancies will result in a better risk selection of the fetus at risk beyond term or that it will increase the risk of interventions without improving perinatal outcome. A cost-effectiveness analysis should be part of this study.
- More studies are needed to methods that can distinguish between low-risk fetus and the fetus at risk for adverse perinatal outcome beyond term.

Chapter 9

Summary

Labour induction in case of post-term pregnancy is a commonly applied intervention which is taken precautionary in order to prevent perinatal mortality. Therefore, midwives regularly try to hasten spontaneous onset of labour beyond term in order to prevent post-term pregnancy. In this thesis, studies related to prevention of post-term pregnancy and midwifery care beyond term are presented.

Chapter 1 outlines the aim of the thesis consisting of 5 main questions:

1. Are there safe and effective methods of non-pharmacological methods of labour induction which can be applied in primary care obstetrics?

2. What is the opinion of Dutch midwives on safety and effectiveness of membrane sweeping for the prevention of post-term pregnancy in relation to the decisive factors of their opinion and the willingness to implement the results of a Dutch sweeping trial in midwifery practice?

3. How safe and effective is sweeping of the membranes at 41 weeks for the prevention of post-term pregnancy in low-risk pregnancies?

4. How accurate is the Bishop score at a gestational age of 41 weeks, prior to membrane sweeping, in predicting spontaneous onset of labour before 42 weeks of gestation?

5. How accurate is clinical estimation of fetal weight beyond term by midwives?

In ***Chapter 2*** the mechanisms of non-pharmacological methods of labour induction applied in primary care obstetrics are discussed and the efficacy and side effects of these methods are evaluated. Only membrane sweeping was associated with reduced duration of pregnancy. Artificial rupture of membranes and breast/nipple stimulation seem promising methods for initiating spontaneous onset of labour. However, there is too little evidence considering the safety and effectiveness for these and other non-pharmacological methods of labour induction applied in primary care obstetrics to justify the use in common practice.

In ***Chapter 3*** a study on the attitude of Dutch midwives regarding the effectiveness and side effects of membrane sweeping for the prevention of post-term pregnancy is presented. A nation-wide survey was held before the start of the Dutch sweeping trial. A semi-structured questionnaire was sent to all 1288 then practising members who were registered as a member of the Royal Netherlands Organisation of Midwives, which accounts for 85% of all practising midwives in the Netherlands. The response was 76 %. A majority of respondents (64 %) were convinced that sweeping the membranes beyond 41 weeks was an effective method to prevent post term pregnancy, 17% were neutral. Only 1 % categorically opposed sweeping while 18 % felt uncertain about the effectiveness of sweeping. The effectiveness of membrane sweeping was judged to be higher in parous compared to nulliparous women. According to the opinion of the majority (65 %) of the midwives the benefits of membrane sweeping outweigh the side effects. The midwife's own experience was the most important factor determining the stated policy on sweeping. Half of the respondents mentioned the experience of associates as a determining factor. The opinion of the midwives was not dependent on the institution of their midwifery training. More then 90 % stated to be willing to adjust their policy on sweeping according to the results of the Dutch sweeping trial.

In ***Chapter 4*** the results are presented of a randomised trial on membrane sweeping for the prevention of post-term pregnancy. The trial was conducted in a low-risk population. Seven-hundred-and-fourty-two women at 41 weeks of gestation were randomly assigned to serial sweeping of the membranes or no intervention. Serial sweeping of the membranes at 41 weeks decreased the risk of post-term pregnancy (87/375 (23%) versus 149/367 (41%); Relative Risk (RR) 0.57; 95% Confidence Interval (CI) 0.46–0.71). This implies that 6 women had to be swept to prevent one post-term pregnancy. Benefits were apparent in nulliparous as well as in parous women. Spontaneous onset of labour was increased in both subgroups. Sweeping increased the likelihood of delivery in a primary care setting (188/375 versus 150/367; RR 1.23, 95% CI 1.05 – 1.44) but stratification according to parity showed that a substantial positive effect was restricted to parous women. Adverse effects were similar in both groups except for light bleeding, which was reported more frequently in the sweeping group than the controls group. Other obstetric outcomes and indicators of neonatal morbidity were similar in both groups. After delivery, 88% of the women of the sweeping group and 79% of the women of the control group would choose

for membrane sweeping in a next pregnancy. The main reason for this choice in both groups was the wish to deliver at home.

In ***Chapter 5*** a study on the predictive ability of the Bishop score (of cervical ripeness) on spontaneous onset of labour before 42 weeks is described. The Bishop score was determined prior to membrane sweeping. The Bishop score and its components were studied prospectively in 364 low-risk women undergoing membrane sweeping at 41 weeks. A logistic regression model was used to assess the predictive ability of the Bishop score and its separate components on spontaneous onset of labour before 42 weeks. We compared area under the receiver operating curves (AUC) to select the optimal model for the prediction of spontaneous onset of labour before 42 weeks. The Bishop score was a moderate predictor of spontaneous onset of labour before 42 weeks after membrane sweeping (AUC 0.67; 95% Confidence Interval (CI) 0.61 – 0.73). The predictive ability of cervical dilatation alone was equivalent to that of the Bishop score (AUC 0.68; 95% CI 0.62 – 0.74). Restriction to actual sweeping showed that cervical dilatation combined with cervical consistency predicted best, though the predictive ability remains moderate. Therefore the clinical relevance of these predictors is questionable.

In ***Chapter 6*** the accuracy of fetal weight estimation beyond term is assessed. Fetal weight was estimated clinically in 704 low-risk pregnant women at 41 weeks of gestation and compared with actual birth weight. In general, actual birth weight was underestimated (mean difference (-) 81 g; 95% CI 52-110 g). Clinical estimation of fetal weight had a mean absolute error of 317 (+/- 245) grams; 67% of the estimations were within 10% of the actual birth weight. Birth weight was predicted most accurate within the category between 3000 – 4000 grams of actual birth weight (mean difference 30 g; 95% CI 1-59, mean absolute error 252 (+/- 192) g). Three quarters of these estimations (75%) were within 10% of actual birth weight. Birth weight below 3000 g was systematically overestimated (mean difference 542 g; 95% CI 406-678, mean absolute error 572 (+/- 289) g). The sensitivity to detect birth weight < 3000 g was 15%, the positive likelihood ratio was 25. Birth weight above 4000 g was systematically underestimated (mean difference (-)399 g; 95% CI 356-441, mean absolute error 423 (+/- 282) g), the sensitivity to detect high birth weight was 38% with a positive likelihood ratio of 4. These results suggests that midwives are accurate in clinical estimation of fetal weight beyond term in the normal birth

weight range, but they overestimate birth weight below 3000 g and underestimate birth weight above 4000 g. Clinical estimation of fetal weight is therefore of limited value regarding detection of low- and high birth weight.

Conclusions

- There is too little evidence regarding the safety and effectiveness for most non-pharmacological methods of labour induction applied in primary care obstetrics to justify recommendation of their use in common practice.

