Human Reproduction Vol.16, No.11 pp. 2278–2282, 2001

# The relationship between cervical secretions and the daily probabilities of pregnancy: effectiveness of the TwoDay Algorithm

**D.B.Dunson[1,4], I.Sinai[2] and B.Colombo[3]**

[1]Biostatistics Branch, MD A3-03, National Institute of Environmental Health Sciences, PO Box 12233, Research Triangle Park, NC 27709, [2]Institute for Reproductive Health, Georgetown University, Washington, DC, USA and [3]Department of Statistics, University of Padua, Padua, Italy

[4]To whom correspondence should be addressed. E-mail: dunson1@niehs.nih.gov

**BACKGROUND: The TwoDay Algorithm is a simple method for identifying the fertile window. It classifies a day as fertile if cervical secretions are present on that day or were present on the day before. This approach may be an effective alternative to the ovulation and symptothermal methods for populations and programmes that find current natural family planning methods difficult to implement. METHODS: We used data on secretions from a large multinational European fecundability study to assess the relationship between the days predicted to be potentially fertile by the TwoDay Algorithm and the day-specific probabilities of pregnancy based on intercourse patterns in 434 conception cycles from the study. RESULTS: The days around ovulation that had the highest fecundability were the days most likely to be classified as fertile by the TwoDay Algorithm. In addition, intercourse on a particular day in the fertile interval was twice as likely to result in a pregnancy if cervical secretions were present on that day or the day before. CONCLUSIONS: The TwoDay Algorithm is effective, both in identifying the fertile days of the cycle and in predicting days within the fertile interval that have a high pregnancy rate. Our data provide the first direct evidence that cervical secretions are associated with higher fecundability within the fertile window.**

*Keywords:* Bayesian/cervical secretions/fecundability/fertile interval/natural family planning

## Introduction

A substantial number of women worldwide attempt to avoid pregnancy by predicting the fertile days of their cycle and abstaining from intercourse on those days (Stanford *et al*., 1998). One of the main methods used to identify the fertile days is the ovulation method, which relies on changes in cervical mucus throughout the cycle. If used perfectly the ovulation method is effective at preventing pregnancy (Guida *et al*., 1997), but efficacy decreases drastically with imperfect use (Trussel and Grummer-Strawn, 1990). Results are similar for the symptothermal method, the most widely used alternative to the ovulation method (Frank-Herrmann *et al*., 1991).

Many couples practising periodic abstinence to avoid pregnancy do not use the ovulation or symptothermal methods, or use them incorrectly, possibly due to the complexity and extensive teaching process needed. The TwoDay Algorithm has been proposed as a simple alternative to these methods (Sinai *et al*., 1999). The TwoDay Algorithm predicts a woman to be fertile on a given day if she notices secretions on that day or the day before, where secretions are broadly defined to include symptoms of dampness without noticeable mucus or discharge, noticeable mucus without discharge, or visible vaginal discharge, excluding that attributable to menstruation, intercourse or known occurrence of disease. The woman using the TwoDay method does not need to distinguish among types of secretions, but merely to note whether or not she has any.

The aim of this article is to assess the relationship between secretions and day-specific fecundability in order to evaluate the theoretical effectiveness of the TwoDay Algorithm. The efficacy of natural family planning (NFP) methods, which rely on mucus characteristics, is thought to be due to accurate prediction of the fertile days through prediction of impending ovulation. Our hypothesis is that the presence of secretions is predictive of not only impending ovulation, but also of the day-specific pregnancy probabilities within the fertile interval defined relative to ovulation. Using data from a large multinational European fecundability study (Colombo and Masarotto, 2000), we estimate (i) the day-specific probabilities that secretions were present on a particular day within the fertile interval or on the day before; (ii) the day-specific probabilities of conception conditional on secretion status for couples having intercourse on a given day relative to a basal body temperature (BBT)-based proxy for ovulation; and (iii) the day-specific probabilities that the TwoDay Algorithm fails

