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### Non-surgical female sterilisation

**SIR—Hieu** and colleagues' report (July 24, p 213) about quinacrine pellets for non-surgical **sterilisation** in women provides encouraging evidence that we may be close to a much-needed, safer, more acceptable alternative to conventional sterilisation. Nevertheless, one of their assertions that operator skill "dominated the determinants of efficacy" is not supported by their data. Indeed, the evidence that they provide on the amount of operator experience contradicts this assertion.

Hieu and co-workers divide operators into two groups (table 3)—**those** who had one or more failures, and those **who** had none. Each of these groups was, in turn, divided by the number of procedures performed. For operators who had at least one failure, the mean failure rate was **5.9** per 100 procedures. Hieu states without providing a test statistic, that "the failure rate was the highest among operators who had done 10 or fewer insertions (**17.2%**) and lowest among those who had done more than 100 (**5.3%**)".

The appearance of a high failure rate in the group with 10 or fewer insertions is an artifact of two imposed conditions: (1)

having at least one failure; and (2) the classification restricting the number of procedures for each member of the group to 10 or fewer. Irrespective of the skills of the operators in this group, by having at least one failure, the failure rate had to be 10% (or more), which is well above the mean. An analogy would be examination of the success of individuals playing the slot machines who both deposited 10 or fewer coins and won a jackpot. The return on investment would be spectacular for those fortunate few individuals, even though overall the first 10 chances of success are no different from any other.

In my view, the meaningful analysis of failure related to experience is the last third of table 3, which does not segregate by whether the operator had at least one failure, and indicates no apparent difference by number of procedures per operator. An alternative analysis might be to look at failure rates of individual operators over time to see if progressively greater experience reduces failure, but these data are not presented. Hieu and colleagues may have some other indication of operation skill besides experience, but these are not reported. Nevertheless, it may well be an advantage of this simple method if success is not dependent on operator experience.

James D Shelton

Office of Population, US Agency for International Development. Washington DC 20523. USA

SIR—One should reserve judgment about efficacy and perhaps safety of quinacrine pellets for non-surgical sterilisation as reported by Hieu and colleagues, because studies included in their life-table analysis (table 2) yield lower pregnancy rates than do the data omitted from the table.

Life-table rates allow inclusion of all durations of follow-up—ie, the scheduled 1, 3, and 6 month and half yearly visits—and of events occurring between follow-up visits. Table 2 shows that hundreds of women with fewer than 6 months of follow-up were included in the life-table analysis. They were in studies labelled Halhung 2, Talbinh, Nghean 1, and Halhung 3. These were studies of at least 50 cases followed for 12 months. The 11 686 cases in the life-table represent 36.8% of all quinacrine sterilisations. By calculation, women represented in the life-table had a total of 412 (SD 5) pregnancies in 14 948 (59) woman-years, an overall rate of 2.76 pregnancies per 100 woman years. The first 6-month failure rate for these subjects was 4.28 per 100 woman years. For the two-insertion procedure, the first 6-month failure rate was 3.13 per 100 woman-years, about double the 6-month life-table cumulative rate for the procedure (because the life-table rate is for half a year).

For all cases, the ectopic pregnancy rate was 0.89 per 1000 woman-years on the basis of 19 ectopic pregnancies. This finding indicates that the total recorded exposure was 20 348 woman-years. There were 818 pregnancies (table 1). Therefore the 20 095 women not in the life-table had 406 (5) (= 8 18.4 12 [5]) pregnancies in 6400 (59) (= 21 348-14 948 [59]) woman-years. Their pregnancy rate, 6.34 per 100 woman-years, is more than double the 6-month failure rate of 3.13 per 100 woman-years for the two-insertion method ( $p < 0.001$ ), suggesting some selection of the studies included in the life-tables (table 2). It is difficult to understand the exclusion of Hatinh province from the life-table analyses, since 25 livebirths were recorded subsequent to the quinacrine procedure, and one guesses that at least 50 women had one year's experience after the procedure. In Hatinh province there were 91 pregnancies after 997 procedures.

