Effectiveness of lactational amenorrhoea in prevention of pregnancy in Manila, the Philippines: non-comparative prospective trial

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Abstract

***Objective*—To determine the contraceptive efficacy of the lactational amenorrhoea method.**

***Design*—Non-comparative prospective trial.**

***Setting*—Urban Manila, the Philippines.**

***Subjects*—485 lower income, educated women with extensive experience of breast feeding.**

***Intervention*—Women were offered all available contraceptives for use after birth. Those who chose the lactational amenorrhoea method were taught the method, screened for the study, and followed for 12 months to determine the risk of pregnancy when the method was used.**

***Main outcome measures*—Life table pregnancy rates during correct and incorrect use of the method, censored monthly in the event of sexual abstinence or the use of another contraceptive method.**

***Results*—The lactational amenorrhoea method was 99% effective when used correctly (that is, during lactational amenorrhoea and full or nearly full breast feeding for up to six months). At 12 months the effectiveness during amenorrhoea dropped to 97%.**

***Conclusions*—The lactational amenorrhoea method provided as much protection from pregnancy as non-breast feeding women experience with non-medicated intrauterine devices and barrier methods. The contraceptive effect of lactation cannot be attributed to lactational or postpartum abstinence.**

Introduction

The natural contraceptive effect of breast feeding has been known for hundreds of years. In 1988, experts in lactational infertility achieved a consensus that breast feeding should be at least 98% effective in preventing pregnancy for the first six months post partum as long as the woman remains amenorrhoeic and is fully or nearly fully breast feeding.[1 2] Guidelines for using lactational amenorrhoea for contraception are known as the lactational amenorrhoea method[3]—the proactive, informed use of lactational amenorrhoea as a contraceptive method under the conditions stated above.

The contraceptive efficacy of this method has been measured prospectively in trials in Chile[4] and Pakistan.[5] These trials, of 422 and 391 women, respectively, have produced pregnancy rates consistent with the 1988 prediction. The validity of these rates has been challenged, however, on the basis that postpartum (especially breast feeding) women may be abstaining from sexual relations. Trials of the contraceptive efficacy of this or any method must determine whether the women using it are sexually active.[6] The Chilean study did not correct for coital abstinence, although the Pakistani study determined on a monthly basis whether the women were sexually active. The current study is a companion project to the one in Pakistan but includes a larger number of women in a distinctly different culture.

The main purpose of this analysis was to determine the contraceptive efficacy of the lactational amenorrhoea method while controlling for sexual activity. Efficacy was estimated during both correct and incorrect use of the method to determine the tolerance of the method for incorrect use.

As presently defined the method is effective for a maximum of six months, yet a large proportion of women remain protected from pregnancy beyond this time. About 5% (3% to 10%) of breast feeding women have been known to conceive during amenorrhoea in the first year post partum.[7-9] In the present study, women were observed prospectively for 12 full months to determine whether the 12 month rate of pregnancy during amenorrhoea is low enough to consider lactational amenorrhoea alone—that is, regardless of whether breast feeding is supplemented—as a period of effective protection from pregnancy for up to a year.

Subjects and methods

All women who attend the antenatal clinic or deliver at the Jose Fabella Memorial Hospital in Manila, or both, are invited to attend a session to review the available postpartum family planning methods. For this study the lactational amenorrhoea method was added to the choice of available methods. All women were assisted in their choice if any. Women who chose the lactational amenorrhoea method were taught the method, including a "jingle" in their native Tagalog to help them remember the three criteria: amenorrhoea, fully or nearly fully breast feeding, and less than six months post partum. They were also taught about the breast feeding practices which maximise both milk supply and the duration of infertility and amenorrhoea.[3] All women who chose to learn the method were invited to be screened for participation in the study. When the eligible women returned to the hospital at one to two weeks post partum for their routine check ups they were admitted into the study if they were still interested, willing, and eligible—that is, still fully breast feeding.

