Lactational amenorrhea for family planning (Review)

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[Intervention Review]

Lactational amenorrhea for family planning

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ABSTRACT

Background

Fifty percent of pregnancies are unwanted. For several reasons, eg difficulty in obtaining contraceptives, no or ineffective contraception is used to prevent these pregnancies. The lactational amenorrhea method (LAM) is a contraceptive method where the mother is informed and supported how to use breastfeeding, also for contraception. LAM is available and accessible to many women.

Objectives

To assess the effectiveness of LAM as a contraceptive method in fully breastfeeding women, who remain amenorrheic. We compared the effectiveness of LAM, as defined in the 1988 Bellagio Consensus statement, with alternative definitions of LAM using pregnancy and menstruation life tables.

Search strategy

MEDLINE 1966 to 2008; EMBASE 1988 to 2008; reference lists of studies; review articles; books related to LAM; published abstracts from breastfeeding, reproductive health conferences; e-mails with study coordinators.

Selection criteria

Out of 459 potentially relevant studies, 159 investigated the risk of pregnancy during LAM or lactational amenorrhea. Inclusion criteria: prospective study, cases (intervention group) and, if available, controls, had to be sexually active; pregnancy had to be confirmed by physical examination or a pregnancy test. Our endpoints were life table menstruation rates and life table pregnancy rates. We included 14 studies reporting on 10 intervention groups and two control groups that met the inclusion criteria. We identified one additional study in the 2007 update.

Data collection and analysis

Two reviewers independently extracted data; disagreements were resolved through discussion. We analyzed the studies using narrative methods because of their heterogeneity.

Main results

For the primary outcome, two controlled studies of LAM users reported life table pregnancy rates at 6 months of 0.45 and 2.45 percent and six uncontrolled studies of LAM users reported 0-7.5 percent. Life table pregnancy rates for fully breastfeeding women who were amenorrheic but not using any contraceptive method were 0.88 percent in one study and 0.9 to 1.2 percent (95% confidence interval 0.0 to 2.4) in a second study, depending on the definition of menstruation used. The life table menstruation rate at 6 months in all studies varied between 11.1 and 39.4 percent.

Authors' conclusions

We found no clear differences in life table pregnancy rates between women using LAM and being supported in doing so, and fully breastfeeding amenorrheic women not using any method. Because the length of lactation amenorrhea in women using LAM was very different between the populations studied, and is population specific, it is uncertain whether the LAM extends lactational amenorrhea.

PLAIN LANGUAGE SUMMARY

Fully breastfeeding and contraception

In appreciating the role of the lactational amenorrhea method (LAM, a contraceptive method where the mother is informed and supported how to use breastfeeding, also for contraception.) in child spacing, breastfeeding itself should be encouraged from a public health point of view. Breastfeeding while not giving supplementary feeds delays the return of fertility and menstruation, which is a physiological protection against pregnancy. It is not clear if practicing LAM as a contraceptive method itself decreases the risk of pregnancy compared with fully breastfeeding while remaining amenorrheic (no menstrual periods) in the first 6 months after childbirth.

BACKGROUND

Description of the condition:

It is estimated that among the annual 150 million pregnancies in the world, 50% are unplanned and generally not wanted, and that most of these occur in developing countries (UNFPA 1996). For several reasons, including difficulties in obtaining contraceptives, no or ineffective contraception is used to prevent these unplanned pregnancies.

Description of the intervention:

The LAM, defined during the 1988 Bellagio Consensus Conference in Italy, is a contraceptive method available and accessible to many women (Family Health 1988; Kennedy 1989). LAM was defined as the informed use of breastfeeding as a contraceptive method by a woman who is still amenorrheic and who does not feed her baby with supplements for up to 6 months after delivery. This would provide more than 98% protection from pregnancy in the first 6 months postpartum according to advocates of this method (Family Health 1988; Kennedy 1989; Kennedy 1992; Labbok 1994). In 1995, during a second conference in Bellagio, it was suggested that women choosing and using the LAM had a life table pregnancy rate at 6 months of less than 2%. This was not based on a systematic review. It was also suggested that "in the studies that included the promotion of appropriate breastfeeding practices, the percentages of women still amenorrheic and still fully breastfeeding at six months postpartum were higher than in control groups not receiving such support" (Kennedy 1996; Van Look 1996). LAM is a 'transitional' form of contraception and is most effective in women planning to breastfeed exclusively during the first 6 months (Labbok 1997).