**Table I.** Classification of mucus symptoms and secretions

| Mucus type | Feeling | Appearance | Secretions[a] |
|---|---|---|---|
| 0 | No information | No information | No information |
| 1 | Dry, rough and itchy or nothing felt | Nothing seen | No secretions |
| 2 | Damp | Nothing seen | Secretions |
| 3 | Damp | Mucus is thick, creamy, whitish, yellowish, not stretchy/elastic, sticky | Secretions |
| 4 | Wet, slippery, smooth | Mucus is transparent, like raw egg white, stretchy/elastic, liquid, watery, reddish | Secretions |

[a]Definitions of 'secretions' for application of TwoDay Algorithm

to predict fertility for a given day in the fertile interval and that intercourse on that day results in a pregnancy.

## Materials and methods

### *Description of study design and data*

The European Study of Daily Fecundability (ESDF) is a prospective cohort study conducted to determine the daily probability of conception on each cycle day relative to ovulation for healthy women in their reproductive years. Initial results of the study have been reported (Colombo and Masarotto, 2000). From 1992–1996, 782 women were recruited from seven European centres (Milan, Verona, Lugano, Düsseldorf, Paris, London and Brussels) providing services on fertility awareness and NFP. Women enrolled in the study were experienced in the use of an NFP method, married or in a stable relationship, 18–40 years of age (mean 28.9, SD 4.0), had at least one menses after cessation of breastfeeding or delivery, and were not currently taking hormonal medication or drugs affecting fertility. In addition, neither partner could have a history of fertility problems and couples were required to not mix unprotected and protected intercourse.

In each menstrual cycle, women kept daily records of BBT, cervical mucus symptoms and coitus. Cycles in which some form of contraception was used (e.g. condom) were excluded from the analysis. For our purposes, the daily mucus symptom data described in Table I are used to classify each day as covered or not covered by the TwoDay Algorithm. The daily BBT data are used to estimate the day of ovulation within each menstrual cycle (for cycles in which sufficient BBT data are available) using the three over six rule (Marshall, 1968) as described by Colombo and Masarotto (Colombo and Masarotto, 2000). We use a BBT-based proxy for ovulation day instead of the cervical mucus peak, since the daily mucus symptom measurements may be informative about measurement error in the peak, causing bias in evaluation of the effects of secretions on the day-specific probabilities of conception. Out of 7288 menstrual cycles of data, there is sufficient information to identify a BBT reference day in 5860 cycles. A total of 2832 cycles remained after excluding cycles with no reported intercourse acts within an 11 day window beginning eight days prior to and ending two days after (–8,2) the identified ovulation day. Out of the remaining cycles, there were 434 detected pregnancies.

### *Bayesian hierarchical modelling approach*

We analysed the data using a Bayesian hierarchical modelling approach in which prior distributions are chosen for each of the unknowns in a statistical model. Inferences about quantities of interest are then based on posterior distributions, which summarize the information in the prior and in the current data. A full description of the Bayesian approach is beyond the scope of this article, and the reader should refer to papers by Dunson, Gurrin *et al*., and Lilford and Braumholtz for more information (Gurrin *et al*., 2000; Lilford and Braumholtz, 2000; Dunson, 2001). Beyond ideological considerations, our primary motivations for using a Bayesian approach were (i) the ease in which information from previous studies of day-specific fecundability can be incorporated into the analysis; and (ii) the availability of software for fitting of Bayesian models of day-specific fecundability using Markov chain Monte Carlo (MCMC) methods (Tierney, 1994).

### *Estimating the day-specific probabilities of coverage*

In order for the TwoDay Algorithm to cover a given day relative to ovulation (say day $k$), there must be noticeable secretions on that day ($k$) or the day before ($k$–1). We were interested in obtaining estimates of the probabilities of coverage for different days in an 11 day (–8,2) fertile window around the identified ovulation day. Although we could simply calculate the proportion of cycles covered on day $k$, for $k$ = –8,–7,...,1,2, binomial standard errors and confidence limits are not valid in the presence of heterogeneity among women and among different menstrual cycles from a given woman. Such heterogeneity can result from differences between women and cycles in the frequency of days with secretions. To account for and obtain information about dependency in the coverage indicators, we fitted a multilevel probit model (Chib and Greenberg, 1998; Dunson, 2000) with vague priors chosen for the parameters as Spiegelhalter *et al*. have described (Spiegelhalter *et al*., 1996).

