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Benchmark Pregnancy Rates and the Assessment of Post-coital Contraceptives: An Update

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Abstract

Objective—In 2001, we provided benchmark estimates of probability of pregnancy given a single act of intercourse. Those calculations assumed that intercourse and ovulation are independent. Subsequent research has shown that this assumption is not valid. We provide here an update of previous benchmark estimates.

Study Design—We reanalyze earlier data from two North Carolina studies that collected daily urine samples and recorded daily intercourse for multiple menstrual cycles. One study comprised 68 sexually active women with either an intrauterine device or tubal ligation. The second was of 221 women who planned to become pregnant and had discontinued use of any birth control at enrollment. Participants had no known fertility problems. New statistical analyses were based on Monte Carlo simulations and Bayesian methods.

Results—The probability that a single act of intercourse occurs within a woman's fertile window is 25%, compared with 20% in previous calculations. The probability of pregnancy with intercourse on a given menstrual cycle day is correspondingly higher than previously estimated, with the largest increases occurring on menstrual days 12–22. These increases are, however, fairly small (for example, the peak chance of conception on menstrual-day 13 increased from 8.6% to 9.7%).

Conclusions—Previous benchmark rates of pregnancy with one act of intercourse were moderately underestimated due to a mistaken assumption about the independence of intercourse and ovulation.

Implications Statement—The chance of pregnancy with a single act of unprotected intercourse is greater than previously estimated. Previous benchmarks may underestimate the efficacy of post-coital contraception.

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Keywords

Emergency contraception; Post-coital contraception

1. Introduction

In 2001, we published estimates of the probability of pregnancy given a single act of intercourse on a given menstrual-cycle day, taking into account the natural variation in day of ovulation [1]. While this paper has been frequently cited (139 citations, Web of Science, 12 December 2014), the estimates rested on the then untested assumption that intercourse and ovulation are independent. That is, we assumed that the timing of ovulation is not influenced by intercourse, and that the physiological events leading to ovulation do not affect the frequency of intercourse.

Subsequent research has shown that this assumption is not accurate: frequency of intercourse rises during the follicular phase, peaks around ovulation, and declines thereafter [2]. The biological mechanisms that link intercourse and ovulation are unknown. The link may be due to cycle changes in a woman's libido [3–6], to an increase in male-initiated intercourse [7] in response to female pheromones [8], or to an act of intercourse accelerating ovulation [9,10]. Regardless of the exact biological mechanism, women who engage in unplanned and unprotected acts of intercourse are presumably more likely to do so when they are close to ovulating and thus vulnerable to pregnancy. Previous estimates of pregnancy probability have not taken this pattern into account, which raises questions about the validity of earlier benchmark estimates of conception probabilities. Any changes in these estimates may have implications for the evaluation of the efficacy of post-coital emergency contraceptives.

We revisit this question using Bayesian statistics and modeling to estimate the probability of conception given unprotected intercourse, taking into account the non-independence of intercourse and ovulation.

2. Materials and methods

As in our earlier analysis, we use data from two North Carolina studies. In one, 68 sexually active women with either an intrauterine device or tubal ligation provided data for up to three menstrual cycles. Of these women, 38 had a non-hormonal intrauterine device (90 cycles) and 30 had tubal ligation (81 cycles). These women collected daily first-morning urine specimens and kept daily diaries of intercourse and menstrual bleeding. Most participants were white, college-educated, parous, and in their late twenties or early thirties. All were in a stable sexual relationship and had no chronic illnesses or history of fertility problems. These data were originally gathered to assess hormone patterns in non-pregnant sexually active women of reproductive age and have been extensively described [11,12].

Data were also drawn from a prospective study of early pregnancy conducted in North Carolina. This study comprised 221 women (696 cycles) who planned to become pregnant by discontinuing any use of birth control, and who had no known fertility problems. These

women also collected daily first-morning urine samples and recorded menstrual bleeding and unprotected intercourse daily. Most were white and well educated, with ages ranging from 21–42 (mean of 30). Further descriptions can be found elsewhere [12,13].

2.1 Identifying day of ovulation

Day of ovulation was identified through serial changes in daily urinary hormones. Daily urinary levels of estrone-3-glucuronide (a primary urinary metabolite of estradiol) and pregnanediol 3-glucuronide (a metabolite of progesterone) were measured using competitive time-resolved fluoroimmunoassays [14]. Day of ovulation was defined using an algorithm based on the rapid change in the ratio of estrogen-to-progesterone metabolites around ovulation [15,16]. This algorithm has subsequently been validated as a marker of ovulation [17,18].

