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[Intervention Review]

Lactational amenorrhoea method for family planning

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ABSTRACT

Background

It is estimated that about 40% of pregnancies in the world are unintended and that the major part of these are unwanted. There are several reasons no or ineffective contraception is used to prevent these pregnancies, including difficulty in obtaining contraceptives. The lactational amenorrhoea method (LAM) is a contraceptive method where the mother is informed and supported in how to use breastfeeding for contraception. LAM is available and accessible to many women.

Objectives

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

Search methods

We searched MEDLINE, EMBASE, POPLINE, and LILACS to 10 October 2014; 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 amenorrhoea. Our inclusion criteria were as follows: 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 15 studies reporting on 11 intervention groups and three control groups. We identified one additional uncontrolled study in the 2007 update and one additional controlled study in this 2015 update.

Data collection and analysis

Two review authors independently extracted data, resolving disagreements through discussion. We analysed the studies using narrative methods because of their heterogeneity.

Main results

For the primary outcome, pregnancy, two controlled studies of LAM users reported life table pregnancy rates at six months of 0.45% and 2.45%, one controlled study reported 5% pregnancies in the absence of life table rates per month, and eight uncontrolled studies of LAM users reported pregnancy rates of 0% to 7.5%. Life table pregnancy rates for fully breastfeeding women who were amenorrhoeic but not using any contraceptive method were 0.88% in one study and 0.9% to 1.2% (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 six months in all studies varied between 11.1% and 39.4%.

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 amenorrhoeic women not using any method. As the length of lactation amenorrhoea in women using LAM differed greatly between the populations studied, and was population specific, it is uncertain whether LAM extends lactational amenorrhoea.

PLAIN LANGUAGE SUMMARY**Lactational amenorrhoea method for family planning**

The lactational amenorrhoea method (LAM) is a contraceptive method where the mother is *informed and supported* how to use breastfeeding for contraception. Breastfeeding while *not* giving supplementary feeds delays the return of fertility and menstrual periods, which is a normal (physiological) protection against pregnancy. In this review we have studied the effectiveness of LAM as a contraceptive method in fully breastfeeding women in comparison to breastfeeding women without any support. We found no clear differences in effectiveness (pregnancy) between women using LAM and being supported in doing so, and fully breastfeeding amenorrhoeic women not using any method. Apart from this we recommend breastfeeding itself from a public health point of view.

BACKGROUND

Description of the condition

It is estimated that among the annual 150 million pregnancies in the world, about 40% are unintended and unplanned and that the major part of these are unwanted. Most of these pregnancies occur in low income countries (Alan Guttmacher Institute 1999; Lakha 2006; Trussell 2008; UNFPA 2014). There are several reasons no or ineffective contraception is used to prevent these unplanned pregnancies, including difficulties in obtaining contraceptives.

Description of the intervention

The lactational amenorrhoea method (LAM) is a contraceptive method available and accessible to many women (Family Health 1988; Kennedy 1989). LAM was defined during the 1988 Bellagio Consensus Conference in Italy (Bellagio 1988) as the informed use of breastfeeding as a contraceptive method by a woman who is still amenorrhoeic and does not feed her baby with supplements for up to six months after delivery. LAM provides more than 98% protection from pregnancy in the first six months postpartum, according to its advocates (Family Health 1988; Kennedy 1989; Kennedy 1992; Labbok 1994). During a second conference in Bellagio in 1995, it was suggested that women choosing and using the LAM had a life table pregnancy rate at six months of less than 2%. This was not based on a systematic review. It was also suggested "in the studies that included the promotion of appropriate breastfeeding practices, the percentages of women still amenorrhoeic 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 six months (Labbok 1997). However, many women 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 that have followed up women claiming to use LAM showed that few of the women actually implemented the method or used it correctly (Romero-Gutierrez 2007; Sebastian 2012; Sipsma 2013).

In a study in Turkey, 34% of the research sample of women with six-month-old infants were said to use LAM to prevent pregnancy after childbirth. However, only 17.2% of the women using LAM successfully fulfilled the LAM criteria, with 82.8% not fulfilling one or more of the LAM criteria. The pregnancy rate of the women using 'LAM' was 32.8% (Türk 2010).