Women were eligible if they were in a stable relationship, were normal and healthy, were aged 18 to 40, had vaginally delivered a normal, healthy, full term infant, chose to use the method and demonstrated understanding of it, had breast fed a previous child for at least one year, planned to delay supplementation for four to six months, gave informed consent, and lived near to the hospital. Women were excluded if they planned to work or otherwise be regularly separated from their infants for more than four hours a day or if they thought that they would not maintain regular sexual activity. The selection criteria are not conditions for method use but facilitated data collection. For example, a woman does not need to have experience of breast feeding to use the method, but by selecting only experienced women we avoided following up women who abandoned breast feeding early.

Mothers were visited in their homes monthly for 12 months. Each month the women were given calendars on which to mark symbols representing any foods or liquids which the child consumed and whether intercourse or any vaginal bleeding had occurred. At follow up a health worker reviewed the information on the calendar and inquired about the use of other

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contraceptive methods. Women ended the study on loss to follow up, when they moved, for other personal reasons, or after 12 months.

The health workers who taught the women were experienced family planning instructors. The home visitors were different people and were trained and supervised by the hospital's family planning staff.

Urinary pregnancy tests were performed whenever the woman, the follow up worker, or the family planning staff suspected pregnancy. The women were asked at every follow up visit whether they suspected pregnancy. Whenever the results of the urinary pregnancy test were ambiguous the test was repeated within a week. The date of conception was estimated by the principal investigators on the weight of the evidence according to generally accepted medical protocol, including date of the last menstrual period, physical examination, and date and apparent gestation of the subsequent delivery.

The start of mixed feeding was defined as the first day of two consecutive weeks when the infant consumed foods or liquids other than breast milk on a daily basis.

Conventional life table methods[10 11] were used to determine the rates of the return of menses, the resumption of coitus, and the start of supplementation. For the pregnancy rates, multiple censoring (making the decision to censor at the beginning of every monthly interval) was performed.[12] Women were entered into the pregnancy life table in only those months in which they had been sexually active. Also, women were temporarily removed from the calculation for various reasons in various tables as noted. The life table pregnancy rates were calculated three times, once each under conditions called "during correct use," "during incorrect use," and "among all women." In the "correct use" calculation, women contribute data only during the time before supplementation and menses—that is, only during correct use. For "incorrect use" they were included only after they started supplementation or experienced menses, or both. For "all women" the two aforementioned groups are combined. In all three conditions the women contributed data only when they were breast feeding, sexually active, and not using another contraceptive method.

The study comprised 509 women. Of these, 24 were omitted from data analysis. Four began supplementation within two weeks of birth and contributed virtually nothing to the assessment of method efficacy. (None of the four became pregnant during follow up.) Also, 20 women had only one or no follow up visits (18 moved away, and two had husbands who went abroad). Of the 485 women in the data analysis, 409 women (84%) remained in the study at the end of one year of follow up.

Table 1—*Characteristics of women who used lactational amenorrhoea method as contraception*

Variable	No of women (n = 485)
Age (years):	
<25	176
25-29	179
30-34	103
≥35	27
Years of education:	
<10	237
10	170
>10	78
No of living children:	
1-2	172
3-4	286
≥5	27
Use of family planning:	
Modern	100
Traditional*	101
None	284

*Primarily withdrawal and rhythm method.

Table 3—*Life table pregnancy rate per 100 sexually active women using lactational amenorrhoea method*