Many women, however, choose not to use this method owing to concerns about its efficacy (Lopez-Martinez 2006) and uptake is low in many countries (Khella 2004). Where LAM is implemented, the information provided to women includes: the physiological mechanism of lactation and its control of reproductive function; the efficacy of LAM as a means of contraception; and the benefits and disadvantages of LAM as a contraceptive method (Lopez-Martinez 2006; Romero-Gutierrez 2007). Several studies, including Romero-Gutierrez 2007, have followed up women claiming to use LAM, which showed that few of the women who were interested actually implemented the method.

How the intervention might work:

The mechanism by which LAM may work is not clear.

Why it is important to do this review:

Many studies on LAM do not include a control group and thus the quality of those studies differs; it is therefore difficult to support the suggestions of the World Health Organization Task Force on Methods for the Regulation of Fertility (WHO 1999b) and those of Labbok (Labbok 1997). If LAM is effective as a contraceptive in the postpartum period there may be implications in offering this method for use in developing countries, in particular where access to or the acceptability of other forms of contraception may be limited. In countries where there is no such limitation, LAM should be studied only if advocating it is not hampering the introduction of longer term methods of contraception.

OBJECTIVES

The objective of this systematic review is to determine the efficacy and safety of LAM as a contraceptive method for lactating women during the 0 to 6 months postpartum period, and to determine all the conditions under which LAM should be used (Stroup 2000). We compared the incidence of menstruation and pregnancy in LAM users to that of recently delivered, fully breastfeeding women who did not use LAM.

METHODS

Criteria for considering studies for this review

Types of studies

It is unlikely that all women remember exactly when they stopped breastfeeding, started giving supplementary feeds to their infant, had their first period after childbirth and resumed sexual activity. We therefore included not only prospective studies, but both controlled and uncontrolled studies (Quandt 1997; Vitzhum 1994).

Types of participants

Sexually active, healthy, fertile women who had recently given birth and practiced the LAM as their only contraceptive method. If women are not sexually active while practicing a family planning method, no pregnancy can occur. We therefore noted if it was mentioned in the included studies if the participants and, if available, the controls were sexually active (including frequency) during the study period (Caldwell 1977; Feyiesetan 1990; Urdry 1993; van de Walle 1993; Visness 1997).

Types of interventions

Women using LAM compared with controls who gave birth recently and used breast-feeding.

Types of outcome measures

Primary outcome measures

Pregnancy and 'menstruation' (after being amenorrheic) were primary outcome measures. The studies had to present the number of women per specific month who experienced 'menstruation' or who became pregnant. Pregnancy had to be confirmed by physical examination or by a pregnancy test.

We considered several definitions of being amenorrheic. The original definition used in the Bellagio Consensus Statement ignores any bleeding before the 56th day postpartum (Family Health 1988). However, in 1995, menstruation was defined in Bellagio as the occurrence, after the 56th day postpartum, of "2 consecutive days of bleeding/spotting, or the women's perception that her menses have returned, whichever of the two comes first" (Kennedy 1996). Labbok used definitions of two continuous days of vaginal bleeding that the woman considered similar to a menstrual period or heavier, or two continuous days of spotting and one day of bleeding, or three continuous days of spotting (Labbok 1997). The World Health Organization (WHO) even used four different definitions to mark the end of amenorrhea (WHO 1999a).

In this systematic review we used three different definitions:

I. The original definition of lactational amenorrhea in fully lactating women, 'ignoring any bleeding before the 56th day postpartum' was used as standard.

II. Any bleeding (including bleeding within 56 days postpartum but separated from the postpartum bleeding by 10 to 14 days or more).

III. The woman's perception that her menses have returned.

Search methods for identification of studies

Electronic searches

We searched the Cochrane Library, issue 4 2007, MEDLINE from 1966 tol 2008 and EMBASE from 1988 until 2008 using the MeSH (or similar) terms

1. LAM/
2. lactation and amenorrhea/
3. breastfeeding and fertility/
4. lactation/
5. family planning and amenorrhea/
6. 1or 2 or 3 or 4 or 5

Searching other sources

In addition, we considered studies which were identified from reference lists and review articles, books related to LAM and abstracts of conferences. Furthermore, we contacted by e-mail coordinators of such studies and made enquiries with contraception orientated

organizations such as the WHO and the Family Health Planning and Population Council. We applied no language restrictions.

Data collection and analysis

Data collection and analysis

Selection of studies

We updated this review in 2008.

Two reviewers independently (CW and Frans Helmerhorst in the original review and CW and JB in the most recent update) selected the studies according to the preset inclusion criteria. They resolved disagreements through discussion. When we identified multiple reports of a study we used only the original results.

Data extraction and management

One reviewer performed data extraction and the second reviewer checked and recorded the data.