How the intervention might work

The suckling stimulus reduces pulsatile secretion of GnRH/LH, thus suppressing ovarian activity (McNeilly 2001).

Why it is important to do this review

Many studies on LAM do not include a control group, thus the quality of these studies varies; it is therefore difficult to support the suggestions of the World Health Organization Task Force on

Methods for the Natural 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 low income 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 its advocacy does not hamper the introduction of longer-term methods of contraception.

OBJECTIVES

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; Shaaban 2013; Urdry 1993; van de Walle 1993; Visness 1997).

Types of interventions

Women using LAM compared with controls who gave birth recently and were breastfeeding without support.

Types of outcome measures

Primary outcome measures

Pregnancy and 'menstruation' (after being amenorrhoeic) 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 amenorrhoeic. The original definition used in the Bellagio Consensus Statement ignores any bleeding before the 56th day postpartum (Family Health 1988). However, in 1995 in Bellagio menstruation was defined 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 used four different definitions to mark the end of amenorrhoea (WHO 1999a).

In this systematic review we used three different definitions:

1. We used the original definition of lactational amenorrhoea in fully lactating women, i.e. "ignoring any bleeding before the 56th day postpartum", as standard.
2. Any bleeding (including bleeding within 56 days postpartum but separated from the postpartum bleeding by 10 to 14 days or more).
3. The woman's perception that her menses have returned.

Search methods for identification of studies

Electronic searches

We searched

- MEDLINE, EMBASE, POPLINE, and LILACS to 10 October 2014 (Appendix 1);
- Cochrane Central Register of Controlled trials (2014)
- reference lists of studies, review articles, books related to LAM, published abstracts from breastfeeding and reproductive health conferences.

We had e-mail contact with study coordinators.

Searching other sources

We also considered studies identified from reference lists and review articles, books related to LAM, and abstracts of conferences. Furthermore, we emailed co-ordinators of such studies and made enquiries with contraception-orientated organisations such as the World Health Organization and Population Council. We applied no language restrictions.

Data collection and analysis

Selection of studies

We updated this review in 2015.

Two review authors (CW and Frans Helmerhorst in the original review; CW and Julie Brown in the 2008 update; CW and CM in this update) independently selected the studies according to the pre-set inclusion criteria. Any disagreements were resolved through discussion. When we identified multiple reports of a study, we used only the original results.

Data extraction and management

One review author performed data extraction, and the second review author 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 enrol 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 amenorrhoea or breastfeeding as confounders. The period of lactational amenorrhoea 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 amenorrhoeic 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 can occur 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, we contacted the study's lead author. 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 review authors, using their subjective judgement, 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 studies 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 have described 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 decrement life tables, but at the time of discontinuation they censor individuals who stop using a method for reasons other than the one being measured. They 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 did not present any subgroup analysis in this review.

Sensitivity analysis

We did not present a sensitivity analysis in this review.

RESULTS

Description of studies

Results of the search

In this updated 2015 review we identified one additional study for inclusion (Shaaban 2013). Thus, from 459 publications (2003 data) identified in the literature, 159 presented original data; 90 were prospective. There were 12 double publications, leaving 78 (2003 data). In 64 (2003 data), 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 co-ordinators). Hence, 15 studies were left, which dealt with 11 original intervention groups and three control groups (2015 data). We included these 15 studies in this systematic review (Cooney 1996; Díaz 1988a; Díaz 1988b; Díaz 1991; Díaz 1992; Egbuonu 2005; Kazi 1995; Labbok 1997; Pérez 1991; Pérez 1992; Ramos 1996; Ravera 1995; Rodríguez 1993; Shaaban 2013; WHO 1999a).

Included studies

See 'Characteristics of included studies'. We identified only three controlled trials (Díaz 1988a; Pérez 1991; Shaaban 2013). However, Díaz presented the data in four separate publications; in three she 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). Pérez presented the same cases in two publications, one with controls and one without (Pérez 1991; Pérez 1992). Thus, 11 (15 minus 4) intervention groups (cases) were left and 3 control groups.

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 to 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.