The life-table analyses should have included all women with follow-up. Table 1, which presented data on all cases, should have shown separate data for the one-insertion and two-insertion procedures to allow their evaluation.

Lrving Sivin

Population Council, Center for Biomedical Research. New York, NY 10021. USA

SIR—The method of non-surgical female sterilisation investigated by Hieu and co-workers has great potential in Vietnam, and the prospect of a full-time family-planning worker at every commune health station, mentioned by Feuerstein in her accompanying commentary (p 188), is encouraging. However, enthusiasm for female sterilisation should be carefully tempered.

The principle of individual choice in family planning means that services must not be prescriptive and that professionals should avoid being patronising about the suitability of specific methods. No drug, device, or procedure is without side-effects: the decision about which family-planning method to use has to rest with the individual, who should be properly informed about the risks and benefits. Sterilisation may provide an expedient way of achieving official targets but coercion should be avoided.

As in most developing countries, the government budget allocated to family planning in Vietnam is inadequate. Now that investigations demonstrating the safety of injectable contraceptives<sup>1,2</sup> have allayed previous concerns, it is to be hoped that research on injectable contraceptives in Vietnam will soon lead to improved health-service delivery. International development agencies should promote the inclusion of injectable contraceptives in the "cafeteria model" aimed at providing a wide range of choice. That may mean advocacy on the agencies' part so that injectable contraceptives are licensed in western donor countries. We must avoid the perception that injectable contraceptives have side-effects that make them inappropriate for donor countries but suitable for dumping in the third world. The unique advantages of injectable contraceptives must be emphasised.

Lindsay Edouard

Department of Community Health and Epidemiology, University of Saskatchewan. Saskatoon S7N 0W0, Canada

- 1 WHO Collaborative Study of Neoplasia and Steroid contraceptives. Breast cancer and depot-medroxyprogesterone acetate: a multinational study. *Lancet* 1991; **338**: 833-38.
- 2 Bonhomme MG, Potts DM, Fortney JA, Allen MY. Safety of depot medroxyprogesterone acetate. *Lancet* 1991; **338**: 942.
- 3 Editorial. DMPA and breast cancer: the dog has had its day. *Lancet* 1991; **338**: 856-57.
- 4 Mangla B, Mangla V. Family planning project stirs Norplant debate. *Lancet* 1993; **341**: 1016.
- 5 Kleinman RL, ed. Hormonal contraception. London: International Planned Parenthood Federation, 1990.

Authors' reply

SIR—Shelton assumes that skill and experience are related, and his comments are based on this premise. We believe that with this method, evidence shows that skill and experience are not related. We defined skill as the "consistent application of proper insertion technique". The application of improper technique or the inconsistent application of proper technique would be poor skill, no matter how much experience an operator had of a method. This large field trial offers a unique opportunity to study differences in failure rates of a large number of clinicians (over 1300). We agree that the most meaningful analysis of failure related to experience is the last third of table 3. We believe that it provides compelling evidence that increasing experience does not improve the skill of the operator. If it did so then the overall failure rate would fall as the size of individual series increased. It did not.

More importantly, we agree with Shelton that a better alternative analysis would be to look at failure rates of individual operators over time to see if progressively greater experience reduces failure. This analysis was initially undertaken and we found that failures were distributed throughout individual clinicians' series (much to our surprise) and not concentrated early in each series as one would expect if

Province	No of pregnancies	No of cases	Life-table failure rates*				12-mo failure rate: Thanhhoa rate
			6	12	18	24	
Thanhhoa	9	1316	0.61	0.71	0.71	0.71	1.0
Haihung	60	3144	0.65	1.45	2.18	2.93	2.0
Hatay	31	1981	1.60	1.60	1.60	1.60	2.3
Habac	36	1982	1.77	1.83	1.83	1.83	2.6
Namha	245	8325	1.51	2.63	3.00	3.22	3.7
Thaibinh	62	2615	2.11	2.73	3.05	3.05	3.8
Ninhbinh	72	2196	2.56	3.53	3.53	3.53	4.8
Nghean	97	2570	3.30	3.87	3.87	3.87	5.5
Hatinh	13	209	6.26	6.26			8.8
Total	625	24 338	1.77	2.52	2.79	3.09	

\*Failure = cumulative failure rate per 100 women. Includes all provinces with a minimum of 50 cases at 12-month follow-up.