Assessment of risk of bias in included studies

To assess the risk of bias in individual studies we used a modification of a previously published checklist from the National Health Service Centre for Reviews and Dissemination (NHS Centre 2001). Items included were: Did the women enroll at a similar entry point? Were the groups comparable on all important confounding factors? Was follow up long enough for the outcomes to occur? Was the drop-out rate less than 10%? Were the outcomes used clear? Were the presented data clear? We considered age, parity and length of previous lactational amenorrhea or breastfeeding as confounders. The period of lactational amenorrhea tends to be longer for older multiparous women than for younger primiparous women (WHO 1998b). Moreover, older age itself has an influence on fertility and the consecutive lactational amenorrheic period of these women tends to be longer (Jain 1969). Regarding loss to follow up, we used a cut-off point of 10% in scoring this criterion. Loss to follow up occurs for various reasons, such as the mother stopping breastfeeding because of the child's death, being dissatisfied with LAM, choosing another family planning method, wishing to become pregnant,becoming pregnant, or moving to a place outside the study area.

Unit of analysis issues

There are no unit of analysis issues in this review; all reports presented data per woman.

Dealing with missing data

Where there were insufficient or missing data the studys lead author was contacted. If no response was forthcoming we included the study but did not describe the data in the text of the review.

Assessment of heterogeneity

After inclusion, two reviewers, using their subjective judgment, assessed heterogeneity of the studies, taking into account study design, and comparability of populations, interventions and controls, outcomes, and reported effects. For studies that we considered sufficiently homogeneous, we planned to perform statistical pooling using life table methods; this was not possible and we thus presented a narrative synthesis.

All intervention groups presented in 13 of the studies were different from each other. At least 26 different populations were used: various cultures and nationalities and both urban and rural locations in the same country. Knowing that fertility and the recurrence of menstruation after childbirth are population specific, we found that the populations themselves were not comparable. These differences indicated to us that statistical pooling would not be appropriate and we have instead presented narrative results.

Assessment of reporting biases

We retrieved studies from as many sources as possible. There were not sufficient to construct a funnel plot to assess reporting biases.

Data synthesis

Owing to heterogeneity among the included studies, we were unable to perform a meta-analysis and therefore describe the results in narrative form. We used a single, not multiple, decrement life table technique to present the data (Trussell 1991a). Multiple decrement life tables measure survival (or failure) of individuals or groups over time. This technique is frequently used in contraceptive research to measure the probability of pregnancy or method continuation. In this context, it measures multiple reasons for discontinuation, including pregnancy, hormonal side effects etc. Single decrement life tables are calculated in the same way as multiple, but at the time of discontinuation they censor individuals who stop using a method for reasons other than the one being measured, and are therefore recommended as the most appropriate method to measure contraceptive outcomes (Trussell 1991a). The life tables presented the number of women per specific month who had a 'menstruation' or who became pregnant.

Subgroup analysis and investigation of heterogeneity

We do not present any subgroup analysis in this review.

Sensitivity analysis

We do not present a sensitivity analysis in this review.

RESULTS

Description of studies

See: Characteristics of included studies; Characteristics of excluded studies.

Results of the search

This is an updated review in which we identified one additional study for inclusion (Egbuonu 2005) and four for exclusion. Thus, from 459 publications identified in the literature, 159 presented original data; 90 were prospective. There were 12 double publications, leaving 78. In 64 one or more inclusion criteria were not fulfilled (no life table rates, sexual activity unknown, no differentiation between full and partial breastfeeding, loss to follow up not specified, highly selective studies according to study coordinators).

Hence, 14 studies were left, which dealt with 10 original intervention groups and two control groups. We included these 14 studies in this systematic review (Cooney 1996; Díaz 1988a; Díaz 1988b; Díaz 1991; Díaz 1992; Egbuonu 2005; Kazi 1995; Labbok 1997; Peréz 1991; Peréz 1992; Ramos 1996; Ravera 1995; Rodríguez 1993; WHO 1999a).

Included studies

See 'Characteristics of included studies'. We identified only two controlled trials (Peréz 1991; Díaz 1988a). Díaz, however, present the data in four separate publications; in three he presented only data about cases (the intervention group) and in one he presented similar data plus data about controls, this suggesting it was a controlled study (Díaz 1988a; Díaz 1988b; Díaz 1991; Díaz 1992). Peréz presented the same cases in two publications, one with con-

Allocation

In two studies (Díaz 1988a; Peréz 1991) allocation concealment was unclear. In the remainder there was no evidence that allocation concealment had been used.

Blinding

There was no blinding to the intervention in any of the studies

Follow up and exclusions

Follow up was acceptable concerning the primary outcome and ranged from 6 months to 1'year.