Month post partum	Woman months of exposure	No of pregnancies	Cumulative failure (95% confidence interval)
During correct use*:			
1	60.2	0	0.00 (0.00 to 0.02)
2	189.2	0	0.00 (0.00 to 0.01)
3	217.8	0	0.00 (0.00 to 0.01)
4	217.2	1	0.46 (0.00 to 1.47)
5	196.5	1	0.97 (0.00 to 2.41)
6	149.6	0	0.97 (0.00 to 2.43)
Among all women†:			
1	61.3	0	0.00 (0.00 to 0.02)
2	204.1	0	0.00 (0.00 to 0.01)
3	251.1	0	0.00 (0.00 to 0.01)
4	272.9	1	0.37 (0.00 to 1.21)
5	266.2	2	1.11 (0.00 to 2.52)
6	242.9	1	1.52 (0.00 to 3.14)
During incorrect use‡:			
1	1.1	0	0.00 (0.00 to 0.85)
2	14.9	0	0.00 (0.00 to 0.33)
3	33.3	0	0.00 (0.00 to 0.23)
4	55.7	0	0.00 (0.00 to 0.19)
5	69.6	1	1.43 (0.00 to 5.36)
6	93.3	1	2.48 (0.00 to 7.04)

*Cases are included in life table during those months in which woman was sexually active and not using another contraceptive method (or using withdrawal) and during period when all method criteria are met—that is, during amenorrhoea and before start of regular supplemention.
†Cases are included in life table during those months in which woman was sexually active and not using another contraceptive method (or withdrawal).
‡Cases are included in life table during those months in which woman was sexually active and not using another contraceptive method and during period after one (or more) criteria were unfulfilled—that is, after return of menses or start of regular supplementation, or both.

Table 2—*Cumulative probability* of menstruation, supplementation, weaning, sexual activity, and protection given by lactational amenorrhoea method per 100 women*

Variable	Month post partum											
	1	2	3	4	5	6	7	8	9	10	11	12
Return to menses	NA†	1.9	10.7	18.9	25.2	33.6	38.1	44.3	48.9	53.7	61.2	67.2
Giving regular supplements‡	2.9	7.0	9.6	13.5	19.2	37.6	83.1	95.3	98.8	100.0	100.0	100.0
Weaning	0.4	1.4	1.7	2.5	3.6	5.6	7.2	8.4	9.3	10.7	13.6	14.4
Sexually active	14.0	52.5	75.6	88.7	94.0	96.7	97.4	97.4	98.4	98.4	99.7	99.7
Percentage still protected	97.1	91.1	81.1	70.4	61.7	44.0	NA§	NA§	NA§	NA§	NA§	NA§
No of cases remaining in follow up	485	485	480	464	457	450	440	433	425	417	415	411

NA = not applicable.
*Probability at end of interval...interval = 30.4 days; determined by conventional life table method.
†All bleeding before day 56 post partum ignored.
‡Water as potential supplement ignored.
§By definition, lactational amenorrhoea method can be effective for maximum of six months.

Table 4—*Life table rates of pregnancy during amenorrhoea*

Month post partum	Woman months of exposure*	No of pregnancies	Cumulative failure (95% confidence interval)
1	61.3	0	0.00 (0.00 to 0.02)
2	200.1	0	0.00 (0.00 to 0.01)
3	231.9	0	0.00 (0.00 to 0.01)
4	232.6	1	0.43 (0.00 to 1.38)
5	221.3	1	0.88 (0.00 to 2.20)
6	194.4	0	0.88 (0.00 to 2.20)
7	148.3	0	0.88 (0.00 to 2.22)
8	116.2	1	1.72 (0.00 to 3.65)
9	116.6	1	2.56 (0.18 to 4.94)
10	96.6	0	2.56 (0.13 to 4.99)
11	83.7	0	2.56 (0.07 to 5.05)
12	72.7	0	2.56 (0.02 to 5.11)

*Cases are included in life table during months in which woman was sexually active and not otherwise using contraception (or using withdrawal).

Results

The mean age of the participants was 26.6 years with 8.8 years of education (table 1). They had a mean of 3.2 pregnancies and 2.9 living children. Nearly 80% had never used a modern contraceptive method before.

By conventional life table methods one third of the women had experienced their first menses by six months (table 2), and two thirds of the women were no longer amenorrhoeic at the end of 12 months. Most women started giving supplements in the sixth or seventh month. Three quarters of the women were sexually active by the end of the third month. The median time to the resumption of coitus was seven weeks. The proportion sexually active in any given month never exceeded 86%.