Allocation

In the study of Shaaban (Shaaban 2013), allocation concealment was clear; in two studies, Díaz 1988a and Pérez 1991, allocation concealment was unclear. There was no evidence that allocation concealment had been used in the remainder.

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 six months to one year.

Selective reporting

There was no evidence of selective reporting in any of the studies.

Other potential sources of bias

One of the main sources of bias within this review is the multiple definitions of 'amenorrhoea' 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 were given in all included studies and those regarding parity in all but one (Shaaban 2013). The confounder length of previous lactational amenorrhoea and breastfeeding were not clear in the studies from the WHO (WHO 1999a), Cooney (Cooney 1996), Díaz (Díaz 1988a), Pérez (Pérez 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), Labbok (Labbok 1997) and Shaaban 2013. The results were presented in a transparent way in all studies, except for Díaz (Díaz 1988a), Pérez (Pérez 1991) and Rodríguez (Rodríguez 1993). In the study of Shaaban 2013, only women were included having a contact phone number.

Effects of interventions

Pregnancy rate in controlled studies

As already noted, we identified three controlled studies (Díaz 1988a; Pérez 1991; Shaaban 2013). Díaz studied breastfeeding women using an intrauterine device (IUD) as a control group. For the purpose of pregnancy rates, we did not consider these controls to be suitable (none of the women became pregnant). In this controlled study, two different definitions were used to mark the end of amenorrhoea. 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, that is any bleeding marking the end of amenorrhoea, a cumulative life table pregnancy rate of 0.45 was calculated.

Pérez 1991 used the standard definition of amenorrhoea. 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, amenorrhoeic women not using any other method of contraception. In the Shaaban 2013, women counseled on LAM were the cases and women counseled on LAM and emergency contraception (EC) served as controls. The EC was provided with instructions to be used in case one of the prerequisites of LAM expired and sexual relations had occurred. No life tables were given, but 29 pregnancies occurred in the 529 LAM users and 2 in the 529 women using LAM and EC.

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

We obtained data from the same three controlled studies already noted (Díaz 1988a; Pérez 1991; Shaaban 2013). Díaz found no difference in re-establishment of 'menstruation' between the intervention and the control groups. Of all fully breastfeeding women (236 cases and 440 controls), 52% were not amenorrhoeic at 6 months. Pérez found that 56% of the fully nursing women in the intervention group remained amenorrhoeic at 6 months (life table menstruation rate 18.78), compared with 22% in the control

group. The objective of Pérez's study was to assess the impact of a breastfeeding promotion campaign and the acceptance and use of LAM for natural child spacing, not to test the effectiveness of LAM. The LAM users and their healthcare providers received an exceptional amount of support. In the study of Shaaban, about 20% had resumed menstruation at 6 months and only 20% were (almost) exclusively breastfeeding. Shaaban defines "exclusive" or "nearly exclusive" breastfeeding as follows: "breastfeeding the infant at least every 4 h during the daytime and at least every 6 h during nighttime, and not giving the infant other additional liquid, semi-solid or solid food"; we therefore put the word "almost" between brackets. Life tables were not given [Shaaban 2013](#).

Pregnancy rate in uncontrolled studies

We identified six uncontrolled studies that used the standard LAM definition ([Cooney 1996](#); [Egbonu 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 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). Egbonu provided no woman months. 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 [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 using LAM correctly or 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 [WHO 1999a](#), 13 pregnancies were reported in 2831 to 2969 WMAC, depending on which definition was used to mark the end of amenorrhoea. The cumulative life table pregnancy rate in fully breastfeeding, amenorrhoeic 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

The above-mentioned studies used the standard definition of LAM, that is ignoring any bleeding before the 56th day postpartum. Unfortunately, [Kazi 1995](#) provided no data about the recurrence of menstruation. The number of menstruation recurrence/woman months of LAM use during the first 6 months were 40/432 (cumulative menstruation rate (CMR) 39.4) according to [Ravera 1995](#) and 27/1179 (CMR 11.1) according to [Cooney 1996](#). [Ramos 1996](#) and [Labbok 1997](#) did not provide these monthly data, giving only CMRs of 18.78 and 27.6, respectively. Only [Díaz 1988a](#) also presented data using the definition of any bleeding marking the end of amenorrhoea, reporting 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 amenorrhoeic women were recruited 6 to 12 weeks after delivery. In the 1999 WHO study ([WHO 1999a](#)), the third definition of the end of amenorrhoea was used, that is a woman's perception that menstruation had resumed, but no menstruation life table rates were given.