### *Modelling the probability of pregnancy*

We were also interested in assessing the relationship between the presence of noticeable secretions and the daily probabilities of pregnancy in cycles with intercourse on a given day relative to ovulation. Since the specific intercourse act responsible for a pregnancy cannot be determined with certainty in cycles having multiple days with intercourse, a statistical model is used to relate the intercourse pattern relative to ovulation to the probability of pregnancy. This approach has been used previously for incorporating information from cycles with multiple intercourse acts in estimating day-specific pregnancy probabilities (Barrett and Marshall, 1969; Wilcox *et al*., 1995; Colombo and Masarotto, 2000).

Most analyses of this type have used either the Barrett and Marshall or the Schwartz *et al*. models (Barrett and Marshall, 1969; Schwartz *et al*., 1980). These models are based on the assumption that batches of spermatozoa introduced into the reproductive tract on different days mingle and then compete independently in attempting to fertilize the ovum. A complication of the ESDF data set (and of most data sets of this type) is that the majority of couples contribute multiple menstrual cycles of data and there is evidence of heterogeneity among couples in biologic fecundability, defined here as the probability of pregnancy in a menstrual cycle conditional on intercourse behaviour. Also, as low concentrations of cervical mucins result in impaired sperm motility (Eriksen *et al*., 1998), we expect that cervical secretions are positively correlated with fecundability even when adjustment is made for the timing of intercourse relative to ovulation.

To account for these important features of our data, we have used the following model for the probability of pregnancy in a menstrual cycle:

$$\Pr(\text{Pregnancy in cycle } j \text{ from couple } i) = A_i \left\{ 1 - \prod_k (1 - p_k R^{1-C_{ijk}})^{X_{ijk}} \right\}$$

where $A_i$ is the 'cycle viability' probability for couple $i$, which is the probability that the aggregate of all factors not related to timing of intercourse or days of cervical secretions are favourable to pregnancy; $C_{ijk}$ and $X_{ijk}$ are indicators of secretions (defined by having secretions that day or the day before, the TwoDay Algorithm) and of intercourse respectively, on day $k$ of cycle $j$ from couple $i$; $p_k$ is interpretable as the probability that pregnancy would occur with intercourse only on day $k$ if the cycle were viable and day $k$ met the criterion for secretions; and $R$ accounts for a multiplicative change in the day-specific pregnancy probabilities due to the absence of secretions on a given day or the day before. The probability of pregnancy for couple $i$ in a cycle with intercourse on only day $k$ is $A_i p_k$ if day $k$ meets the criterion for secretions, and is otherwise $A_i p_k R$. If the occurrence of secretions conveys an increased likelihood that intercourse on a particular day results in a clinical pregnancy, then $R$ should be $<1$. By accounting for differences in the day-specific pregnancy probabilities between days covered and those not covered by the TwoDay Algorithm, this model extends an approach proposed in earlier work (Dunson and Zhou, 2000).

Following Dunson and Zhou, we used a probit mixture model for the couple-specific cycle viability probability $A_i$ (Dunson and Zhou, 2000). Informative prior distributions were chosen for the parameters in this probit model and for the day-specific $p_k$ based on results from an analysis (Dunson and Weinberg, 2000a) of the Wilcox *et al*. data (Wilcox *et al*., 1995). Since, to our knowledge, there are no previous data relating the occurrence of secretions directly to changes in day-specific fecundability, we chose a vague (i.e. non-informative) prior for $R$. We used an MCMC algorithm (Dunson and Zhou, 2000) to fit the model, after incorporating a Metropolis-Hastings step (Hastings, 1970) for the parameter $R$ and a data augmentation step (Tanner and Wong, 1987) for imputing the coverage indicators for days on which coverage data are unavailable (e.g. due to missing secretion information).

