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LIFE TABLE RATES AND PERSON MONTH RATIOS AS SUMMARY STATISTICS FOR CONTRACEPTIVE TRIALS

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SUMMARY

Person month statistics consist of ratios of events divided by months of exposure to the risk of such events. They are required as part of the procedure for computing life table rates. If person month statistics are presented for relatively short intervals of contraceptive use, such as the first three months, the second three months, etc. the pitfalls in their use are averted and they constitute a simple and useful statistical methodology. For those who are interested in converting them to life table rates, they can easily do so from published person year data.

This paper will focus on the statistical tools used to analyze and report on data that have been collected to evaluate a contraceptive agent. In particular, we shall discuss the use of person year statistics and life tables. In neither case shall we be concerned with the detailed procedures of computation. This has been done extensively for the life table[1, 2] and to a lesser extent for person years [3].

The design of the study from which the data originate will not influence the choice of these tools. The issues would be the same for a randomized trial, for a non-randomized comparative trial, for a clinical trial of a single agent, or even for the retrospective review of reproductive histories.

Also independent of the choice of statistical tools is the need to define the kinds of events which are of interest. An especially important event, of course, is unplanned pregnancy. At various stages in the evaluation of a contraceptive, interest will be focused on (a) pregnancies during proper use of a contraceptive (b) pregnancies during use whether proper or no, and (c) pregnancies after starting a regimen independent of whether the agent is being used properly or not, or for that matter whether the contraceptive is still being used at all. These three levels of efficacy are referred to as theoretical, use, and extended use effectiveness, respectively [4]. Each of these is important in characterizing a contraceptive and the potential and real role that it can play in fertility control.

We have then the problem common to several study designs of summarizing a clinical experience in which pregnancy events have been identified, as have other events that cause discontinuation of use of the contraceptive method being evaluated, the two methods usually considered being the person months method and the life table.

The life table

The concept of the life table is an old one, often credited to John Graunt, a 17th century English statistician. His area of interest was mortality, for which the method has since been most often used. If the numerical computations are not simple, the purpose of the exercise is. It is to estimate the expected number of deaths at selected points of time for a hypothetical population.

The simple survivorship curve in Fig. 1 is an example. One could summarize this curve by saying that out of 1000 persons starting at time t_0, about 750 are still alive at time t_1, and roughly 500 at time t_2. The life table would be used to organize the data in such a way as to make probability statements of that same type. In contrast to person year statistics, these are true rates, the numerator being part of the denominator, and with the rate being between 0 and 1. These statements are analogous to those about the chance of a head in a coin toss, or of a number appearing in roulette.

The extension to more than one cause of death, as in Fig. 2, is natural. The 500 deaths occurring by time t_2 are subdivided into causes A, B and other causes. These are, of course, the same descriptive tools that have been used for fertility. Substitute for causes A, B and other causes, discontinuation for pregnancy,

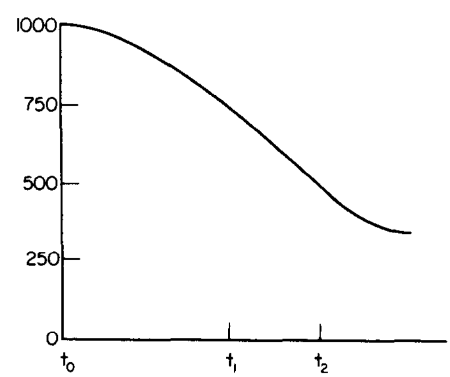

Fig. 1. Simple survivorship curve.

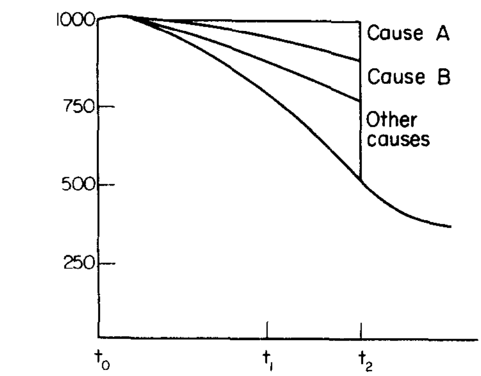

Fig. 2. Survivorship curve with several causes of death.