Selective reporting

There was no evidence of selective reporting

Other potential sources of bias

One of the main sources of bias within this review is the multiple definitions of 'amenorrhea' that were used. This means there is also considerable selection bias in the type of women enrolled in the studies. In most studies women were included just after delivery. Díaz (Díaz 1988a) and Rodríguez (Rodríguez 1993) started to include women between 6 and 12 weeks after delivery, thus creating a selection bias. The confounders of age and parity were given in all included studies but those of length of previous lactational amenorrhea and breastfeeding were not clear in the studies from the WHO (WHO 1999a), Cooney (Cooney 1996), Díaz (Díaz 1988a), Peréz (Peréz 1991), Ravera (Ravera 1995) and Rodríguez (Rodríguez 1993). In the studies by Cooney, Ravera and the WHO the drop-out rate was more than 10%, but was not specified. For example, Cooney's study (Cooney 1996) took place during the civil war in Rwanda. The definitions of the endpoints were not clear in the reports by Cooney (Cooney 1996) and Labbok (Labbok 1997). The results were presented in a transparent way in all studies, except for Díaz (Díaz 1988a), Peréz (Peréz 1991) and Rodríguez (Rodríguez 1993).

Other potential sources of bias

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Excluded studies

The main reason for excluding studies was the lack of reported life table rates, sexual activity unknown, no differentiation between full and partial breastfeeding, loss to follow up not specified, and highly selective studies according the co-ordinators of these studies (see 'Characteristics of excluded studies').

Risk of bias in included studies

see 'Characteristics of included studies' and Table 1

studies. In most studies women were included just after delivery. Díaz (Díaz 1988a) and Rodríguez (Rodríguez 1993) started to include women between 6 and 12 weeks after delivery, thus creating a selection bias. The confounders of age and parity were given in all included studies but those of length of previous lactational amenorrhea and breastfeeding were not clear in the studies from the WHO (WHO 1999a), Cooney (Cooney 1996), Díaz (Díaz 1988a), Peréz (Peréz 1991), Ravera (Ravera 1995) and Rodríguez (Rodríguez 1993). In the studies by Cooney, Ravera and the WHO the drop-out rate was more than 10%, but was not specified. For example, Cooney's study (Cooney 1996) took place during the civil war in Rwanda. The definitions of the endpoints were not clear in the reports by Cooney (Cooney 1996) and Labbok (Labbok 1997). The results were presented in a transparent way in all studies, except for Díaz (Díaz 1988a), Peréz (Peréz 1991) and Rodríguez (Rodríguez 1993).

Effects of interventions

Pregnancy rate in controlled studies

As already noted, we identified two controlled studies (Díaz 1988a; Peréz 1991). Díaz studied breastfeeding women using an intrauterine device (IUD) as a control group. For the purpose of pregnancy rates these controls were not considered to be suitable (none of them became pregnant). In this 'controlled' study two different definitions were used to mark the end of amenorrhea. The standard definition, ignoring any bleeding before day 56 postpartum, gave a cumulative life table pregnancy rate of 2.45 after 6 months. Using the second definition of any bleeding to mark the end of amenorrhea, a cumulative life table pregnancy rate of 0.45 was calculated.

In the other controlled study, Peréz used the standard definition. The life table pregnancy rate was 0.45 (one pregnancy in 1671 woman months accumulated (WMAC)) for the women using the

LAM, compared with zero (none in 690 WMAC) for the controls, who were fully breastfeeding, amenorrheic women not using any other method of contraception.

Recurrence of 'menstruation' (vaginal blood loss) in controlled studies

We obtained data from the same two controlled studies already noted (Díaz 1988a; Peréz 1991). Díaz found no difference in re-establishment of 'menstruation' between the intervention and the control groups. Of all fully breastfeeding women (236 cases + 440 controls) 52% were not amenorrheic at 6 months. Peréz found that 56% of the fully nursing women in the intervention group remained amenorrheic at 6 months (life table menstruation rate 18.78), compared with 22% in the control group. The objective of Peréz's study was to assess the impact of a breastfeeding promotion campaign and the acceptance and use of LAM for natural child spacing, not testing the effectiness of LAM. The LAM users and their health care providers received an exceptional amount of support.