## Results

### *Day-specific probabilities of coverage*

We estimated the probability of coverage by the TwoDay Algorithm for each day in the (–8,2) interval, which begins eight days prior to and ends two days after the identified ovulation day. The estimated coverage probabilities are shown in Figure 1 for women and cycles falling in different percentiles of the population distribution for the frequency of days in the (–8,2) interval on which secretions were noticed or had been noticed the day before. The coverage probabilities were high across the (–8,2) window of potential fertility for typical cycles from typical women, where 'typical' is defined as being in the middle (50th percentile) of the population distribution for the frequency of days covered. Although the coverage probabilities were noticeably lower for women and cycles in the 10th percentile, these probabilities were still high on the days of peak fertility. Our data suggest that, for most women, the TwoDay Algorithm is very effective in identifying the fertile

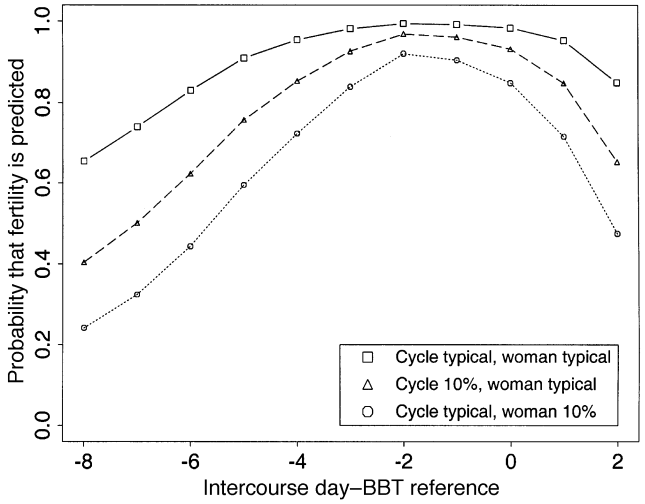


**Figure 1.** Estimated probabilities of coverage by the TwoDay Algorithm, which covers a particular day (that is, predicts the day to be potentially fertile) if there are noticeable secretions on that day or the day before. Estimates are based on data for 2832 cycles from 660 women. Typical cycles and women are in the 50th percentile of the estimated population distribution for the frequency of days in the (–8,2) interval that are covered by the TwoDay Algorithm. Estimates are also provided for cycles and women in the 10th percentile.

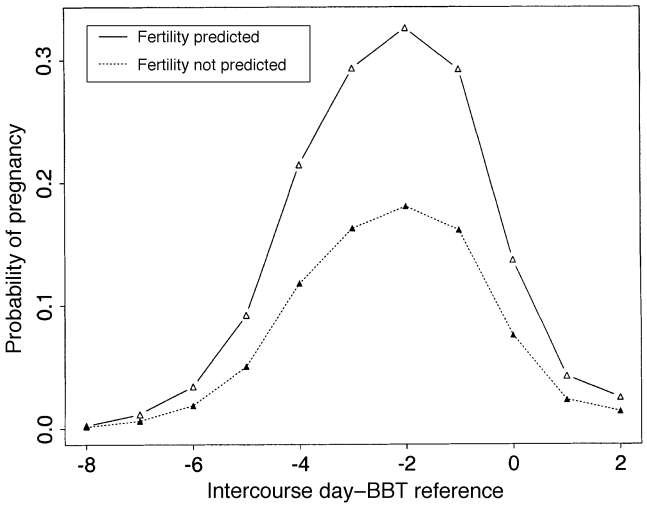


**Figure 2.** Estimated probability of achieving a clinical pregnancy based on a single act of intercourse conditional on whether or not the TwoDay Algorithm classified the index day as potentially fertile. The TwoDay Algorithm predicts the index day to be potentially fertile, and hence covers that day, if noticeable secretions were present on the index day or day –1.

days of the cycle. We also found that most of the heterogeneity among cycles in the frequency of days predicted to be fertile by the TwoDay Algorithm is attributable to differences between women and not to differences between cycles from a given woman (posterior $P$-value: $P < 0.001$).