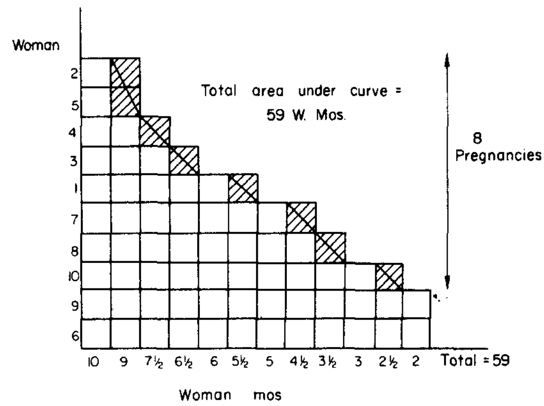

Fig. 3. Representation of data in Table 1 as a pregnancy curve.

bleeding, and for other reasons, and the extension to contraception is apparent.

Person month statistics

The person month statistics take the form of a ratio of events (such as pregnancies) divided by the sum of months of experience of the patient being studied, taking from each the duration of time from starting the treatment, until an event causing termination of the study experience such as pregnancy, bleeding, loss to follow-up, or the end of the clinical trial itself. Where the life table statistic characterizes the survivorship curve in Fig. 1 with the change in height divided by the starting height, the person year statistic uses in the denominator the area under the curve.

Some simple examples may be helpful in illustrating these ideas.

Table 1 shows the exact experience in a clinical trial of ten women. Woman number 1 became pregnant in the sixth month of the study, woman number 2 in the second month, etc. Women number 6 and 9 did not become pregnant in the twelve months that the study lasted.

These same ten women have had their months of experience rearranged in Fig. 3, so that the curve of probability of pregnancy emerges. Woman number 2, for example, appears first and is represented by two squares, the second one shaded to illustrate her pregnancy in the second month. The women months are summed at the bottom of the Fig. Half months are credited for months in which pregnancies occur

Table 1. Month of pregnancy in ten women in one year of study

Woman	Month of pregnancy
1	6
2	2
3	4
4	3
5	2
6	None after 12 mos.
7	8
8	9
9	None after 12 mos.
10	11

on the simplifying assumption that they were in the middle of the month.

Some illustrative computations are now possible. There were eight pregnancies, now possible. There were eight pregnancies, and a total of 59 woman months. Therefore the woman month ratio was 8 pregs./59 w. mos., or 13·6 pregs./100 w. mos., or equivalently 8 pregs./4·9 w. yrs. The Pearl Rate is a person year statistic arbitrarily scaled at pregnancies per 100 women years. The value that would be yielded here is 163. It is interesting to note that the person year ratio can exceed 1, unlike the life table rate.

The observed rate incidentally is 8 pregnancies in 10 women observed for one year of study. The life table statistic provides an estimate of this rate, which in this case would be exactly the same, 8/10. To compute the life table rate two elementary procedures at the heart of the arithmetic are required. (1) The first is to compute the risk of pregnancy in each month, estimated as pregnancies divided by (person mos. plus one half the pregnancy), or

$$\frac{\text{Pregs.}}{\text{P. Mos.} + \text{Pregs.}/2}.$$

The complements of these rates are used to estimate the risk of not becoming pregnant. (2) The second procedure is that the probability of not becoming pregnant after one year, for example, is the product of the probabilities of not becoming pregnant in each of the first twelve months. By this method the probability of not becoming pregnant after one year is the product of the twelve rates

$$\left(1-\frac{0}{10}\right)\left(1-\frac{2}{9+1}\right)\left(1-\frac{1}{7\frac{1}{2}+\frac{1}{2}}\right)\cdots\left(1-\frac{0}{2}\right),$$

or

$$\frac{10}{10}\times\frac{8}{10}\times\frac{7}{8}\cdots\times\frac{2}{2}, \text{ or } \frac{2}{10}.$$

The probability of becoming pregnant would then be 8/10.

Two further points might be noted. The total of the woman months is exactly equal to the area under the curve.