Pregnancy rate in uncontrolled studies

We identified six uncontrolled studies, that used the standard LAM definition (Cooney 1996; Egbuonu 2005; Kazi 1995; Labbok 1997; Ramos 1996; Ravera 1995). The number of pregnancies per woman month of LAM use during the first 6 months were according to Egbuono (no woman months is provided), Kazi 1/131.3 (cumulative pregnancy rate (CPR) 0.58), Ravera 0/432, Cooney 0/1264, Ramos 2/1030.5 (CPR 0.97) and Labbok 5/2718 (CPR 1.5). It should be noted that the life table pregnancy rates in the multicentre study of Labbok varied from 0 to 7.5 per site.
In the study by Ramos et al. (Ramos 1996) the cumulative pregnancy risk was given for both correct and incorrect users of LAM as 0.88. This included all breastfeeding, sexually active, women correctly or using LAM incorrectly (which means experiencing vaginal blood loss and not using any contraceptive method). The CPR for women using LAM correctly was even higher, being 0.97.
In a WHO study (WHO 1999a), 13 pregnancies were reported in 2831 to 2969 WMAC, depending which definition was used to mark the end of amenorrhea. The cumulative lifetable pregnancy rate in fully breastfeeding, amenorrheic women not using any contraceptive method in that study was 0.9 to 1.2 (95% confidence interval 0 to 2.4).

Recurrence of 'menstruation' (vaginal blood loss) in uncontrolled studies

In the above-mentioned studies the standard definition of LAM, ignoring any bleeding before the 56th day postpartum, was used. Unfortunately, Kazi (Kazi 1995) gave no data about the recurrence of menstruation. The number of menstruation recurrence/woman months of LAM use during the first 6 months were, according to Ravera (Ravera 1995), 40/432 (cumulative menstruation rate (CMR) 39.4) and to Cooney (Cooney 1996) 27/1179 (CMR 11.1). Ramos (Ramos 1996) and Labbok (Labbok 1997) did not provide these monthly data, giving only CMRs of 18.78 and 27.6 respectively. Only one study also presented data using the definition 'any bleeding is considered a menstruation': Díaz (Díaz 1988a) reported a life table menstruation rate after 6 months of using LAM of 135/937 (CMR 53.2). These data must be seen in the context that amenorrheic women were recruited 6 to 12 weeks after delivery. In the 1999 WHO study (WHO 1999a) definition III was used (woman's perception that menstruation had resumed), but no menstruation life table rates are given.
In Rodriquez' uncontrolled study, the women using LAM were fully breastfeeding and using an IUD. The CMR at 6 months was 32 (Rodríguez 1993).
In the WHO study (WHO 1999a), the women in the intervention group were fully breastfeeding and their CMR at 6 months varied from 26.5 to 69.5. An interesting point to note in this study is that 25.4% of these women experienced bleeding before the 56th day. In 44.4% (11.3/25.4) of them this was separated by more than 14 days from the puerperal bleeding and in 83.4% it was followed by a second bleed within 21 to 70 days. No cumulative rates or monthly life tables were provided by Egbuonu 2005, who reported that menstrual flow returned in 33.8% of women by the sixth week of lactation and in 70.2% at 6 months.

DISCUSSION

A systematic review of observational studies has many limitations owing to publication and language biases (Blettner 2000; Concato 2000; Sim 1996; Stroup 2000). In this review, 13 studies were finally included, reporting on nine intervention and two control groups. The ways in which definitions were used, intervention and control groups composed and data presented were not clear. Even when they were clear, it did not make sense to pool these data, because fertility and the length of amenorrhea in fully breastfeeding women turned out to vary between different populations (Bonte 1974; Ford 1987; Ford 1993; Jones RE 1989; Lewis 1991; Sutton 2000; WHO 1999a). Serious heterogeneity among the women recruited was observed. For example, Cooney studied the efficacy of LAM in Rwanda, where the national mean duration of breastfeeding was 25.9 months and lactational amenorrhea 16.8 months before the introduction of LAM (Cooney 1996). In the study by Kazi, only women who had breastfed their previous child for at least 1 year were recruited (Kazi 1995). Realising that pregnancy is the most important reason for weaning, it is likely that the women studied did not become pregnant during the first 6 months of their previous lactational amenorrhea (Feinstein 1986; Jakobson 1996; Marandi 1993). The length of a previous amenorrhea influences that of the next amenorrhea, which will probably last longer. It

may have been that the women studied would not be likely to become pregnant in the 6 months of using LAM during the study period (Delvoye 1977; Salber 1968; WHO 1999a).

Another weak point in the design of most included studies was the lack of a control group. A control group from the same culture/site is a prerequisite because the length of lactational amenorrhea in fully breastfeeding women is culture and site specific (Trussell 1991a; WHO 1998a).

The LAM was introduced as being a safe contraceptive method and a method to delay menstruation. Much effort and money was put into its promotion. However, in this review no differences could be found in pregnancy rates between motivated and supported LAM users and women 'just' fully breastfeeding and staying amenorrheic. The suggestion that LAM delays the recurrence of menstruation more than does exclusive breastfeeding could not be supported.