### *Day-specific probabilities of pregnancy*

We estimated the day-specific probabilities of pregnancy due to a single intercourse act in the (–8,2) window of potential fertility for days covered and those not covered by the TwoDay Algorithm. These estimates are shown in Figure 2 for typical

**Table II.** Estimated probabilities that a given day relative to ovulation is not covered by the TwoDay Algorithm and that unprotected intercourse on that day results in a clinical pregnancy[a]

| Day relative to ovulation[b] | Estimated probability | Standard error | 95% Interval |
|---|---|---|---|
| –8 | 0.0005 | 0.0006 | 0.0000, 0.0024 |
| –7 | 0.0017 | 0.0012 | 0.0003, 0.0050 |
| –6 | 0.0032 | 0.0016 | 0.0011, 0.0073 |
| –5 | 0.0045 | 0.0020 | 0.0017, 0.0095 |
| –4 | 0.0053 | 0.0020 | 0.0022, 0.0101 |
| –3 | 0.0030 | 0.0011 | 0.0012, 0.0056 |
| –2 | 0.0011 | 0.0005 | 0.0004, 0.0023 |
| –1 | 0.0013 | 0.0005 | 0.0005, 0.0026 |
| 0 | 0.0012 | 0.0006 | 0.0004, 0.0028 |
| +1 | 0.0011 | 0.0006 | 0.0003, 0.0028 |
| +2 | 0.0021 | 0.0012 | 0.0005, 0.0052 |

[a]Estimates are for a typical cycle from a typical couple.
[b]Last day of hypothermia is used as marker of ovulation day.

couples; that is, couples in the middle of the population distribution for biologic fecundability. The pregnancy rate peaks two days prior to the estimated ovulation day and is highest in the six day interval starting five days prior to and ending on the estimated ovulation day. Intercourse on any particular day relative to ovulation had a higher probability of resulting in a pregnancy if secretions were present on that day or the day before (considered fertile days by TwoDay Algorithm) ($P < 0.001$). We estimate that on a given day relative to ovulation (estimated by the last day of hypothermia prior to post-ovulatory rise in BBT), the probability of pregnancy is reduced by nearly 50% for women who have not had secretions for 2 days [$R = 0.56$, 95% confidence interval (0.25, 0.94)].

### *Day-specific failure rates*

In addition to the day-specific coverage and pregnancy probabilities, we estimated the day-specific probabilities that the TwoDay Algorithm fails to cover a particular day in the (–8,2) interval and that non-contracepting intercourse on that day results in a clinical pregnancy. These estimates are presented in Table II. For each day in the (–8,2) window of potential fertility, the estimated failure probabilities are $<0.01$. Although these day-specific probabilities are very small, the cumulative pregnancy rate in a year of perfect-use for couples having frequent intercourse on days identified as infertile is more moderate. We estimate that a normal couple that abstains from intercourse on days classified as fertile and has intercourse on one quarter of the days that are classified as infertile has a first-year pregnancy rate (assuming 13 menstrual cycles per year) of 8.2% [95% interval (3.9, 13.3)].

## Discussion

A substantial proportion of women are interested in using fertility-awareness methods of contraception, based on identifying the fertile days in the menstrual cycle (Stanford *et al*., 1998). Such methods are appealing for many women since they are low cost, have no side effects, and do not involve drugs or the use of devices with intercourse. Fertility-awareness is particularly important for women in developing countries in which hormonal contraceptives are not widely available. In such countries, control of population size is a major public health concern and there is a critical need for low cost and easily distributed contraceptive methods. In addition to the necessity of abstaining from intercourse on the identified fertile days, the primary drawback cited for fertility-awareness methods is low effectiveness. However, if used properly, several methods are available that have been shown to be highly effective in preventing pregnancy. These include the widely used Billing's ovulation method, based on monitoring of changes in cervical mucus, and the symptothermal method. Unfortunately, most providers of fertility-awareness do not offer these methods due to their complexity. Based on Demographic and Health Survey data, substantial numbers of women in developing countries attempt to time intercourse to avoid pregnancy using unvalidated methods. There is clearly a need for simple and effective approaches, such as the TwoDay Algorithm (Sinai *et al*., 1999).