Table: Quinacrine sterilisation failure rates in two-insertion studies in nine provinces of Vietnam

experience improved skill. However, this analysis was complicated by the fact that the name of the clinician was not recorded at the time of the second insertion in 47.2% of the cases (as noted), and for this reason we did not report this analysis.

We have now completed another analysis that offers additional evidence that skill, as we have defined it, accounts for most of the failures. As can be seen from the table, the range of pregnancy failure among the nine provinces where most of the two-insertion cases with 12-month follow-up have been done is considerable (eg, 0.7 failures per 100 women at 1 year in Thanhhoa Province vs 6.3 in Hatinh Province, a nine-fold difference). However, the quinacrine used, its dose, and the insertion device are the same. Skill, to include patient selection, the actual insertion technique, and immediate follow-up care, and their consistent application, undoubtedly differs.

In Thanhhoa, the failure rate is the same as that for surgical sterilisations and we believe that this rate is achievable everywhere if we can identify the correct technique and ensure that it is applied in every case through appropriate training. We are presently planning a study to identify this technique and we agree with Shelton that the fact that success is not dependent on operator experience is an important advantage of this remarkably simple method.

We agree with Sivin that one should reserve judgment about efficacy of the quinacrine pellet non-surgical sterilisation method. A major conclusion of our study was that efficacy varies greatly by inserting clinician, and therefore by location of the study.

The life-table rates in our table 2 are not meant to represent the total data set but are, rather, illustrative of the great variation in failure rates by study. Our report is the first to show variation in any field trial, and we have documented that the rates are probably due to variation in insertion technique and/or inconsistent application of the correct technique.

The most important questions are what should the recommended technique be, and how do we ensure that this technique is consistently applied? Research is now underway to answer these questions. We believe that this approach will lead to lower pregnancy rates than those reported in our table 2.

The ectopic pregnancy rate of 0.89 per 1000 woman-years was estimated only from data of the Namha studies, as we stated in our results section. We have a report in progress showing wide variation in ectopic pregnancy risk by province. For this reason, Sivin's estimation method is unsound.

As our report makes clear, even if we had included all patients in the life-table analysis, as Sivin suggests, the result would not be useful in judging efficacy of the method. Clearly, the overwhelming reason for pregnancy failure is incorrect insertion technique or inconsistent application of proper

technique rather than some inherent shortcoming of the method. This difficulty must be resolved before we can adequately judge the efficacy of this method. Sivin does not attempt to substantiate his reservations about the safety of this method. Our findings show that the quinacrine method is clearly safer than surgical sterilisation.

We wholly agree with Edouard that the widest possible range of choice should be made available to all women. Since 60% of Vietnamese women of reproductive age say that they want no more children, it is no surprise to find considerable demand for sterilisation services. The Vietnam government has not made any systematic effort to promote the quinacrine method. Namha Province has the largest number of cases sterilised by this method. In the first 10 months of 1992, women requested the quinacrine method eleven times more often than they did surgical sterilisation, even though surgical sterilisation has been offered there for 10 years and the quinacrine method for only 4. There is no coercion in our programme.

We intend to make every effort to offer one or more injectables to every Vietnamese woman. However, we have found that the menstrual pattern disturbances, in particular intermenstrual bleeding, often seen as a side-effect with these drugs, has seriously hampered their acceptance in Vietnam.

Do Trong Hieu, Tran Thi Tan, Do Ngoc Tan, Pham Jhi Nguyet, Pham Than, Dao Quang Vinh

Maternal and Child Health/Family Planning Department, Ministry of Health, Hanoi, Vietnam: Maternal and Child Health/Family Planning Centre, Namha Province; Gynaecology/Obstetrics Sector, Myvan Hospital, Haihung Province; Maternal and Child Health/Family Planning Centre, Thaibinh Province; Maternal and Child Health/Family Planning Centre, Nghean Province; end Maternal and Child Health/Family Planning Department, Ministry of Health, Hanoi