Advocates of LAM have also suggested that its use would motivate women who have never used contraception before to use another contraceptive method after using LAM. Data supporting this suggestion gathered from a health centre may be biased. Owing to a lack of pregnancy tests, only women using LAM as a contraceptive method were allowed to have an IUD fitted without having a pregnancy test before insertion. Breastfeeding, amenorrheic women not using any method did not receive an IUD because a pregnancy test could not be carried out before its insertion (Hardy 1998; Kennedy 1998a).

LAM has been promoted especially in developing countries where it is difficult to obtain contraceptives. The results of Egbuonu (Egbuonu 2005) are in this case alarming. In his study, LAM was not introduced as a contraceptive method; instead, exclusive breastfeeding for 178 women was promoted. No data on parity or on previous breastfeeding experience were given, so the results presented could be even more, or perhaps less, alarming. Only 3.9% of these women were exclusively breastfeeding at 6 months, and 27.8% of the 144 mothers exclusively breastfeeding resumed sexual activity at 6 weeks after delivery and seven of the seven women exclusively breastfeeding at 6 months. A return of menstrual flow occurred in 33.3% of the 144 exclusively breastfeeding women at 6 weeks and in 57.1% of the 7 women exclusively breastfeeding at 6 months (70.2% for all breastfeeding women at 6 months).

In Nigeria where it is likely to be more difficult to obtain contraceptives compared with a high income country, it might be asked if this method is applicable. In these countries, waiting for the end of the amenorrhea before commencing another 'method' is not acceptable. Using the first months after childbirth for the promotion of breastfeeding in the interest of the baby's health and to motivate the mother to use another contraceptive method - if required - and then arranging this, would be a wiser course of action (Bracher 1992; Hardy 1998; Hight-Laukaran 1993; Kennedy 1991; Kennedy 1998a; Labbok 1991; Potter 1973; Trussell 1991b).

AUTHORS' CONCLUSIONS

Implications for practice

Fully breastfeeding women who remain amenorrheic have a very small risk of becoming pregnant in the first 6 months after delivery when relying on lactational subfertility (Bracher 1992; Hardy 1998; Hight-Laukaran 1993; Kennedy 1991; Kennedy 1998a; Labbok 1991; Potter 1973; Trussell 1991b). According to the studies in this review, amenorrhea should be redefined as no vaginal blood loss for at least 10 days after postpartum bleeding (WHO 1999b).

When amenorrhea is likely to end is unpredictable and because LAM was promoted especially in countries where it is difficult to obtain contraceptives, a dilemma was created. In these countries, waiting for the end of amenorrhea before starting to use a contraception is not acceptable. Using the first months after childbirth for the promotion of breastfeeding and to motivate the mother to use another contraceptive method - if needed - and also arranging this, might be a wiser way forward (Bracher 1992; Hardy 1998; Hight-Laukaran 1993; Kennedy 1991; Kennedy 1998a; Labbok 1991; Potter 1973; Trussell 1991b). During breastfeeding an IUD is preferable. Progestin-only pills or barrier methods are alternatives that could be considered.

Implications for research

If new research is to be undertaken in the future, uniform and transparent definitions should be used, intervention groups and controls should be from the same population, and be comparable for culture, age, parity and previous breastfeeding experience or lactational amenorrhea. A careful description of populations and settings is essential. Even then it would be doubtful whether such newly achieved results could be generalised. An economic analysis would also be useful, in which postpartum and postamenorrheic strategies for contraception should be compared (Kennedy 1998b).

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* *Indicates the major publication for the study*

CHARACTERISTICS OF STUDIES

Characteristics of included studies *[ordered by study ID]*

Cooney 1996

Methods	Prospective follow-up study
Participants	419 Rwandan couples, mean age 31, parity 3.2
Interventions	LAM, education, monthly group meetings, monthly follow- up and completion of a checklist, individual counseling sessions for couples
Outcomes	816 couples started the method, 286 were analysed. No pregnancies in 1264 WMAC. CMR 11 (in 1264 WMAC)
Notes	LAM extended for 9 months was studied. Definition of menstruation used not clear

Risk of bias

Item	**Authors' judgement**	**Description**
Allocation concealment?	Unclear	D - Not used

Díaz 1992

Methods	
Participants	See Rodríguez 1993
Interventions	
Outcomes	
Notes	Data given in other publications

Risk of bias

Item	**Authors' judgement**	**Description**
Allocation concealment?	Unclear	D - Not used