- A majority of midwives is convinced of the effectiveness of membrane sweeping beyond 41 weeks while a vast majority of midwives is prepared to adjust their policy on sweeping in either direction when reliable data will become available.

- Membrane sweeping at 41 weeks will substantially reduce the proportion of women with post-term pregnancy.

- The Bishop score, determined prior to membrane sweeping, is a moderate predictor of spontaneous onset of labour before 42 weeks. Restriction to actual sweeping showed that cervical dilatation combined with cervical consistency predicted best, though the predictive ability remains moderate. Therefore the clinical relevance of this predictor is questionable.

- Midwives are accurate in clinical estimation of fetal weight beyond term in the normal birth weight range, but they overestimate birth weight below 3000 g and underestimate birth weight above 4000 g.

Chapter 10

Samenvatting

Het inleiden van de baring vanwege serotiniteit (zwangerschap van ≥ 42 weken) wordt algemeen toegepast ter voorkoming van perinatale sterfte. Het inleiden geschiedt door het toedienen van weeën opwekkende middelen. Vanwege de toegenomen kans op placenta-insufficiëntie vereist inleiding bij serotiniteit tweedelijns bewaking van de baring in het ziekenhuis waarbij door middel van elektronische hartfrequentieregistratie de conditie van het kind kan worden beoordeeld in relatie met de duur, intensiteit en frequentie van de opgewekte weeën. Om serotiniteit te voorkomen proberen verloskundigen regelmatig het spontaan op gang komen van de baring te stimuleren bij het naderen van een zwangerschapsduur van 42 weken. In dit proefschrift worden onderzoeken beschreven die gericht zijn op de preventie van serotiniteit en daaraan gerelateerde zorgverlening door verloskundigen.

Hoofdstuk 1 beschrijft het doel van het proefschrift bestaande uit 5 hoofdvragen:

1. Zijn er veilige en effectieve niet-farmacologische methoden van inleiden die kunnen worden toegepast binnen de eerstelijns verloskundige zorgverlening?

2. Wat is de mening van Nederlandse verloskundigen over de veiligheid en effectiviteit van het strippen van de vliezen ter voorkoming van serotiniteit en welke factoren zijn hierin bepalend? In hoeverre is men bereid het verloskundig beleid aan te passen aan de resultaten van de Nederlandse Stripstudie?

3. Hoe veilig en effectief is het strippen van de vliezen bij 41 weken ter voorkoming van serotiniteit in laagrisico zwangerschappen?

4. Is de Bishop score, voorafgaand aan het strippen van de vliezen bij een zwangerschapsduur van 41 weken, een betrouwbare voorspeller van het spontaan op gang komen van de baring voor 42 weken?

5. Hoe accuraat is de uitwendige gewichtschatting door verloskundigen aan het einde van de a terme periode?

In ***Hoofdstuk 2*** worden de mechanismen besproken van niet-farmacologische methoden van inleiden die worden toegepast binnen de eerstelijns verloskundige zorgverlening. Tevens worden de effectiviteit en bijwerkingen van deze methoden

geëvalueerd. Alleen het strippen van de vliezen kon aantoonbaar in verband worden gebracht met een kortere zwangerschapsduur. Het kunstmatig breken van de vliezen en borst/tepel stimulatie lijken veelbelovende methoden voor het spontaan op gang brengen van de baring. Er is echter tot op heden te weinig bewijs beschikbaar aangaande de veiligheid en effectiviteit voor deze en andere niet-farmacologische methoden voor het inleiden van de baring in de eerste lijn om het gebruik ervan in de dagelijkse praktijk aan te bevelen.

In ***Hoofdstuk 3*** wordt de attitude van verloskundigen aangaande de werkzaamheid en bijwerkingen van strippen ter voorkoming van serotiniteit besproken. Voorafgaande aan de Stripstudie, die wordt beschreven in hoofdstuk 4, werd een anonieme gestructureerde enquête verstuurd naar alle 1288 praktiserende leden van de Koninklijke Nederlandse Organisatie van Verloskundigen; dit betrof 85% van alle destijds praktiserende verloskundigen in Nederland. De respons was 76%. Een meerderheid van de respondenten (64%) was ervan overtuigd dat het strippen van de vliezen tussen de 41 en 42 weken een effectieve methode is om serotiniteit te voorkomen, 17% was neutraal. Slechts 1% was een absolute tegenstander van strippen terwijl 18% niet geheel overtuigd was van het nut van strippen. De verloskundigen oordeelden strippen bij multipara effectiever dan bij nullipara. Een meerderheid van de verloskundigen (65%) vond de voordelen van strippen opwegen tegen de bijwerkingen. Als bijwerkingen werden genoemd: onrustige uterus (54.2 %), vroege/valse start (29.3 %), bloedverlies (15.4 %), psychische onrust/verkeerde verwachtingen (6.7 %), langdurige baring (4.5%), voortijdig breken van vliezen (3.5 %) and pijn (2.1 %); 6.4 % van de respondenten had nooit bijwerkingen gezien. De eigen ervaring van de verloskundige was de meest bepalende factor voor de meningsvorming. De helft van de respondenten noemde de ervaringen van de collegae uit de eigen praktijk als bepalende factor. De mening van de verloskundigen was niet afhankelijk van het opleidingsinstituut waar de initiële opleiding werd doorlopen. Meer dan 90% verklaarde bereid te zijn het verloskundig beleid aan te passen aan de uitkomsten van de Nederlandse Stripstudie, ongeacht de uitkomst van het onderzoek.

In ***Hoofdstuk 4*** wordt de Stripstudie beschreven. Dit betreft een gerandomiseerde studie naar het strippen van de vliezen ter voorkoming van serotiniteit. Het onderzoek werd verricht in verloskundige praktijken bij laagrisico zwangeren. Zevenhon-

derdtweeënveertig vrouwen werden bij een zwangerschapsduur van 41 weken at random toegewezen aan serieel strippen van de vliezen of geen interventie. Serieel strippen van de vliezen verlaagde het risico op serotiniteit (87/375 (23%) versus 149/367 (41%); Relatief Risico (RR) 0.57, 95% Betrouwbaarheids Interval (BI) 0.46-0.71). Om één serotiene zwangerschap te voorkomen zullen 6 vrouwen gestript moeten worden. Het voordeel was zowel voor nulliparae als voor multiparae aantoonbaar. De kans op het spontaan op gang komen van de baring voor de 42 weken was verhoogd in de strippengroep (253/375 (68%) versus 198/367 (54%); RR 1.25, BI 1.11-1.41). Strippen verhoogde de kans op een baring in een eerstelijns setting (188/375 versus 150/367; RR 1.23 , 95% BI 1.05-1.44) maar stratificatie naar pariteit liet zien dat een substantieel positief effect was voorbehouden aan multiparae. Nadelige effecten waren gelijk in beide groepen behalve licht bloedverlies, hetgeen meer gerapporteerd werd in de strippengroep. Andere obstetrische uitkomsten en indicatoren van neonatale morbiditeit waren gelijk in beide groepen. Strippen werd door 51% van de vrouwen als enigszins pijnlijk ervaren en 17% vond strippen pijnlijk of erg pijnlijk. Na de bevalling gaf 88% van de vrouwen uit de strippengroep aan in een volgende zwangerschap gestript te willen worden, ongeacht of strippen wel of niet als pijnlijk werd ervaren. In de controlegroep koos 79% voor strippen in een volgende zwangerschap. Belangrijkste reden in beide groepen om voor strippen te kiezen in een volgende zwangerschap was de wens om thuis te kunnen bevallen.