The cumulative pregnancy rate during correct use to the end of the sixth month was 0.97% (95% confidence interval 0% to 2.4%; table 3). During incorrect use, the pregnancy rate was 2.48% (0% to 7.0%) at the end of six months. Among all women during correct or incorrect use pregnancy occurred at a rate of 1.52% (0% to 3.1%) at six months.

At the end of the sixth month, the cumulative rate of pregnancy was 0.88% (0% to 2.2%) among breast feeding amenorrhoeic women (table 4). This rate is virtually the same as the rate of effectiveness of the lactational amenorrhoea method used correctly. At 12 months post partum the rate of pregnancy during lactational amenorrhoea was 2.56% (0% to 5.1%).

Discussion

This study establishes that the lactational amenorrhoea method is effective during correct use. The difference between the rates of pregnancy at six months during correct (1.0%) versus incorrect use (2.5%) was small, suggesting that the method is tolerant of incorrect use.

The efficacy of the method was calculated on the basis of only those months when sexual activity occurred. Therefore effectiveness cannot be attributed to postpartum or lactational abstinence. When intervals of abstinence were removed from the denominator of the pregnancy rate each month, higher but more accurate pregnancy rates are produced than in conventional life tables.[6] This also adjusts appropriately for the first month after birth, when many women abstain. This adjustment should be made for any postpartum method of contraception.

Whether this method affords a high or low amount of contraceptive protection is indicated by comparing these rates with rates for other methods used by breast feeding women up to the sixth month post partum, although contraceptive clinical trials generally exclude breast feeding and postpartum women. (As this study simply established the efficacy of a new method no comparison group was studied.) One study in Buenos Aires involved the early initiation of Ovrette (a progestogen only pill) and non-hormonal methods (75% intrauterine devices).[13] The six month life table pregnancy rate in each group of 250 was 0.5%, although the confidence limits were not stated and the rates were not censored for abstinence. These pregnancy rates compare with the present study during correct use of the method (0.96%) and during lactational amenorrhoea alone (0.88%).

By recruiting only experienced breast feeders we avoided women who would contribute data for only brief durations. Because the subjects were highly selected the study cannot estimate contraceptive effectiveness in an unselected population. Accordingly, the results about effectiveness should be generalised only to women with experience of breast feeding, although it is reasonable to suspect that primiparous women who have no early breast feeding problems would experience a similar degree of protection from pregnancy. As in most contraceptive clinical trials, however, these results can also be viewed as a best case scenario as the women received thorough counselling at the beginning, received frequent follow up, and were highly appropriate candidates for the method.

At the end of a year, one third of the women were still amenorrhoeic. The 12 month life table rate of pregnancy during lactational amenorrhoea was 2.6 per 100. This rate compares with the lowest expected 12 month life table rates for non-breast feeding, normally cycling users of non-medicated intrauterine devices, barrier methods, or spermicides, though less effective than hormonal methods.[14]

The six month rates of pregnancy during use of the method and during lactational amenorrhoea are virtually the same. It seems possible then that the method can potentially be simplified by relaxing the supplementation criterion when women have been educated about the methods of breast feeding that maximise both milk production and the duration of lactational infertility. As good breast feeding practices cause lactational infertility, however, a breast feeding factor such as "fully or nearly fully breast feeding" seems critical to the method algorithm. It may be crucial that women understand how breast feeding causes lactational infertility if they are to gain the contraceptive efficacy seen in this study.

Where use of contraceptives is low the lactational amenorrhoea method may be an acceptable introduction to family planning for people who might not otherwise seek contraception.