Díaz 1988a

Methods	Observational, comparative follow-up study.
Participants	236 cases (entering at day 330 postpartum), on demand feeding Chilean women relying on lactational infertility. Age 23.5, parity 1.7.Controls: 440 (non-hormonal IUD within first 2 postpartum months; 125 entering at 30 days; 315 enetring at 60 days postpartum) on demand feeding urban Chilean women using an IUD. Age 23.7, parity 1.8
Interventions	LAM, education for the cases; cases and controls monthly follow-up, reinforcement of breastfeeding instructions
Outcomes	CPR 2.45 or 0.45 (788 WMAC) depending on the definition used. 52% of cases experienced menses at 6 months
Notes	Selection bias at point of entry. Controls: two different definitions of amenorrhea used

Risk of bias

Item	**Authors' judgement**	**Description**
Allocation concealment?	Unclear	B - Unclear

Díaz 1988b

Methods	
Participants	See Rodríguez 1993 for 48 women; see Díaz 1988a for the 236 cases
Interventions	
Outcomes	
Notes	Data given in other publications

Risk of bias

Item	**Authors' judgement**	**Description**
Allocation concealment?	Unclear	D - Not used

Díaz 1991

Methods	
Participants	See Díaz 1988a
Interventions	
Outcomes	

Díaz 1991 (*Continued*)

Notes	Data given in other publications	
Risk of bias		
Item	**Authors' judgement**	**Description**
Allocation concealment?	Unclear	D - Not used

Egbuonu 2005

Methods	Prospective, non-comparative study	
Participants	178 women in Nigeria attending infant welfare clinics	
Interventions	LAM education and questionnaires completed at 6, 10 and 14 weeks, and 6 months post-partum	
Outcomes	There were no pregnancies in any of the women during the study period	
Notes	No clear definition of menstruation; no life tables	
Risk of bias		
Item	**Authors' judgement**	**Description**
Allocation concealment?	Unclear	D - Not used

Kazi 1995

Methods	Prospective non-comparative study	
Participants	399 Pakistani women, previous breastfed an infant for more than 1 year. Age 27.2, parity 4.4;25% rural, 37.6 % literate	
Interventions	LAM, education, weekly interviews	
Outcomes	CPR 0.6 (1 pregnancy in 1313 WMAC). CPR lactational amenorrhea alone 0.41. CMR not given	
Notes	Selection bias	
Risk of bias		
Item	**Authors' judgement**	**Description**
Allocation concealment?	Unclear	D - Not used

Labbok 1997

Methods	Multicenter prospective study; 11 sites in 10 different countries
Participants	491 women; age 27.5; parity 2.4. Education level 4-10 years in developing countries; 13-17 in other countries
Interventions	LAM health education during monthly follow-up visits checking LAM criteria over 6 months, contact at 9 and 12 months
Outcomes	Efficacy rates of LAM 92.5-100 (2718 WMAC). Lactational amenorrhea alone protected for 98.0 (2828 WMAC)
Notes	3 definitions of menstruation used. Selection bias

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	D - Not used

Peréz 1991

Methods	Comparative prospective intervention study
Participants	422 cases urban lower-middle class breastfeeding Chilean women from Santiago: age 27.1, parity 2.0. 313 controls: age 26.8, parity 1.7. Education level of controls slightly higher
Interventions	LAM breastfeeding promotion campaign; extensive health education and support; controls received 'usual care'
Outcomes	Cases: CPR 0.45 (1671 WMAC); CMR 18.78 (1671 WMAC). Controls: CPR 0 (690 WMAC); 52% experienced menstruation before 6 months
Notes	Lactation performance in cases better than in controls. 97% of cases completed the study: number of controls that completed the study unknown

Risk of bias

Item	Authors' judgement	Description
Allocation concealment?	Unclear	B - Unclear

Peréz 1992

Methods	
Participants	See Peréz 1991
Interventions	

Peréz 1992 (*Continued*)

Outcomes		
Notes	Data given in another publication	
Risk of bias		
Item	**Authors' judgement**	**Description**
Allocation concealment?	Unclear	D - Not used

Ramos 1996

Methods	Non-comparative prospective trial	
Participants	485 lower income, Filipino, educated women with extensive experience of breastfeeding. Age 26.6, parity 3.2	
Interventions	LAM education	
Outcomes	CPR 0.97 (1030.5 WMAC). 1/3 experienced menses before day 180. CPR all breastfeeding amenorrheic women 0.88 (1141.6 WMAC)	
Notes	Selection bias	
Risk of bias		
Item	**Authors' judgement**	**Description**
Allocation concealment?	Unclear	D - Not used

Ravera 1995

Methods	Prospective follow-up study,	
Participants	154 Ugandese women. Age 24.4; parity 2.2.	
Interventions	LAM education, breastfeeding practices reinforced with monthly follow up	
Outcomes	No pregnancy recorded (432 WMAC); CMR 39.4 (432 WMAC)	
Notes	154 women started, 134 completed the study	
Risk of bias		
Item	**Authors' judgement**	**Description**