2.2 Statistical analyses overview

Our purpose is to estimate the probabilities of conception following a single act of intercourse, both unconditional and conditional on menstrual cycle day. Ideal data for this purpose would come from a large sample of cycles from non-contracepting, sexually active women with a single act of unprotected intercourse in each cycle and an accurate marker of ovulation day. Such data are unavailable and are unlikely to become available. Women who do not want to become pregnant would not participate in such a study, and women who wish to become pregnant are unlikely to naturally engage in a single act of intercourse every cycle. Furthermore, a woman trying to become pregnant would presumably be unwilling to seek emergency contraception.

Instead, we rely on flexible statistical models that combine data from various sources to obtain indirect but reliable estimates. Specifically, we use statistical models to characterize (i) variability among women and cycles in the lengths of their luteal and follicular phases; (ii) the probability of intercourse on each day of the cycle relative to ovulation; and (iii) the probability of conception from a single act of intercourse on a given day of the cycle relative to ovulation. Additional details about the models can be found in subsection 2.3.

The probabilities of interest can then be estimated based on the parameters from these component models. Our Monte Carlo simulations assume for the sake of simplicity that acts of intercourse in the empirical data are independent of one other, that cycle length is not related to the association of intercourse and ovulation, and that follicular and luteal phase lengths are independent. We simulate a large number of menstrual cycles with varying cycle lengths, varying days of ovulation, and a single act of intercourse. We also simulate whether or not each cycle resulted in conception. This simulation statistically estimates the hypothetical but infeasible clinical study mentioned above. From these simulations, we can directly estimate the probabilities of interest.

2.3 Component models

To model the within- and between-women variability in follicular and luteal phase lengths, we combined data from all datasets described above. This assumes that a woman's cycle length is not influenced by her intercourse behavior or by whether she is trying to conceive.

We modeled follicular and luteal phase lengths with two separate log-t hierarchical models. As had been done earlier, we modeled the observed follicular- and luteal-phase lengths with two different log-t distributions [1]. However, instead of weighting a woman's observed number of ovulatory cycles by the reciprocal of her total number of observed cycles, we included a random effect for women (one effect for luteal-phase length and another independent effect for follicular-phase length) to prevent less-fertile women from being overrepresented. This approach takes into account the observed right-skewed distributions of phase lengths, while allowing for average follicular and luteal lengths to vary across women. For each phase, we estimated a mean parameter that represented the average phase length for all women, a variance parameter that estimated the variability of a woman's phase lengths, and a second variance parameter that estimated how much each woman's average phase length varied relative to the total average. This model provided an excellent fit to the data.

To estimate the probability of intercourse on each day relative to day of ovulation, we excluded the 221 women attempting conception and restricted analysis to the 68 women using birth control. Intercourse frequencies reach their highest levels during the 6 fertile days of the cycle (the 6 consecutive days ending with ovulation) [2]. To account for this dependence, and also to acknowledge potential errors in the estimated day of ovulation, we allowed the probability of intercourse to vary between days -6 to +1 relative to ovulation, while assuming as a simple approximation that the probability of intercourse was constant outside this fertile window. In other words, we estimated nine total probabilities of engaging in a single act of intercourse: one for each day between -6 to +1 days relative to ovulation, and one for all days outside this interval. We put a non-informative beta prior (i.e. a uniform distribution) on each of these 9 probabilities, and modeled acts of intercourse with a Bernoulli distribution. Non-informative priors are more objective and allow for the data to drive the results of the analyses. A Bernoulli distribution is used, as there are only two possible outcomes for each probability parameter (intercourse or no intercourse).

For estimating the probability of conception given intercourse on a given day of the menstrual cycle, we used our earlier methods. The mean probability of a clinical pregnancy with a single act of intercourse had been estimated as 0.04, 0.13, 0.08, 0.29, 0.27, and 0.08 for the 6 consecutive days ending with ovulation. Additional details about this method can be found elsewhere [19]. Outside this six-day interval, the estimated probability was <0.01, and we therefore fixed the probability of clinical pregnancy outside the six-day window as zero [1].

3. Results

If intercourse and ovulation were completely independent (as had been assumed earlier), then the probability of a single act of intercourse occurring on the day of ovulation would simply be 1 divided by the number of days in the menstrual cycle. In our models this probability is 3.3%. However, when we take into account the observed dependence of intercourse and ovulation, the estimated probability of intercourse falling on day of ovulation is actually 4.5%. Table 1 provides the observed and expected probabilities of a single act of intercourse occurring on the day of ovulation and the week leading to

ovulation. The five days before ovulation and the day of ovulation itself comprise the 6 fertile days of the cycle. The probability of intercourse is higher than expected on each of the fertile days, and then falls below expectation on the sixth day before ovulation.

Table 2 provides the estimated probability of ovulation within a certain number of days, given that a single unplanned act of intercourse has occurred. The probability that a woman is in her fertile days after a single act of intercourse is 25% (0.247 chance of ovulation on the day of intercourse or within five days after), compared with 20% (0.198) if there were no association between intercourse and ovulation.