Table 2. Comparison of probabilities estimated from crude person year ratios with probabilities obtained from Life Table with monthly units

Drug	P. Mo. ratio (1)	(1)/2	(2)	P (3)	Prob. estimated from P.M. Q (4)	$Q_{1-6} \times Q_{7-12}$ (5)	L. Table Q (6)
Meg. acetate							
1–6 Mos.	5·8	2·9	19·6	0·30	0·70		0·71
1–12 Mos.	5·3	2·6	10·9	0·49	0·51	0·54	0·55
7–12 Mos.	4·4	2·2	18·9	0·23	0·77		0·77
Noreth acetate							
1–6 Mos.	3·0	1·5	18·2	0·16	0·84		0·85
1–12 Mos.	2·4	1·2	9·5	0·25	0·75	0·76	0·77
7–12 Mos.	1·6	0·8	17·5	0·09	0·91		0·91
Chlormad acetate							
1–6 Mos.	3·8	1·9	18·6	0·20	0·80		0·81
1–12 Mos.	3·4	1·7	10·0	0·34	0·66	0·68	0·68
7–12 Mos.	2·8	1·4	18·1	0·15	0·85		0·83
Norgestrel							
1–6 Mos.	9·1	4·6	21·1	0·43	0·57		0·57
1–12 Mos.	6·8	3·4	11·7	0·58	0·42	0·48	0·49
7–12 Mos.	2·8	1·4	18·1	0·15	0·85		0·86
Nuvacon							
1–6 Mos.	3·0	1·5	18·2	0·16	0·84		0·85
1–12 Mos.	2·5	1·2	9·5	0·26	0·74	0·68	0·76
7–12 Mos.	3·5	1·7	18·4	0·19	0·81		0·89

$$(2)_{7-12} = (2)_{1-6} = \frac{100}{6} + \frac{(1)}{2}; \quad (2)_{1-12} = \frac{100}{12} + \frac{(1)}{2}$$

$$(3)_{1-12} = (3)_{7-12} = (3)_{1-6} = \frac{(1)}{(2)}; \quad (4) = 1 - (3)$$

Source of Columns (1) and (6): Vessey and others. Reference 5.

Second, the life table calculation employs the person month ratios in each month, but corrects the denominators by one half the pregnancies to obtain estimates of monthly rates, that are then used to estimate rates over longer periods of time such as one year. Therefore, in order to estimate life table rates, all that one requires are the person year ratios.

This last point quite properly implies that published data with person month ratios can be used to estimate the comparable life table values. Table 2 illustrates this important point. Columns (1) and (6) are from an excellent paper by Vessey and others [5], which provides both person month ratios and life table curves for five contraceptive compounds. The values in Column 1 are taken directly from Vesset; the values in Column 6 are read from life table curves in his paper. Columns 4 and 5 are estimates of the life table values that we have calculated using Vessey's 6-month person month ratios. Vessey's life table values, it should be recalled, were obtained with detailed computations on single months of data. The values in columns 4 and 5 are remarkably close to Vessey's life table values, with at most two exceptions.

The moral of this exercise is an important one. Clinical trials that report significant events and properly computed person months, in relatively short time periods, can often be used to estimate the life table probabilities with not very great error, should they be of interest.

It would be a mistake to omit some discussion of how one can be mislead by faulty use of person year ratios. In the opinion of this author, all such examples stem from reporting of person year ratios over time periods which are too long. Comparison between studies is especially hazardous if one study has had its person months experience distributed differently from the other. In such instances one may see differences in person year ratios, where life table ratios would show no differences.

On the side of person year ratios, they are easier to compute, and make more sense for the analysis of events which do not cause termination, and which therefore can occur more than once. Further, life table rates will be identical for curves which approach the same one year value quite differently; person year ratios would in such instances reflect the differences in the curves.

DISCUSSION

We have emphasized the close interrelationship in the computation of person month ratios and life table rates. In particular, the point has been made that person month ratios are required as a fundamental arithmetic step in the life table. Using an illustrative example, it has been shown that published person month ratios can easily be converted, if required, to life table rates. This is important, because the person year statistics are easier to compute and require less sophisticated statistical personnel. In a field in which investigators from very many countries must exchange clinical experiences, simple but informative statistical procedures should not be discouraged.

The two statistics are described as attempts, in different ways, to characterize pregnancy experiences. The life table value estimates a true rate, the person month ratio having in its denominator, the area under the pregnancy curve.

The hazards in the use of person months statistics are avoided by reporting of events and person months for short intervals of time, certainly no longer than six months.

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