Ravera 1995 (*Continued*)

Allocation concealment?	Unclear	D - Not used

Rodríguez 1993

Methods	Prospective follow-up study
Participants	50 fully breastfeeding Chilean women using an IUD
Interventions	Non-LAM, reinforcement of breastfeeding instructions, filling in a monthly calendar. Blood samples taken fortnightly in the first 3 months and 2 per week thereafter
Outcomes	CPR unsuitable (IUD users); CMR at 6 months 32 (126.5 WMAC)
Notes	Selection bias: only women fully breastfeeding and amenorrheic on days 60 to 90 postpartum enrolled

Risk of bias

Item	**Authors' judgement**	**Description**
Allocation concealment?	Unclear	D - Not used

WHO 1999a

Methods	Prospective longitudinal study
Participants	4118 breastfeeding, literate women in China, India, Australia, Nigeria, Chile and Sweden. 3422 completed the study
Interventions	Non- LAM, infant feeding practices, menstrual status and pregnancy recorded. Participants kept a daily record
Outcomes	Censored CPR 0.9-1.2 (2831-2969 WMAC) depending which definition of menstruation was used
Notes	4 different definitions of menstruation used; 696 women left the study (150 of whom had only 1 unconfirmed bleeding, 546 had no bleeding when they left the study)

Risk of bias

Item	**Authors' judgement**	**Description**
Allocation concealment?	Unclear	D - Not used

CMR, cumulative menstruation rate at 6 months according life tables
CPR, cumulative pregnancy rate at 6 months according life tables
IUD, intrauterine device
LAM, lactational amenorrhea method

WMAC, woman months accumulated

Characteristics of excluded studies *[ordered by study ID]*

Study	Reason for exclusion
Gross 2002	Study is part of a WHO trial
Short 1991	No life table rates, no differentiation between full and partial breastfeeding; loss to follow up more than 10% or not specified
Tazhibayev	Aim of the study was promotion of LAM. Endpoints were knowledge of LAM and other methods of contraception and number of pregnancies. No details on sexual activity, no pregnancy life tables; no definitions and a lack of clarity for 'menstruation'
Valdes 2000	Aim of the study was to assess the efficacy of LAM under certain conditions. No information on sexual activity; the definition of LAM is unclear, no life tables for menstruation ; no definition of menstruation

DATA AND ANALYSES

This review has no analyses.

ADDITIONAL TABLES

Table 1. Quality of the included studies according to the NHS Centre 2001 table

Trials	Entry point	Confounding of cases	Confounding of controls	Follow-up length	Drop outs < 10%	Data clear	Endpoints clear	Same population
Cooney 1996	+	Unclear		+	Unclear	+	Unclear	-
Díaz 1988a	-	Unclear	Unclear	+	+ Cases	-	+	-
Kazi 1995	+	-		+	+	+	+	-
Labbok 1997	+	-		+	+	+	Unclear	-
Peréz 1991	+	Unclear	Unclear	+	+ Cases	-	+	-
Ramos 1996	+	-		+	+	+	+	-
Ravera 1995	+	Unclear		+	Unclear	+	+	-
Rodríguez 1993	-	Unclear		+	+	-	+	-
WHO 1999a	+	Unclear		+	Unclear	+	+	-

LAM, lactational amenorrhea method
WHO, World Health Organization

WHAT'S NEW

Last assessed as up-to-date: 6 February 2008.

Date	Event	Description
15 April 2008	Amended	Converted to new review format.

HISTORY

Protocol first published: Issue 4, 1998

Review first published: Issue 4, 2003

Date	Event	Description
8 July 2003	New citation required and conclusions have changed	Substantive amendment

CONTRIBUTIONS OF AUTHORS

CvdW and JB contributed to the selection of and data extraction from studies in the update and the updating of the manuscript.

CvdW and TV contributed to the preparation of the original protocol and examined trials found after the literature search.

CvdW and JK drafted, revised and approved the original review.

Rob Schouten from the Dutch Cochrane Centre and Frans Helmerhorst helped with the logistics of the original; Margaret Carver and FH edited the amended review.

DECLARATIONS OF INTEREST

None

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Internal sources

- Written in author's own time, Netherlands.

External sources

- No sources of support supplied

INDEX TERMS

Medical Subject Headings (MeSH)

*Amenorrhea; *Contraception Behavior; *Postpartum Period; Breast Feeding; Contraception [*methods]; Family Planning Services; Lactation

MeSH check words

Female; Humans; Pregnancy