In ***Hoofdstuk 5*** wordt een studie beschreven naar de voorspellende waarde van de Bishop score op het spontaan op gang komen van de baring voor de 42 weken. De Bishop score werd bepaald voorafgaande aan het strippen van de vliezen. De onderdelen van de Bishop score en de Bishop score zelf werden beoordeeld bij 364 laagrisico zwangeren die gestript werden bij een zwangerschapsduur van 41 weken. Een logistisch regressie model werd gebruikt om de voorspellende waarde van de Bishop score te bepalen op het spontaan op gang komen van de baring voor de 42 weken. Vervolgens werden “receiver operated charasteristic” (ROC) analyses verricht waarbij de “area under the receiver operating curves” (AUC) vergeleken werden om het optimale model te selecteren voor de predictie van het spontaan op gang komen van de baring voor 42 weken.
De Bishop score was een matige voorspeller van het spontaan op gang komen van de baring voor de 42 weken (AUC 0.67; 95% BI 0.61 – 0.73). De voorspellende waarde van ontsluiting alleen was gelijk aan die van de Bishop score (AUC 0.68;

95% BI 0.62 – 0.74). Bij de groep vrouwen die daadwerkelijk gestript was bleek ontsluiting in combinatie met cervicale consistentie de beste voorspeller te zijn hoewel de voorspellende waarde matig bleef. De klinische relevantie van de Bishop score, of onderdelen daarvan, als voorspeller van het spontaan op gang komen van de baring voor de 42 weken is daarom twijfelachtig.

In ***Hoofdstuk 6*** worden de resultaten beschreven van een onderzoek naar de nauwkeurigheid van de uitwendige gewichtschatting. Het foetale gewicht werd uitwendig geschat door verloskundigen bij 704 laagrisico zwangeren met een zwangerschapsduur van 41 weken en dit werd vergeleken met het geboortegewicht. Er werd gecorrigeerd voor groei gedurende het aantal dagen tussen de schatting en de geboorte. Het geboortegewicht in het algemeen werd onderschat (gemiddelde verschil (-) 81 g; 95% BI 52-110 g, gemiddelde absolute fout 317 g (+/- 245 g). Indien een marge van 10% werd aangehouden viel 67% van de schattingen binnen 10% van het geboortegewicht. Het geboortegewicht werd het meest accuraat geschat in de categorie van het normale geboortegewicht (≥ 3000 - ≤ 4000 gram; gemiddelde verschil 30 g; 95% BI 1-59, gemiddelde absolute fout 252 (+/- 192) g). Driekwart van deze schattingen (75%) vielen binnen de 10% van het geboortegewicht. Geboortegewicht onder de 3000 gram werd systematisch overschat (gemiddelde verschil 542 g; 95% BI 406-678, gemiddelde absolute fout 572 (+/- 289) g). De sensitiviteit om geboortegewicht < 3000 g op te sporen was 15% (positieve likelihood ratio 25). Geboortegewicht boven de 4000 gram werd systematisch onderschat (gemiddelde verschil (-) 399 g; 95% BI 356-441, gemiddelde absolute fout 423 (+/- 282) g). De sensitiviteit om hoog geboortegewicht op te sporen was 38% (positieve likelihood ratio 4). Deze resultaten duiden erop dat verloskundigen het geboortegewicht goed kunnen schatten met behulp van uitwendige gewichtsschatting indien het geboortegewicht zich bevindt binnen de range van het normale geboortegewicht. Geboortegewicht onder de 3000 gram wordt echter overschat en geboortegewicht boven de 4000 gram wordt onderschat. Uitwendige gewichtschatting tegen het einde van de a terme periode is daarom niet goed bruikbaar als diagnostische test voor het onderkennen van geboortegewichten onder en boven het normale geboortegewicht.

Conclusies

- Er is te weinig beschikbaar bewijs aangaande de veiligheid en effectiviteit van de meeste niet-farmacologische methoden van inleiding die wel worden toegepast binnen de eerstelijns verloskunde om het gebruik ervan in de dagelijkse praktijk te kunnen aanbevelen.

- Een meerderheid van de verloskundigen is overtuigd van het nut van strippen als methode om de baring op gang te brengen tussen de 41 en 42 weken. Een grote meerderheid van de Nederlandse verloskundigen is bereid het beleid ten aanzien van strippen aan te passen aan de resultaten van betrouwbaar onderzoek, ongeacht de uitkomst.

- Strippen vanaf 41 weken zal het aantal serotiene zwangerschappen substantieel verminderen.

- De Bishop score voorafgaand aan strippen is een matige voorspeller van het spontaan op gang komen van de baring voor 42 weken. De klinische relevantie van deze voorspeller is daarom beperkt.

- Verloskundigen kunnen het geboortegewicht goed schatten met behulp van uitwendige gewichtschatting aan het einde van de a terme periode indien dit zich bevindt binnen de range van het normale geboortegewicht. Geboortegewicht onder de 3000 gram wordt echter overschat en geboortegewicht boven de 4000 gram wordt onderschat. Uitwendige gewichtschatting tegen het einde van de a terme periode is daarom geen geschikte diagnostische test voor het onderkennen van geboortegewichten onder en boven het normale geboortegewicht.

Chapter 11

Addendum

Stripstudie	**STRIPPENGROEP** **Vragenlijst behorende bij** **2e stripinterventie**	**CRF** **C**

Deze vragen gaan over de periode **<u>ná</u>** de 1e keer strippen **<u>tot</u>** de 2e keer strippen.