In [Rodríguez 1993](#), the women using LAM were fully breastfeeding and using an IUD. The CMR at 6 months was 32.

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. Of note in this study was that 25.4% of these women experienced bleeding before the 56th day postpartum. 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. [Egbonu 2005](#) provided no cumulative rates or monthly life tables, reporting that menstrual flow returned in 33.8% of women by the sixth week of lactation and in 70.2% at six 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, we finally included 15 studies, reporting on 11 intervention and three control groups. The ways in which definitions were used, intervention and control groups composed, and data presented were not always clear. Even when they were clear, it did not make sense to pool these data, because we discovered that fertility and the length of amenorrhoea in fully breastfeeding women varied between different populations ([Bonte 1974](#); [Ford 1987](#); [Ford 1993](#); [Jones 1989](#); [Kramer 2012](#); [Lewis 1991](#); [Radwan 2009](#); [Sutton 2000](#); [Valdés 2002](#); [WHO 1999a](#)). We observed serious heterogeneity among the women recruited. For example, Cooney studied the efficacy of LAM in Rwanda, where the national mean duration of breastfeeding was 25.9 months and lactational amenorrhoea 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 one year were recruited ([Kazi 1995](#)). Realizing that pregnancy is the most important reason for weaning, it is likely that the women studied did not become pregnant during the first six months of their previous lactational amenorrhoea ([Feinstein 1986](#); [Jakobson 1996](#); [Marandi 1993](#)). The length of a previous amenorrhoea influences that of the next amenorrhoea, which will probably last longer. It may have been that the women studied would not likely become pregnant in the six months of using LAM during the study period ([Delvoe 1977](#); [Salber 1968](#); [WHO 1999a](#)).

Another weak point in the design of most of the 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 amenorrhoea in fully breastfeeding women is culture and site specific ([Kramer 2012](#); [Trussell 1991a](#); [WHO 1998a](#)).

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

Even after counseling, the percentage of women self reporting and evaluated as using LAM correctly is about 20% to 26% ([Fabric 2013](#); [Shaaban 2013](#); [Sipsma 2013](#)), and certain barriers (for example misconception about return of fertility) to LAM users' timely transition to regular contraceptive practice still exist ([Kouyaté 2014](#)).

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 idea 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, amenorrhoeic women not using any

contraceptive method did not receive an IUD because a pregnancy test could not be carried out before its insertion (Hardy 1998; Kennedy 1998a). LAM may even slow the transition to regular contraceptive practice, as suggested in the recent study of Shaaban (Shaaban 2013). In the LAM group, 45.2% of women started regular contraceptive practice in the six months after delivery compared to 73.4% in the LAM and emergency contraception group.

LAM has been promoted especially in low income countries, where it is difficult to obtain contraceptives. The results of 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. Only 3.9% of these women were exclusively breastfeeding at 6 months, and 27.8% of the 144 women exclusively breastfeeding resumed sexual activity at 6 weeks after delivery. A return of menstrual flow occurred in 33.3% of the 144 exclusively breastfeeding women at 6 weeks and in 70.2% at 6 months for all breastfeeding women.

In Nigeria, where it is likely more difficult to obtain contraceptives compared with a high income country, it might be asked if the LAM method is applicable. In countries with a limited access to contraceptives, waiting for the end of the amenorrhoea before commencing another 'method' is not acceptable (Georgetown University 2008). A wiser course of action would be to use 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 (Bracher 1992; Hardy 1998; Hight-Laukaran 1993; Kennedy 1991; Kennedy 1998a; Kunwar 2010; Labbok 1991; Potter 1973; Trussell 1991b).

AUTHORS' CONCLUSIONS

Implications for practice

Fully breastfeeding women who remain amenorrhoeic have a very small risk of becoming pregnant in the first six 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, amenorrhoea should be redefined as no vaginal blood loss for at least 10 days after postpartum bleeding (WHO 1999b).