Key messages

- The lactational amenorrhoea method provided protection from pregnancy equal to that reported for non-breast feeding women during the use of non-medicated intrauterine devices, barrier methods, or spermicides
- Henceforth, data from clinical trials on contraceptives must be subject to the rigours of multiple censoring such as applied here. By excluding periods of abstinence from the calculation of risk of pregnancy, the contraceptive protection of the method cannot be attributed to postpartum or lactational abstinence
- During the first year post partum, the rate of pregnancy before the return of menses in lactating women was less than 3%

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Effectiveness of the BBC's *999* training roadshows on cardiopulmonary resuscitation: video performance of cohort of unforewarned participants at home six months afterwards

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Abstract

***Objective*—To examine the competence of a cohort trained in cardiopulmonary resuscitation by the BBC's 999 training roadshows.**

***Design*—Descriptive cohort study applying an innovative testing procedure to a nationwide systematic sample. The test sample received an unsolicited home visit and without warning were required to perform cardiopulmonary resuscitation on a manikin while being videoed. The videos were then analysed for effectiveness and safety using the new test.**

***Setting*—Nine cities and surrounding areas in the United Kingdom.**

***Subjects*—280 people aged between 11 and 72.**

***Results*—Thirty three (12%) trainees were able to perform effective cardiopulmonary resuscitation, but of these 14 (5%) performed one or more elements in a way that was deemed to be potentially injurious. Thus only 19 (7%) trainees were able at six months to provide safe cardiopulmonary resuscitation. In addition, large numbers of subjects failed to shout for help, effectively assess the status of the patient, or alert an ambulance. Significantly better performances were recorded by those under 45 years old (31 (14%) *v* 2 (4%) gave effective performances respectively, P<0.05), those who had attended a subsequent cardiopulmonary resuscitation course (8 (40%) *v* 25 (10%) gave effective performances respectively, P<0.0001), and those confident in their initial ability (26 (20%) *v* 7 (6%) gave effective performances respectively, P<0.005). Females were significantly less likely than males to perform procedures in a harmful way (117 (62%) *v* 10 (12%) performed safely respectively, P<0.005).**

***Conclusion*—Television is an effective means of generating large training cohorts. Volunteers will cooperate with unsolicited testing in their home, such testing being a realistic simulation of the stress and lack of forewarning that would surround a real event. Under such conditions the performance of cardiopulmonary resuscitation was disappointing. However, retraining greatly improves performance.**

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Introduction

Bystander cardiopulmonary resuscitation improves survival in people who have a cardiac arrest outside hospital.[1] Consequently, increased emphasis has been placed on training the public in these techniques as a means of reducing mortality from ischaemic heart disease.[2 3] Since 1994 the BBC has organised annual training roadshows on cardiopulmonary resuscitation throughout the United Kingdom to coincide with the broadcasting of its *999* television programme.

Although the effectiveness of bystander cardiopulmonary resuscitation has been shown, the effectiveness of mass training courses such as the BBC's *999* roadshow is less clear. Much evaluation of cardiopulmonary resuscitation training has been concerned with the performances of medical and allied professional staff rather than the lay public.[4-6] With few exceptions,[7] studies that have tried to evaluate training of the lay public have prewarned subjects of testing either explicitly or immediately before retraining.[8] Despite this, most results have been disappointing.[9] We describe an innovative method of evaluating how an unforewarned lay person trained on a roadshow would perform cardiopulmonary resuscitation should a cardiac arrest occur in their home.

Subjects and methods

At each of the 10 roadshows held between April and June 1994, participants were asked to complete an optional card consenting to take part in further unspecified research. A total of 7584 course attenders completed an anonymised demographic questionnaire, and of these 6123 (81%) completed a consent card. The research entailed "cold calling" on a sample of trainees and video recording a simulated attempt at cardiopulmonary resuscitation using a Laerdal Recording Anne Manikin (Norway). Trainees from Londonderry, Northern Ireland, were excluded owing to the sensitivity at that time of undertaking unsolicited house calls there. Those who lived in a postal district outside a 32 km radius of their training centre were also excluded on logistical grounds. This left 4651 cards, from which a 6% (n = 280) stratified random sample was chosen by