*Indien cliënte in partu is gekomen vóórdat de 2e stripinterventie gedaan kon worden dan doorgaan naar **CRF F** (de baring).*

Vragenlijst (aankruisen hetgeen van toepassing is)

- Heeft mw. bloedverlies gehad na het strippen? nee ☐ ja ☐ <u>Zo ja:</u>
- Was dit bloedverlies ter grootte van

  kwartje ☐ gulden ☐ grote vlek☐ lichte menstr ☐ zw. menstr ☐

  anders ☐ , n.l:----------

- Heeft cliënte krampen gehad na de 1e keer strippen? nee ☐ ja ☐ <u>Zo ja:</u>
- Waren deze te vergelijken met:

  lichte krampen ☐ menstr.achtige krampen ☐ zware krampen ☐

  anders ☐ , n.l.:----------
- Vond cliënte de krampen meer of minder storend? (Kies het best passende antwoord)

  niet storend ☐ licht storend ☐ storend ☐ zeer storend ☐
- Hoe lang heeft cliënte krampen gehad? < 1 uur ☐ 1-<3 uur ☐ 3–6 uur ☐ >6 uur ☐
- Heeft cliënte onbeschermde gemeenschap gehad de afgelopen 48 uur? ja☐ nee ☐
- Heeft cliënte nog andere hier niet nader genoemde sensaties en/of klachten ervaren naar aanleiding van het strippen? nee ☐ ja ☐ zo ja,wat……..……..
- Samenvattend heeft cliënte: geen ☐ weinig ☐ enigszins ☐ veel ☐ last gehad van bijwerkingen

In te vullen door verloskundige ☐☐ **of cliënte zelf** ☐☐ (initialen)

Stripstudie	**CONTROLEGROEP** **Vragenlijst 1**	**CRF** **E**

Deze vragen gaan over de periode **<u>ná</u>** de randomisatiecontrole **<u>tot</u>** ± 48 uur (twee dagen) daarna.

*Indien cliënte in partu is gekomen vóórdat dit formulier ingevuld kon worden dan doorgaan naar **CRF F** (de baring).*

Vragenlijst (aankruisen hetgeen van toepassing is)

- Heeft mw. bloedverlies gehad na de vorige controle? nee ☐ ja ☐ <u>Zo ja:</u>
- Was dit bloedverlies ter grootte van

  kwartje ☐ gulden ☐ grote vlek☐ lichte menstr ☐ zw. menstr ☐

  anders ☐ , n.l:----------

- Heeft cliënte krampen gehad na de vorige controle? nee ☐ ja ☐ <u>Zo ja:</u>
- Waren deze te vergelijken met:

  lichte krampen ☐ menstr.achtige krampen ☐ zware krampen ☐

  anders ☐ , n.l.:----------
- Vond cliënte de krampen meer of minder storend? (Kies het best passende antwoord)

  niet storend ☐ licht storend ☐ storend ☐ zeer storend ☐
- Hoe lang heeft cliënte krampen gehad? < 1 uur ☐ 1-<3 uur ☐ 3–6 uur ☐ >6 uur ☐
- Heeft cliënte onbeschermde gemeenschap gehad de afgelopen 48 uur? ja☐ nee ☐
- Heeft cliënte nog andere hier niet nader genoemde sensaties en/of klachten ervaren?

  nee ☐ ja ☐ zo ja,wat……..

In te vullen door verloskundige ☐☐ **of cliënte zelf** ☐☐

Stripstudie	**Satisfactie onderzoek nacontrole strippengroep** **Studienummer** ☐☐☐☐☐	**AMC Verloskunde / Medical Research**

Geboortedatum cliënte ☐☐ ☐☐ ☐☐☐☐

1e letters voornaam + meisjes achternaam ☐☐

datum enquête ☐☐ ☐☐ ☐☐☐☐

U bent inmiddels bevallen. We hopen dat alles goed is verlopen en dat wij u van harte kunnen feliciteren! Hartelijk dank voor uw medewerking aan het onderzoek tot nu toe.
Graag zouden wij u tot slot noch enkele vragen willen stellen. Wilt u het gekozen antwoord aankruisen?
Zoals u weet zijn er in Nederland tenminste drie vormen van verloskundig beleid in de periode tussen de 41 en 42 weken zwangerschap.

A. Tot 42 weken de normale controle bij de verloskundige en afwachten totdat de bevalling op gang komt.

B. Tot 42 weken de normale controle bij de verloskundige plus aanvullend echo- en/of CTG onderzoek (een hartregistratiefilmpje bij de baby) in het ziekenhuis waarbij afgewacht wordt totdat de bevalling op gang komt of totdat er een reden ontstaat, op basis van de uitkomsten van de echo- en/of CTG controle, om de bevalling op te wekken.

C. Tot 42 weken de normale controle bij de verloskundige met daarbij het “strippen”als methode om de bevalling op gang te brengen.

In het onderzoek vergelijken we aanpak A en C met elkaar. Het is mogelijk dat er bij u ook een echo en CTG is gemaakt maar we kijken primair naar de gevolgen van het strippen in vergelijking met niet-strippen, vandaar de indeling voor het onderzoek in twee groepen.

Vraag 1
U heeft te maken gehad met aanpak C. Klopt dat?

☐ ja

☐ nee Zo nee, met welke aanpak heeft u dan te maken gehad? Vraag nadere toelichting bij uw verloskundige. …….

Vraag 2
Is bestemd voor de controlegroep, hier niet van toepassing.

Vraag 3
Wat is uw mening ten aanzien van strippen? Strippen werkt:

☐ voor mijn gevoel wel

☐ voor mijn gevoel niet

☐ geen mening / moeilijk te zeggen

Vraag 4
Het strippen zelf vond ik:
□ A niet pijnlijk
□ B enigszins pijnlijk
□ C pijnlijk
□ D zeer pijnlijk
□ E zo pijnlijk dat de striphandeling gestaakt moest worden

Vraag 5
Het strippen is mogelijk gepaard gegaan met bijwerkingen.
Welke bijwerkingen heeft u ervaren? *Meerdere antwoorden zijn mogelijk.*
□ A bloedverlies
□ B harde buiken
□ C weeënactiviteit zonder bevalling als gevolg
□ D ik heb geen bijwerkingen gehad

Vraag 6
Als u een volgende zwangerschap zou mogen kiezen uit één van de onderstaande mogelijkheden, welke van de twee zou dan uw voorkeur hebben en welke mogelijkheid zou op de tweede plaats komen?
□ strippen *(indien u dit antwoord hebt gegeven ga dan door met vraag **7** en sla vraag **8** over)*
□ niet strippen *(indien u dit antwoord hebt gegeven sla dan vraag **7** over en ga door naar vraag **8**)*

Vraag 7
U heeft bij vraag 6 het antwoord strippen gegeven. Kunt u ook aangeven wat de ***belangrijkste*** reden is voor uw voorkeur om gestript te worden? *Wilt u slecht**s één** item aankruisen?*
□ A ik denk dat strippen de bevalling zal vervroegen
□ B ik wil graag onder begeleiding van de verloskundige bevallen
□ C ik wil het liefst zo natuurlijk mogelijk bevallen (zonder inleiding e.d.)
□ D dit is in mijn omgeving ook zo gegaan
□ E omdat: (u kunt een eigen reden invullen)……..
□ F ik wil graag thuis bevallen

Vraag 8
U heeft bij vraag 6 het antwoord "niet strippen" gegeven. Kunt u aangeven wat de ***belangrijkste*** reden is voor uw om niet gestript te willen worden?
*Wilt u slechts **één** item aankruisen?*
□ A ik wil de natuur haar gang laten gaan
□ B ik denk dat strippen de bevalling niet zal vervroegen
□ C ik heb teveel last gehad van bijwerkingen
□ D dit is in mijn omgeving ook zo gegaan
□ E omdat: (u kunt een eigen reden invullen)……..