When amenorrhoea is likely to end is unpredictable, and because LAM has been promoted especially in countries where it is difficult to obtain contraceptives, a dilemma is created. In these countries, waiting for the end of amenorrhoea before starting contraceptive use is not acceptable. A wiser way forward may be to use 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 (Bracher 1992; Hardy 1998; Hight-Laukaran 1993; Kennedy 1991; Kennedy 1998a; Labbok 1991; Potter 1973; Shaaban 2008; Trussell 1991b). During breastfeeding an IUD is preferable. Progestin-only pills or barrier methods could also be considered.

Implications for research

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

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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

Cooney 1996 (Continued)

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

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	D - Not used

Díaz 1992

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

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	D - Not used

Díaz 1988a

Methods	Observational, comparative follow-up study
Participants	Cases: 236 Chilean women (entering at day 30 postpartum) practicing on-demand feeding and relying on lactational infertility. Age 23.5, parity 1.7 Controls: 440 urban Chilean women (non-hormonal IUD within first 2 postpartum months; 125 entering at 30 days; 315 entering at 60 days postpartum) practicing on-demand feeding 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: 2 different definitions of amenorrhoea used

Risk of bias

Bias	Authors' judgement	Support for judgement
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Díaz 1988a *(Continued)*

Allocation concealment (selection bias)	Unclear risk	B - Unclear
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Díaz 1988b

Methods

Participants	See Rodríguez 1993 for 48 women; see Díaz 1988a for the 236 cases
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Interventions

Outcomes

Notes	Data given in other publications
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Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	D - Not used

Díaz 1991

Methods

Participants	See Díaz 1988a
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Interventions

Outcomes

Notes	Data given in other publications
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Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	D - Not used

Egbuonu 2005

Methods	Prospective, non-comparative study
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Participants	178 women in Nigeria attending infant welfare clinics
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Interventions	LAM education and questionnaires completed at 6, 10, and 14 weeks, and 6 months postpartum
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Outcomes	There were no pregnancies in any of the women during the study period
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Lactational amenorrhoea method for family planning (Review)

Egbuonu 2005 *(Continued)*

Notes No clear definition of menstruation; no life tables

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	D - Not used

Kazi 1995

Methods	Prospective, non-comparative study
Participants	399 Pakistani women, previously 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 amenorrhoea alone 0.41. CMR not given
Notes	Selection bias

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	D - Not used

Labbok 1997

Methods	Multicentre 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 high income 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 to 100 (2718 WMAC). Lactational amenorrhoea alone protected for 98.0 (2828 WMAC)
Notes	3 definitions of menstruation used. Selection bias

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	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 better in cases than in controls. 97% of cases completed the study; number of controls that completed the study unknown

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	B - Unclear

Peréz 1992

Methods	
Participants	See Peréz 1991
Interventions	
Outcomes	
Notes	Data given in another publication

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	D - Not used

Ramos 1996

Methods	Non-comparative prospective trial
Participants	485 lower-income, educated Filipino 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 amenorrhoeic women 0.88 (1141.6 WMAC)

Lactational amenorrhoea method for family planning (Review)

Ramos 1996 (Continued)

Notes Selection bias

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	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

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	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 amenorrhoeic on days 60 to 90 postpartum enrolled

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	D - Not used

Shaaban 2013

Methods	RCT between women using LAM and women using LAM and counseled to use EC if 1 of the prerequisites of LAM expire and provided with 1 packet of EC
Participants	1158 women in Egypt attending infant welfare clinics, age 25.9. Past deliveries: 1-3 75.6%, > 3 24.4%
Interventions	LAM education and LAM and EC education. Self reported length of breastfeeding, resumption of menstruation, and pregnancy. Intercourse after expiration of LAM prerequisites
Outcomes	Initiation of regular contraception; pregnancy in LAM users 29 (5%) in 529 women. At 6 months, 20% resumed menstruation and only 20% were still (almost) exclusively breastfeeding (see under "Effects of interventions")
Notes	No objectivation of pregnancy; no clear definition of menstruation; no life tables