The primary goal of this article was to assess the relationship between secretions and the daily probabilities of pregnancy in order to evaluate the theoretical effectiveness of the TwoDay Algorithm. We focused our evaluation on the sensitivity of the TwoDay Algorithm and not on the specificity, since estimates of the average number of days identified as fertile (9.0) and of the probabilities of misclassification for days outside the fertile interval have been reported (Sinai *et al*., 1999). In addition, although the data from the ESDF are extremely informative about the association between fecundability and the occurrence of secretions within the fertile interval, other data sets are more appropriate for evaluation of the distributions of mucus characteristics across the cycle.

We found that the days relative to ovulation on which intercourse has a non-negligible probability of resulting in a pregnancy are typically predicted to be fertile by the TwoDay Algorithm. In addition, we found that intercourse on any given day relative to ovulation is significantly more likely to result in a pregnancy if the TwoDay Algorithm predicts that day to be fertile; that is, if there were noticeable secretions on that day or the day before. Finally, we found that if typical women use the TwoDay Algorithm, their estimated probability of becoming pregnant will be low; though the acceptability of the approach among users and providers of natural family planning methods remains to be fully evaluated. In addition, it appears that secretion data are informative about not only the timing of the fertile days in the cycle but also the probability of pregnancy on a given day relative to ovulation.

Although the efficacy of methods that use mucus and secretion data to identify the fertile days of the menstrual cycle has long been recognized (Guido *et al*., 1997), to our knowledge these are the first data demonstrating a relationship between secretions and day-specific fecundability adjusting for the timing of intercourse relative to the identified ovulation day. Considering the imprecision and subjectivity inherent in classifying a day as having detectable secretions, the magnitude of the difference in the probabilities of pregnancy between days covered and those not covered by the TwoDay Algorithm

is striking. Intercourse on a particular day is ~half as likely to result in a pregnancy if there were no noticeable secretions on that day or the day before. Our data provide further evidence of the important link between mucus and vaginal moisture and human fertility. These results have important implications for clinicians treating couples attempting pregnancy. It appears that couples can increase their chance of achieving pregnancy by simply timing intercourse on days with noticeable secretions. This simple approach may even outperform use of expensive urinary LH kits, which can miss the majority of the fertile interval occurring one or more days prior to ovulation (Dunson *et al*., 1999).

The estimated day-specific probabilities of pregnancy presented in Figure 2 based on the European data follow a similar pattern to that seen in the North Carolina Early Pregnancy Study (Wilcox *et al*., 1998). For the European study, the day of ovulation was estimated from the last day of hypothermia preceding the post-ovulatory rise in BBT. The North Carolina study instead estimated ovulation day from the rapid decline in the ratio of oestrogen to progesterone that accompanies luteinization of the ovarian follicle, based on urinary hormone metabolites (Baird *et al*., 1991). For both data sets, the estimated day-specific pregnancy probabilities peak two days prior to the identified ovulation day and are low outside of the six day interval ending on the estimated day of ovulation. The Baird *et al*. approach used in the North Carolina study to estimate ovulation day has been shown to be highly accurate in a recent validation study that used ultrasound to document directly the time of follicular rupture for a large number of menstrual cycles (Baird *et al*., 1991; Rene Ecochard, personal communication). Thus, the similarity between the day-specific estimates in the European and North Carolina studies suggests that bias caused by measurement error in the BBT-based marker of ovulation may be low. Although measurement error may have contributed to the non-zero pregnancy rates estimated from the European data for intercourse outside the six day fertile interval (Dunson *et al*., 1999; Dunson and Weinberg, 2000b), these non-zero estimates may also reflect the much larger number of cycles and pregnancies in the European data set.

## Acknowledgements

We would like to thank Donna Baird, Allen Wilcox, Clarice Weinberg, and Joseph Stanford for their many helpful comments.

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*Received on January 15, 2001; accepted on June 14, 2001*