Vraag 9
Als u nu gevraagd zou worden een advies te geven over één van de beleidsmogelijkheden, welke zou u dan adviseren?
□ A tot 42 weken controle bij de verloskundige
□ B tot 42 weken controle bij de verloskundige plus om de dag strippen

Eventuele toelichting:……..

Dit was het einde van de vragenlijst. Hartelijk dank voor uw medewerking!

Stripstudie	**Satisfactie onderzoek nacontrole controlegroep** **Studienummer** □□□□□	**AMC Verloskunde / Medical Research**

Geboortedatum cliënte □□ □□ □□□□

1e letters voornaam + meisjes achternaam □□

datum enquête □□ □□ □□□□

U bent inmiddels bevallen. We hopen dat alles goed is verlopen en dat wij u van harte kunnen feliciteren! Hartelijk dank voor uw medewerking aan het onderzoek tot nu toe.
Graag zouden wij u tot slot noch enkele vragen willen stellen. Wilt u het gekozen antwoord aankruisen?
Zoals u weet zijn er in Nederland tenminste drie vormen van verloskundig beleid in de periode tussen de 41 en 42 weken zwangerschap.

A. Tot 42 weken de normale controle bij de verloskundige en afwachten totdat de bevalling op gang komt.

B. Tot 42 weken de normale controle bij de verloskundige plus aanvullend echo- en/of CTG onderzoek (een hartregistratiefilmpje bij de baby) in het ziekenhuis waarbij afgewacht wordt totdat de bevalling op gang komt of totdat er een reden ontstaat, op basis van de uitkomsten van de echo- en/of CTG controle, om de bevalling op te wekken.

C. Tot 42 weken de normale controle bij de verloskundige met daarbij het "strippen"als methode om de bevalling op gang te brengen.

In het onderzoek vergelijken we aanpak A en C met elkaar. Het is mogelijk dat er bij u ook een echo en CTG is gemaakt maar we kijken primair naar de gevolgen van het strippen in vergelijking met niet-strippen, vandaar de indeling voor het onderzoek in twee groepen.

Vraag 1
U heeft te maken gehad met aanpak A. Klopt dat?

□ ja
□ nee Zo nee, met welke aanpak heeft u dan te maken gehad? Vraag nadere toelichting bij uw verloskundige. …….

Vraag 2
Hoe heeft u de controles tot 42 weken bij de verloskundige ervaren?

□ A zonder problemen
□ B het afwachten vond ik moeilijk
□ C ik had achteraf graag in de strippengroep willen zitten

Vraag 3
Is bestemd voor de strippengroep, hier niet van toepassing.

Vraag 4
Is bestemd voor de strippengroep, hier niet van toepassing.

Vraag 5
Is bestemd voor de strippengroep, hier niet van toepassing.

Vraag 6
Als u een volgende zwangerschap zou mogen kiezen uit één van de onderstaande mogelijkheden, welke van de twee zou dan uw voorkeur hebben en welke mogelijkheid zou op de tweede plaats komen?

□ strippen *(indien u dit antwoord hebt gegeven ga dan door met vraag **7** en sla vraag **8** over)*
□ niet strippen *(indien u dit antwoord hebt gegeven sla dan vraag **7** over en ga door naar vraag **8**)*

Vraag 7
U heeft bij vraag 6 het antwoord strippen gegeven. Kunt u ook aangeven wat de ***belangrijkste*** reden is voor uw voorkeur om gestript te worden? *Wilt u slechts **één** item aankruisen?*

□ A ik denk dat strippen de bevalling zal vervroegen
□ B ik wil graag onder begeleiding van de verloskundige bevallen
□ C ik wil het liefst zo natuurlijk mogelijk bevallen (zonder inleiding e.d.)
□ D dit is in mijn omgeving ook zo gegaan
□ E omdat: (u kunt een eigen reden invullen)……..
□ F ik wil graag thuis bevallen

Vraag 8
U heeft bij vraag 6 het antwoord "niet strippen" gegeven. Kunt u aangeven wat voor u de ***belangrijkste*** reden is om niet gestript te willen worden?
*Wilt u slechts **één** item aankruisen?*

□ A ik wil de natuur haar gang laten gaan
□ B ik denk dat strippen de bevalling niet zal vervroegen
□ C ik heb teveel last gehad van bijwerkingen
□ D dit is in mijn omgeving ook zo gegaan
□ E omdat: (u kunt een eigen reden invullen)……..

Vraag 9
Als u nu gevraagd zou worden een advies te geven over één van de beleidsmogelijkheden, welke zou u dan adviseren?

□ A tot 42 weken controle bij de verloskundige
□ B tot 42 weken controle bij de verloskundige plus om de dag strippen

Eventuele toelichting:……..

Dit was het einde van de vragenlijst. Hartelijk dank voor uw medewerking!

Stripstudie	**Satisfactie onderzoek nacontrole controlegroep *mét stripinterventie!*** **Studienummer** □□□□□	**AMC Verloskunde / Medical Research**

Geboortedatum cliënte □□ □□ □□□□

1e letters voornaam + meisjes achternaam □□

datum enquête □□ □□ □□□□

U bent inmiddels bevallen. We hopen dat alles goed is verlopen en dat wij u van harte kunnen feliciteren! Hartelijk dank voor uw medewerking aan het onderzoek tot nu toe.
Graag zouden wij u tot slot noch enkele vragen willen stellen. Wilt u het gekozen antwoord aankruisen?
Zoals u weet zijn er in Nederland tenminste drie vormen van verloskundig beleid in de periode tussen de 41 en 42 weken zwangerschap.

A. Tot 42 weken de normale controle bij de verloskundige en afwachten totdat de bevalling op gang komt.

B. Tot 42 weken de normale controle bij de verloskundige plus aanvullend echo- en/of CTG onderzoek (een hartregistratiefilmpje bij de baby) in het ziekenhuis waarbij afgewacht wordt totdat de bevalling op gang komt of totdat er een reden ontstaat, op basis van de uitkomsten van de echo- en/of CTG controle, om de bevalling op te wekken.

C. Tot 42 weken de normale controle bij de verloskundige met daarbij het “strippen”als methode om de bevalling op gang te brengen.

In het onderzoek vergelijken we aanpak A en C met elkaar. Het is mogelijk dat er bij u ook een echo en CTG is gemaakt maar we kijken primair naar de gevolgen van het strippen in vergelijking met niet-strippen, vandaar de indeling voor het onderzoek in twee groepen.

Vraag 1
U heeft in eerste instantie te maken gehad met aanpak A. Klopt dat?

□ ja
□ nee Zo nee, met welke aanpak heeft u dan te maken gehad? Vraag nadere toelichting bij uw verloskundige. …….