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Low risk	Computer-generated and serially numbered, opaque, closed envelope

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 on which definition of menstruation was used
Notes	4 different definitions of menstruation used; 696 women left the study (150 had only 1 unconfirmed bleeding, 546 had no bleeding)

Risk of bias

Bias	Authors' judgement	Support for judgement
Allocation concealment (selection bias)	Unclear risk	D - Not used

CMR: cumulative menstruation rate at 6 months according to life tables

CPR: cumulative pregnancy rate at 6 months according to life tables

EC: emergency contraception

IUD: intrauterine device

LAM: lactational amenorrhoea method

RCT: randomised controlled trial

WMAC: woman months accumulated

Characteristics of excluded studies [ordered by study ID]

Study	Reason for exclusion
Gross 2002	Study is part of a World Health Organization 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 contraception methods 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 was unclear, no life tables for menstruation; no definition of menstruation

LAM: lactational amenorrhoea method

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	Dropouts < 10%	Data clear	Endpoints clear	Same population
Cooney 1996	+	Unclear		+	Unclear	+	Unclear	-
Díaz 1988a	-	Unclear	Unclear	+	+ Cases	-	+	-
Egbuonu 2005	+	-		+	+	+	-	+
Kazi 1995	+	-		+	+	+	+	-
Labbok 1997	+	-		+	+	+	Unclear	-
Peréz 1991	+	Unclear	Unclear	+	+ Cases	-	+	-
Ramos 1996	+	-		+	+	+	+	-
Ravera 1995	+	Unclear		+	Unclear	+	+	-
Rodríguez 1993	-	Unclear		+	+	-	+	-
Shaaban 2013	+	-	-	+	+	-	Unclear	+
WHO 1999a	+	Unclear		+	Unclear	+	+	-

LAM: lactational amenorrhoea method

WHO: World Health Organization

APPENDICES

Appendix 1. Search strategy

The MeSH (or similar) terms (lactational amenorrhea OR LAM OR (lactation AND amenorrhea) OR (breastfeeding AND fertility)) AND (contraception OR family planning OR fertility control) OR 'lactational amenorrhea' OR 'amenorrhea'/exp OR amenorrhea AND ('lactation'/exp OR lactation OR breast*feeding) AND ('family planning'/exp OR 'family planning' OR contracept* OR 'fertility regulation' OR 'fertility'/exp OR fertility) AND ('controlled study'/exp OR 'controlled study' OR 'clinical trial'/exp OR 'clinical trial' OR (lactational amenorrhea OR LAM OR lactation OR lactancia OR lactacao OR breastfeeding OR breast feeding OR lactancia materna OR aleitamento materno) AND (contraception OR anticoncepcion OR anticoncepcao OR family planning OR planficacion familiar OR planejamento familiar OR fertility control or control de fertilidad or controle de fertilidade) AND (amenorrhea OR amenorrea OR amenorreia)

WHAT'S NEW

Date	Event	Description
30 September 2015	New search has been performed	updated with one new trial
22 June 2015	New citation required but conclusions have not changed	1 new trial included

HISTORY

Protocol first published: Issue 4, 1998

Review first published: Issue 4, 2003

Date	Event	Description
15 April 2008	Amended	Converted to new review format
6 February 2008	New search has been performed	No new trials to be found
8 July 2003	New citation required and conclusions have changed	Substantive amendment

CONTRIBUTIONS OF AUTHORS

2003

Carla Van der Wijden and Toos Van den Berk contributed to the preparation of the original protocol and examined trials found after the literature search.

Carla Van der Wijden and Jos Kleinen drafted, revised, and approved the original review.

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

2008

Carla Van der Wijden and Julie Brown contributed to the selection of and data extraction from studies in the 2008 update.

2015

Carla Van der Wijden and Carol Manion contributed to the selection of and data extraction from studies in the 2008 update. Carla Van der Wijden updated the review and Frans Helmerhorst 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

DIFFERENCES BETWEEN PROTOCOL AND REVIEW

None

INDEX TERMS

Medical Subject Headings (MeSH)

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MeSH check words

Female; Humans; Pregnancy