Figure 1 plots the new estimated probabilities of conception from a single act of unprotected intercourse on a given day of the menstrual cycle, taking into account the dependence of intercourse and ovulation. Figure 2 compares the new probabilities (smoothed curve) with the earlier estimates (which had assumed intercourse and ovulation are independent). The updated probabilities are greater on every menstrual day from day 1 through 28, with the largest differences occurring in mid-cycle (days 12 to 22). The menstrual day with the highest probability of pregnancy is day 13 in both analyses, with absolute probability rising from 8.6% to 9.7% (a relative increase of 13%).

As expected, these probabilities differ for women who reported regular cycles and women who reported irregular cycles (Figure 3). (We could not separate intercourse behaviors by cycle regularity, as there were only six sexually active women who reported having irregular cycles.) Women with irregular cycles have lower probabilities of pregnancy in mid-cycle and higher probabilities late in the cycle. Table 3 provides the raw data for these figures, together with estimated values from the previous benchmark paper.

4. Discussion

In our previous paper estimating benchmark conception rates with a single act of intercourse, we assumed that intercourse and ovulation are independent. Subsequent analyses showed that intercourse is in fact more likely around ovulation (and specifically within the fertile days of the cycle). We estimate that a single act of intercourse occurs during the fertile window for 25% of women, compared with only 20% if intercourse were random with regard to ovulation.

It follows that the previous analysis underestimated the chance of pregnancy with a single act of intercourse. The extent of underestimation, however, is not simple to calculate. We use Bayesian methods and simulations to incorporate the dependence of intercourse and ovulation, and thus to provide new benchmark rates of pregnancy. For menstrual cycle days 1 through 28, our updated probabilities are higher than previous estimates. Differences are largest in late mid-cycle (days 13 through 20), during which the absolute increase in daily probabilities of pregnancy ranged from 1.0% to 1.7%. Differences late in the menstrual cycle (from day 30 on) are more difficult to interpret and may be caused by small changes in our methodology (such as modeling follicular phase lengths differently, incorporating luteal phase lengths, and adding in new data). While our revised methods suggest lower late-cycle rates of pregnancy than previously calculated, these estimates are based on small numbers and are less likely to reflect real differences.

We had earlier reported striking differences in daily probabilities of pregnancy between women with regular cycles and those with irregular cycles [1]. Compared with women who have regular cycles, women with irregular cycles (which presumably could include young women whose cycles may not yet have established a regular pattern) are at markedly higher risk of pregnancy with intercourse later in the menstrual cycle (after day 20 or so). These trends persist in our re-analysis (Table 3).

Our results have implications for the evaluation of efficacy of post-coital contraceptives. The most common emergency contraception pill is levonorgestrel (Plan B One-Step®) [20]. Levonorgestrel works by suppressing ovulation and delaying the luteinizing hormone surge [21–23]. Ulipristal acetate acts by a mechanism similar to levonorgestrel, but is longer-acting [20]. A pharmacodynamics study assessed the ability of these two emergency contraceptive products to postpone ovulation until after sperm has lost its viability (i.e. after 5 days) [24]. Investigators gave the medications close to ovulation (when the follicle had reached a diameter of 18 mm) and monitored subsequent ovulation by daily ultrasound. Levonorgestrel postponed ovulation by a mean of 2 days, while ulipristal acetate postponed ovulation 6 days.

A direct evaluation of efficacy of post-coital contraceptives presents logistic and ethical challenges [25]. One indirect approach has been through the application of baseline pregnancy rates such as those we previously published [1]. Our revised estimates (showing higher risks of pregnancy during most of the cycle) suggest that the efficacy of post-coital contraceptives based on our earlier benchmarks [26] may have been somewhat underestimated. Another application of these data could be in comparing efficacy among post-coital contraceptives. Given that various post-coital contraceptives may differ in the length of time they are able to disrupt ovulation after administration, the results in Tables 1 and 2 may be of utility in specifying comparative efficacy.

Important limitations in our study include demographic differences between women in our studies and women who seek emergency contraception. Women in our studies were in stable sexual relationships, with the majority trying to conceive. Most women were 25–35 years of age and well educated, and none had known fertility problems. However, aside from possible differences in baseline fertility, there are no obvious biological differences between our study women and users of post-coital contraceptives that would limit the application of these estimates.

Other limitations include relatively small sample sizes in certain analytic strata. Only 40 women with irregular cycles contributed to modeling cycle lengths, of whom 6 contributed to modeling intercourse probabilities (compared with 244 and 62 women for regular cycles). If there are differences in the intercourse behaviors between women with regular and irregular cycles, these differences may influence our estimates.