Vraag 2
Bent u ondanks dat u in de controlegroep zat toch gestript?

□ ja zo ja, ga door met de rest van deze vragenlijst
□ nee zo nee, vul dan de satisfactie vragenlijst in op de een na laatste bladzijde van uw dossier

Vraag 3
U bent gestript. Door wie bent u gestript?
□ verloskundige uit de praktijk waarbij ik onder controle was
□ gynaecoloog of assistent-gynaecoloog
□ anders, n.l:……..……..

Vraag 4
Waarom bent u gestript?
□ mijn eigen verzoek
□ medisch - verloskundige reden, n.l.:…….
□ anders, n.l:…….
□ weet ik niet

Vraag 5
Wat is uw mening ten aanzien van strippen? Strippen werkt:
□ voor mijn gevoel wel
□ voor mijn gevoel niet
□ geen mening / moeilijk te zeggen

Vraag 6
Het strippen zelf vond ik:
□ A niet pijnlijk
□ B enigszins pijnlijk
□ C pijnlijk
□ D zeer pijnlijk
□ E zo pijnlijk dat de striphandeling gestaakt moest worden

Vraag 7
Het strippen is mogelijk gepaard gegaan met bijwerkingen.
Welke bijwerkingen heeft u ervaren? *Meerdere antwoorden zijn mogelijk.*
□ A bloedverlies
□ B harde buiken
□ C weeënactiviteit zonder bevalling als gevolg
□ D ik heb geen bijwerkingen gehad

Vraag 8
Als u een volgende zwangerschap zou mogen kiezen uit één van de onderstaande mogelijkheden, welke van de twee zou dan uw voorkeur hebben en welke mogelijkheid zou op de tweede plaats komen?
□ strippen *(indien u dit antwoord hebt gegeven ga dan door met vraag **9** en sla vraag **10** over)*
□ niet strippen *(indien u dit antwoord hebt gegeven sla dan vraag **9** over en ga door naar vraag **10**)*

Vraag 9
U heeft bij vraag 8 het antwoord strippen gegeven. Kunt u ook aangeven wat de ***belangrijkste*** reden is voor uw voorkeur om gestript te worden? *Wilt u slecht**s één** item aankruisen?*

□ A ik denk dat strippen de bevalling zal vervroegen
□ B ik wil graag onder begeleiding van de verloskundige bevallen
□ C ik wil het liefst zo natuurlijk mogelijk bevallen (zonder inleiding e.d.)
□ D dit is in mijn omgeving ook zo gegaan
□ E omdat: (u kunt een eigen reden invullen)……..
□ F ik wil graag thuis bevallen

Vraag 10
U heeft bij vraag 8 het antwoord “niet strippen” gegeven. Kunt u aangeven wat de ***belangrijkste*** reden is voor uw om niet gestript te willen worden?
*Wilt u slechts **één** item aankruisen?*

□ A ik wil de natuur haar gang laten gaan
□ B ik denk dat strippen de bevalling niet zal vervroegen
□ C ik heb teveel last gehad van bijwerkingen
□ D dit is in mijn omgeving ook zo gegaan
□ E omdat: (u kunt een eigen reden invullen)……..

Vraag 11
Als u nu gevraagd zou worden een advies te geven over één van de beleidsmogelijkheden, welke zou u dan adviseren?

□ A tot 42 weken controle bij de verloskundige
□ B tot 42 weken controle bij de verloskundige plus om de dag strippen

Eventuele toelichting:……..

Dit was het einde van de vragenlijst. Hartelijk dank voor uw medewerking!

Korte anonieme enquête naar uw mening ten aanzien van "STRIPPEN"

Wat is uw mening over het strippen van de vliezen als methode om de baring op gang te brengen bij een zwangerschapsduur tussen de 41 en 42 weken?

S.V.P. aankruisen wat voor u van toepassing is.

1. **Ik ben:**
   O zeer overtuigd van het nut van strippen
   O redelijk overtuigd van het nut van strippen
   O neutraal ten aanzien van het nut van strippen
   O niet geheel overtuigd van het nut van strippen
   O absolute tegenstander van strippen

2. **Bijwerkingen van strippen zie of zag ik:**
   O altijd
   O vaak
   O soms
   O niet vaak
   O nooit
   O niet van toepassing omdat: .....

3. **De bijwerkingen van strippen zijn naar mijn mening:**
   O minder zwaar dan de voordelen van strippen
   O even zwaar als de voordelen van strippen
   O zwaarder dan de voordelen van strippen

4. **De belangrijkste bijwerking(en) vind ik:**

5. **Mijn mening ten aanzien van strippen heb ik gebaseerd op:**
   meerdere antwoorden mogelijk
   O hetgeen ik in theorie geleerd heb op de opleiding
   O hetgeen ik in de stages geleerd heb tijdens de opleiding
   O mijn eigen praktijkervaring
   O de ervaring van collegae
   O publicaties in het Tijdschrift voor Verloskundigen
   O anders, n.l.: .....

6. **Mijn *beleid* ten aanzien van strippen heb ik gebaseerd op:**
   meerdere antwoorden mogelijk
   O hetgeen ik op de opleiding geleerd heb
   O mijn eigen mening
   O ervaring van collegae
   O praktijkafspraken
   O afstemming met de tweedelijn
   O anders, n.l.: .....
   O niet van toepassing omdat ik niet praktiseer (*bij dit antwoord kunt u de vragen 9 en 10 overslaan)*

7. **Ik vind strippen effectief bij primi's**
   O altijd
   O vaak
   O soms
   O niet vaak
   O nooit

8. Ik vind strippen effectief bij multi's
O altijd
O vaak
O soms
O niet vaak
O nooit

9. Ik pas strippen tussen de 41 en 42 weken als volgt toe in de situaties die ik hieronder beschrijf.
U kunt invullen wat voor u van toepassing is.

..... **O** altijd
..... **O** vaak
..... **O** soms
..... **O** niet vaak
..... **O** nooit

10. Bent u bereid uw beleid aan te passen aan de uitkomst van wetenschappelijk onderzoek naar het effect van strippen?
O ja
O nee
O ja, tenzij
O nee, tenzij

11. Hoe voert u de striphandeling uit?
U kunt dat hieronder in het kort beschrijven.

12. Waar bent u opgeleid?
O Amsterdam
O Heerlen / Kerkrade
O Rotterdam
O Buitenland, n.l.:

13. Hoe lang bent u werkzaam als verloskundige?
O 0 – 5 jaar
O 6 – 10 jaar
O 11 – 15 jaar
O 16 – 20 jaar
O > 20 jaar

14. Waar bent u werkzaam?
O solopraktijk
O groepspraktijk
O gezondheidscentrum
O tweede- of derdelijn
O waarneming
O staffunctie (b.v. opleiding verloskundigen0
O anders, n.l.:

Lijst van deelnemende praktijken aan de Stripstudie

Verloskundige praktijk Dijkstraat te Aalten
Verloskundige praktijk Rembrandtlaan te Almelo
Verloskundige praktijk Laan van de Helende Meesters te Amstelveen
Verloskundige praktijk Millingenhof te Amsterdam
Het Geboortecentrum Genestetstraat te Amsterdam
Verloskundige praktijk Slotervaartziekenhuis Louwesweg te Amsterdam
Verloskundige praktijk "Doevendans" Arnhemseweg te Apeldoorn
Groepspraktijk van Verloskundigen v. Lawick v. Pabstraat te Arnhem
Samenwerkende verloskundigen Melanendreef te Bergen op Zoom
Verloskundige praktijk Zomergemstraat te Breda
Verloskundigen praktijk Generaal de la Reijlaan Bussum
Verloskundigen praktijk Buitenwatersloot te Delft
Verloskundigenpraktijk, Zagwijnpad te Delft
Verloskundige praktijk "Tuya" te Den Haag
Verloskundige praktijk Salomonszegel te Deventer
Verloskundige praktijk Van Oldenielstraat te Deventer
Verloskundigenpraktijk "Juffrouw Kroost" te Doetinchem
Verloskundige Praktijk 't Stroomdal Burgemeester J.G. Legroweg te Eelde
Verloskundige praktijk "Gestel-Strijp" te Eindhoven
Verloskundige praktijk 't Klaverblad te Elburg
Verloskundige praktijk "'t Hartje van Elst" te Elst
Verloskundige praktijk Bisschopsmolenstraat te Etten-Leur
Vroedvrouwen praktijk Peperstraat te Gouda
Verloskundige praktijk Kleverpark te Haarlem
Verloskundige praktijk Tesselschadeplein te Haarlem
Verloskundige praktijk Hogeweg te Harderwijk
Maatschap verloskundigen de Vuurdoorn te Hoogerheide
Verloskundige praktijk "De Wijzend" Streekweg te Hoogkarspel
Vroedvrouwenpraktijk "Zuiderzee" Oostkade te Huizen
Verloskundige praktijk "De Kern" Kernstraat te Leiden
Verloskundige praktijk Bruine Akkers te Maarheze
Verloskundige praktijk Rijstegoed te Nijkerk
Verloskundige praktijk Nijverdal Oranjestraat te Nijverdal

Verloskundige praktijk Beethovenlaan te Nunspeet
Verloskundige praktijk Kempenaerstraat te Oegstgeest
Verloskundige praktijk “Artemis” Jan Gielenplein te Oudenbosch
Verloskundige praktijk Lindelaan te Roermond
Verloskundigen praktijk “Ma Lune” Kanaalstraat te Roden
Verloskundige maatschap West Rochussenstraat te Rotterdam
Verloskundige praktijk Pasmanhaard te Ruurlo
Maatschapspraktijk voor verloskunde Kade te Steenbergen
Verloskundige praktijk Havezatestraat te Tubbergen
Verloskundige praktijk Parkelerweg te Twello
Verloskundige praktijk, Westerkade te Utrecht
Vroedvrouwenpraktijk Aletta Jacobsstraat te Velserbroek
Verloskundige praktijk Grotestraat te Wehl
Verloskundige praktijk “Wierden/Vriezenveen” Dorsvloer te Wierden
Verloskundige praktijk Wilhelminastraat te Winterswijk
Verloskundige praktijk Witte Vlinderweg te Wormerveer
Verloskundig centrum “Mopti” Dunantstraat te Zoetermeer
Verloskundige praktijk Willemskade te Zwolle

Authors and affiliations

From the Department of Obstetrics, Academic Medical Center, Amsterdam:
Otto P. Bleker, Martine Eskes, Esteriek de Miranda

From the Department of Social Medicine – Public Health Epidemiology, Academic Medical Center, Amsterdam:
E. Birnie, Gouke J. Bonsel

From the Department of Clinical Epidemiology, Leiden University Medical Center, Leiden:
Anske G. van der Bom, Frits R. Rosendaal

List of publications

de Miranda E. Een vroedvrouwelijke benadering van onderzoek. *Tijdschr Verlosk* 1992; 7(8):299-31.

de Miranda E. De vroedvrouw; een schakel in de vrouwengezondheidszorg. *Tijdschr Verlosk* 1992;12:496-99.

de Miranda E. Moet de huisarts de thuisbevalling redden ? Onderzoek onder de loep. *Tijdschr Verlosk* 1996;3:13-16.

de Miranda E. De Huidekoper Onderzoeksprijs (De WOS-prijs). *Tijdschr Verlosk* 1996;4:43.

de Miranda E. Eerstelijns onderzoek in de praktijk. *Tijdschr Verlosk* 1999;12:840-1.

de Miranda E. Serotiniteit. In : Kleiverda G, Vervest H, editors. *Voorlichting over voorlichting. Een gids voor zorgverleners in de verloskunde en gynaecologie.* Utrecht: van der Wees uitgeverij, 2000:347-51.

Buitendijk SE, de Miranda E. Gerandomiseerde trials. Methoden van wetenschappelijk onderzoek II. *Tijdschr Verlosk* 2001;1:29-37.

Storm M, de Miranda E. Risicoselectie door echo- en CTG-onderzoek? *Tijdschr Verlosk* 2001;6:521-3.

de Miranda E. Evidence-based medicine. *Tijdschr Verlosk* 2001;6:536-7.

Buitendijk SE, de Miranda E. Confounding. Methoden van wetenschappelijk onderzoek IV. *Tijdschr Verlosk* 2001;7(8): 597-601.

de Miranda E. Niet medicamenteus inleiden in de eerste lijn: van amniotomie tot wonderolie. In: Scherjon SA, Beekhuizen W, Kanhai HH, editors. *Beëindiging van de zwangerschap: abortus, inductie en bijstimulatie.* Leiden: Boerhaave Commissie, 2003: 179-201.

de Miranda E, van der Bom JG, Bonsel GJ, Bleker OP, Rosendaal FR. Membrane sweeping and prevention of post-term pregnancy in low risk pregnancies: a randomised controlled trial. *BJOG* 2006; 402-8.

Stichting Perinatale Registratie Nederland. *Perinatale zorg in Nederland 2003*. van Huis AM, de Miranda E, Bruinse HW, Tamminga P, Brouwers HA, Ravelli AC, Bonsel GJ, Eskes M, editors. Bilthoven: Stichting Perinatale Registratie Nederland, 2006.

de Miranda E, Bonsel GJ, Eskes M, Birnie E, Bleker OP. A survey of membrane sweeping in low – risk pregnancies between 41 and 42 weeks of gestation to prevent post-term pregnancy. *Midwifery:* accepted

de Miranda E, van der Bom JG, Bonsel GJ, Bleker OP, Rosendaal FR. Cervical score and prediction of successful sweeping. S*ubmitted*

de Miranda E, Rosendaal FR, Bonsel GJ, Bleker OP. The accuracy of clinical estimation of fetal weight beyond term in low risk pregnancies. *Submitted*

Heel veel dank aan:

Iedereen die op een of andere wijze heeft bijgedragen aan het onderzoek en de totstandkoming van dit proefschrift, in het bijzonder:

Alle zwangeren die hebben geparticipeerd in de Stripstudie.