In conclusion, the probability of pregnancy given a single act of intercourse is moderately higher than we had previously estimated, owing to the dependence of intercourse and ovulation. The efficacy of post-coital contraception may be greater than estimates based on our earlier data.

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Figure 1.

New Conception Probabilities.

Probability of clinical pregnancy after observing one unprotected act of intercourse relative to the day of the menstrual cycle. Dots are estimated probabilities, while the line is a smoothed function of the estimated probabilities.

Figure 2.

New and Old Conception Probabilities

Smoothed estimated probabilities of clinical pregnancy after observing one act of unprotected intercourse on a given day of the menstrual cycle. The updated estimates account for an increase in the frequency of intercourse near ovulation, while the old estimates [1] assume that intercourse and ovulation are independent.

Figure 3.
New Conception Probabilities by Cycle Regularity
Smoothed estimated probabilities of clinical pregnancy after observing one act of unprotected intercourse on a given day of the menstrual cycle for women with regular and irregular cycle lengths.

Table 1

Probability that one act of intercourse will occur on the day of ovulation or the week before. (Intercourse on the day of ovulation or within the five days before ovulation defines potentially fertile days.)

Intercourse on a given day relative to ovulation	Observed (based on Bayesian modeling)	Expected if intercourse and ovulation were independent
Day of ovulation ^a	0.045	0.033
1 day before ^a	0.040	0.033
2 days before ^a	0.041	0.033
3 days before ^a	0.039	0.033
4 days before ^a	0.039	0.033
5 days before ^a	0.042	0.033
6 days before	0.032	0.033
7 days before	0.030	0.033

^aPotentially fertile day

Table 2

Cumulative probability of ovulation within a certain number of days from intercourse, given one act of intercourse (ovulation on the day of intercourse or within five days after intercourse defines potentially fertile days.)

Days Since Intercourse	Cumulative Probability of Ovulation	Cumulative Probability of Ovulation (if intercourse independent of ovulation)	Difference (95% central credible interval)
0 ^a	0.045	0.033	0.012 (0.003, 0.024)
1 ^a	0.086	0.066	0.020 (0.006, 0.036)
2 ^a	0.124	0.099	0.028 (0.011, 0.047)
3 ^a	0.166	0.132	0.034 (0.016, 0.056)
4 ^a	0.205	0.165	0.040 (0.021, 0.064)
5 ^a	0.247	0.198	0.049 (0.028, 0.073)
6	0.279	0.231	0.048 (0.024, 0.072)
7	0.309	0.264	0.045 (0.023, 0.068)

^a Intercourse within the fertile window

Table 3

Probability of clinical pregnancy given one act of unprotected intercourse on a specific day of the menstrual cycle after accounting for an increase in the frequency of intercourse near ovulation

Cycle Day	All women	Women with regular cycles	Women with irregular cycles	Previous estimates (all women)
1	0.001	0.001	0.001	0.000
2	0.001	0.001	0.002	0.000
3	0.002	0.003	0.003	0.001
4	0.005	0.005	0.006	0.002
5	0.009	0.006	0.012	0.004
6	0.011	0.014	0.018	0.009
7	0.021	0.024	0.029	0.017
8	0.037	0.038	0.041	0.029
9	0.049	0.051	0.051	0.044
10	0.064	0.070	0.064	0.061
11	0.081	0.088	0.070	0.075
12	0.094	0.095	0.077	0.084
13	0.097	0.101	0.082	0.086
14	0.093	0.092	0.080	0.081
15	0.088	0.082	0.074	0.072
16	0.076	0.078	0.066	0.061
17	0.062	0.064	0.064	0.050
18	0.057	0.052	0.060	0.040
19	0.043	0.042	0.056	0.032
20	0.036	0.034	0.052	0.025
21	0.034	0.026	0.041	0.020
22	0.028	0.020	0.043	0.016
23	0.021	0.015	0.034	0.013
24	0.016	0.012	0.025	0.011
25	0.014	0.008	0.024	0.009
26	0.012	0.006	0.023	0.008
27	0.008	0.006	0.017	0.007
28	0.009	0.007	0.017	0.007
29	0.006	0.006	0.018	0.007
30	0.006	0.005	0.014	0.007
31	0.005	0.005	0.012	0.008
32	0.007	0.005	0.013	0.008
33	0.005	0.007	0.014	0.009
34	0.004	0.007	0.013	0.009
35	0.005	0.007	0.013	0.010
36	0.006	0.008	0.013	0.011
37	0.006	0.008	0.012	0.012
38	0.010	0.009	0.010	0.013

Cycle Day	All women	Women with regular cycles	Women with irregular cycles	Previous estimates (all women)
39	0.010	0.010	0.011	0.014
40	0.011	0.010	0.012	0.015

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