Alle verloskundigen die zich hebben ingezet, vaak onder hoge werkdruk, voor het laten slagen van de Stripstudie. Dankzij jullie motivatie om te willen bijdragen aan "evidence based midwifery" kon de inclusie van zwangeren uiteindelijk voltooid worden.

De leden van de begeleidingscommissie in het AMC: Prof. dr. Otto Bleker, dr. Martine Eskes en Prof. dr. Gouke Bonsel.
Otto, voor het faciliteren van dit onderzoek. Je bent een groot voorstander van academisering van de opleiding van Verloskundigen, de mogelijkheid om te kunnen promoveren hoort daar in jouw optiek nadrukkelijk bij. Dank dat je mij die kans hebt willen geven. Het is een eer je laatste promovenda te mogen zijn.
Martine, bescheiden betrouwbare rots in de branding, dank voor je grote betrokkenheid.
Otto en Gouke ook veel dank voor jullie snelle en waardevolle reacties tijdens het schrijfproces.
Erwin Birnie voor de begeleiding tijdens de analysefase van het enquête onderzoek onder praktiserende verloskundigen.
Ria van der Bij, zonder jouw enorme inzet voor het onderzoek en administratieve support was het nooit gelukt.

José van Teylingen, studiemaatje en voor anderhalf jaar collega bij dit onderzoek, voor het mede organiseren van de Stripstudie logistiek en de invoer van de enquête gegevens van de verloskundigen.

Stafleden en medewerkers van de afdeling Klinische Epidemiologie van het LUMC voor twee jaar gastvrijheid, scholing en collegialiteit.

Prof. dr. Frits Rosendaal voor de begeleiding gedurende de data-analyse fase waarvoor ik op de “Epi” terecht kon als gastmedewerker, voor de geboden mogelijkheid het promovendi onderwijs van de afdeling Klinische Epidemiologie te volgen, voor het onderricht in het schrijven van SPSS syntax en voor de altijd snelle reacties op conceptartikelen.
Ingeborg de Jonge voor het opzetten en beheer van de Stripstudie database en de begeleiding bij het leren werken met de database.
Suzanne Cannegieter en Anske van der Bom, mijn kamergenoten op de Epi, voor het beantwoorden van vele vragen op epidemiologisch gebied. Anske, ook veel dank voor je consciëntieuze begeleiding tijdens de analysefase van de Stripstudie.
Yvonne Souverein, spil van de Epi, dank voor alle regeldingen.

Mijn ouders, (schoon-)familie, vrienden en collegae voor alle belangstelling en steun.

Humph, voor alle begrip en geduld met “een promoverende vrouw in huis”. Als ervaringsdeskundige wist jij als geen ander wat me te wachten stond. Om begeleidingsverwarring te voorkomen heb je geen inhoudelijke bemoeienis willen hebben met dit project maar je hebt op vele andere manieren voor me klaar gestaan. Je vaste overtuiging dat ik in staat was om deze klus te klaren was voor mij een belangrijke steun in de rug. Heel veel dank voor alles!

Julian, lieve grote zoon, jij gaat écht nooit promoveren vertelde je me onlangs. Maar er is nu toch écht tijd voor alle leuke plannen die we hebben want het is KLAAR!!!

Curriculum Vitae

1958	Geboren op 13 september te Amsterdam
Scholing	
1977	Eindexamen aan “Het Waterlant College” te Amsterdam-Noord
1977 - 1978	Uitgeloot voor drie studies: 1 jaar avondopleiding M.O. Geschiedenis
1984	Afgestudeerd aan de Lerarenopleiding “d’Witte Leli” van de Stichting Nutsseminarium aan de Universiteit van Amsterdam in de vakken Geschiedenis en Nederlands.
1988	Afgestudeerd aan de Kweekschool voor Vroedvrouwen te Amsterdam
1991-2005	Scholing in klinische epidemiologie en biostatistiek (Erasmus Universiteit PAOG klinische epidemiologie, AMC Science Education, EMGO Instituut postinitieel masteronderwijs epidemiologie, LUMC promovendi onderwijs afd. Klinische Epidemiologie)
Werk	
1984 – 1985	Lerares Geschiedenis en Nederlands aan de Rijksscholengemeenschap te Purmerend.
1988 - 1989	Waarneming verloskundige praktijken
1989	Waarneming stafverloskundige kraam-zwangeren afdeling Slotervaart Ziekenhuis/Kweekschool voor Vroedvrouwen te Amsterdam
1989 - 1991	Klinisch verloskundige verloskamerafdeling Academisch Ziekenhuis Leiden (nu LUMC)
1991 - 1994	Verloskundige opleidingspraktijk Kweekschool voor Vroedvrouwen te Amsterdam.
1994 - 1999	Staflid theoretische opleiding/coördinator afstudeeropdracht Kweekschool voor Vroedvrouwen te Amsterdam
1999 - 2005	Onderzoeker AMC Medical Research BV
2001 - 2005	Waarnemingen verloskundige praktijk Oegstgeest
2003 - 2005	Gastmedewerker afdeling Klinische Epidemiologie LUMC
2006 - heden	Klinisch verloskundige/echoscopiste Bronovo Ziekenhuis te Den Haag
Nevenfuncties	
1989 – 1994	Redactielid Tijdschrift voor Verloskundigen
1991 – 1997	Bestuurslid Werkgroep Psychosomatische Obstetrie en Gynaecologie van de Nederlandse Vereniging voor Obstetrie en Gynaecologie
1993 – 1997	Mede oprichter-bestuurslid Stichting Astrid Limburg Prijs (bevordering gedachtegoed fysiologische verloskunde)
1994 – 2000	Voorzitter Werkgroep Onderzoek & Scholing van de Koninklijke Nederlandse Organisatie van Verloskundigen (KNOV)
1996 – 2003	Lid commissie nascholing KNOV

1998 – 2002	Lid Kleine Advies Commissie Project Verloskunde ministerie VWS t.b.v. doelmatigheidsbevordering verloskunde en stimulering thuisbevalling
2001 – 2002	Lid Regiegroep Vervolgopleiding Verloskundigen namens de KNOV
2002 – 2006	Lid Wetenschappelijke Commissie Stichting Perinatale Registratie Nederland namens de KNOV
2005 - heden	Lid Raad van Advies Master of Science Verloskunde AMC
2005 – heden	Voorzitter Accreditatiecommissie KNOV
2007 – heden	Voorzitter Deelnemersraad Stichting Perinatale Registratie Nederland namens de KNOV

Esteriek is getrouwd met Humphrey Kanhai, samen kregen zij dochter Merel (1996 ✈) en zoon Julian (1997).