THE LONG-TERM MENSTRUAL SIDE-EFFECTS ASSOCIATED WITH TUBAL STERILIZATION

A LITERATURE REVIEW AND CASE-CONTROL STUDY WITH SPECIAL REFERENCE TO WOMEN OF SOUTH ASIA

By

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Summary

This dissertation investigates the association between long-term menstrual problems such as heavy bleeding and tubal sterilization, with special reference to women in South Asia.

The first section describes the increasingly important role played by voluntary sterilization in the family planning programmes of many countries in the world and discusses the development of different techniques of female sterilization.

The literature survey includes studies conducted nationally and internationally, published in journals available in this country. A critique of the studies pinpoints the main methodological controversies which make assessment of the association difficult.

The next section discusses the special problems related to trying to research sensitive and intimate subjects in rural parts of South Asia. A case-control study was carried out in Bangladesh, comparing women who had been sterilized some years before with matched controls.

The results showed that more of the sterilized women complained of problems in menstruation in the last few years. However, the data were very subjective which is a fault common to many studies on this topic.

A more objective approach is essential to assess the possibility of this association, in which direct measurements are made of menstrual losses and hormonal cycles. Very few studies of that nature have been conducted to date.
1 - INTRODUCTION
2 - HISTORY OF FEMALE STERILIZATION
3 - ANATOMY OF FEMALE REPRODUCTIVE SYSTEM
4 - SURGICAL PROCEDURES
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Voluntary sterilization is becoming increasingly prevalent as a method of fertility control and it is estimated that more than 80 million couples in the world have now used this form of family limitation (1). Because of growing anxiety in this century on the part of governments and international bodies about the expansion of populations in various countries, voluntary sterilization has often played a prominent role in national and international family planning strategies.

Puerto Rico and Japan were at the forefront of the spread of sterilization in the 1940s. By 1961 almost 6% of Japanese couples practising contraception used sterilization. The emphasis was on female sterilization and by 1965 an estimated 30% of all Puerto Rican mothers aged between 20-49 had been sterilized. At present the majority of the world's sterilizations are performed in Asia especially India and the People's Republic of China. However in the USA in 1976 approximately one million couples a year were using sterilization as a permanent form of contraception with roughly half the acceptors being female. The cumulative number exceeded 8 million in 1976 at a rate of 25% of all fertility control (2). In Brazil and Costa Rica 15% of married women of reproductive age had been sterilized and for Panama the rate is nearly 30% of married women between 15-44 years of age, one of the highest rates in the world (3).

World-wide there are now more than 60 million women who relied on voluntary sterilization to control their fertility (4).

Along with this expansion in female sterilization, there has been concern as to whether any serious side-effects arise from this surgical intervention. One of the foci of this concern has been subsequent menstrual problems, since some clinicians considered that women who had been sterilized
returned more frequently with menstrual difficulties, in particular heavy bleeding. This obviously of vital interest especially since the average age at which sterilization takes place has decreased with greater acceptance of smaller families. In developing countries where the majority of women are anaemic, in some cases severely, heavy bleeding in menstruation may impair their health even further.

In this study I have attempted to review critically published work on the association between sterilization and menstrual difficulties. I also include the results of a small study I have conducted to investigate this association.
Table 1: Estimated number of couples using birth-control, worldwide, by method (1) (millions)

<table>
<thead>
<tr>
<th>Method</th>
<th>1970</th>
<th>1977</th>
</tr>
</thead>
<tbody>
<tr>
<td>Voluntary sterilization</td>
<td>20</td>
<td>80</td>
</tr>
<tr>
<td>Oral contraceptives</td>
<td>30</td>
<td>55</td>
</tr>
<tr>
<td>Condoms</td>
<td>25</td>
<td>35</td>
</tr>
<tr>
<td>Intra-uterine devices (IUD)</td>
<td>12</td>
<td>15</td>
</tr>
<tr>
<td>Others *</td>
<td>60</td>
<td>65</td>
</tr>
<tr>
<td>Abortions (annual incidence)</td>
<td>40</td>
<td>40</td>
</tr>
</tbody>
</table>

* diaphragm, spermicides, rhythm, withdrawal, etc.

By 1975 sterilization had become an accepted method among many women and became the most widely used birth control method in the world. (See table 1.)
3 - HISTORY OF FEMALE STERILIZATION

The American surgeon Lungren pioneered the procedure of tying the fallopian tubes (without excision) with silk thread at the end of the nineteenth century. Laparotomy during this period was a major surgical procedure carrying a mortality of 10-12% (5).

The use of female sterilization was not widespread until the introduction of the Pomeroy technique of tubal occlusion in 1920-30. Prior to that hysterectomy was commonly carried out as a contraceptive measure (1). As operative methods became safer and more effective, sterilization was used increasingly as a form of permanent birth-control for women for whom further pregnancies were undesirable. A study in Los Angeles of over 400 sterilizations carried out during 1930 showed that 90% were "at least ostensibly done for therapeutic reasons", and some hospitals refused to perform abortions unless the women in question agreed to undergo sterilization as well (5).

By 1975 sterilization had been introduced to many countries and became the most widely used single contraceptive method in the world. (see table 1.)

3 - ANATOMY OF THE FEMALE REPRODUCTIVE SYSTEM

To facilitate appreciation of the different methods of female sterilization, a brief description of the relevant anatomy is necessary (5,6,7,).

The uterus, pair-shaped and fist-sized, sits centrally in the lower pelvis with the pubic bone and bladder in front of it and the sigmoid
Diagram 1. *Posterior view of uterus and broad ligament:*

infundibulo-pelvic ligament
mesosalpinx
ampulla of tube
fimbria ovarica
ovary

fundus of uterus
interstitial part of uterine tube
round ligament
ovarian ligament
uterine artery
ureter
cervix
vagina

Diagram 2. *Blood vessels of the pelvis:*

ovarian artery
internal iliac vein
uterine veins
vaginal veins
internal pudendal veins
anterior division of internal iliac artery
uterine artery
vaginal artery
internal pudendal artery
colon and rectum behind it. It is freely mobile, opening as the cervix into the vagina, a canal which opens on to the exterior of the body between the vulva. The cervix has a small opening in the non-pregnant state, allowing menstrual fluid to pass but during childbirth it expands to allow the delivery of the baby.

The fallopian tubes extend out from each upper corner of the uterus, at a length of about 10 cms., then widening to a funnel-shaped, fringed end, the fimbria. The ovaries, oval and about 3.5 cms. long, lie in close proximity to the fimbria. The peritoneum, a membrane of connective tissue lining the abdominal cavity, covers the uterus which is in the pelvis, and forms two transverse folds at each side of the uterus known as the broad ligaments, which are attached to the walls of the pelvis (infundibulo-pelvic ligaments). The upper part of this covering encloses the fallopian tubes (the mesosalpinx). The ovaries are attached to the back of the broad ligaments (see diagram 1) and the ovarian blood vessels and nerves pass between its layers.

Physiology of ovulation: During each lunar month one of the ovaries releases an egg-cell (ovum) which passes out of the ovary, into the fimbria, and travels along the fallopian tube, pushed along by waves of contractions of the tube. If sperm cells are present the ovum may be fertilized in the tube, otherwise it will pass on to the uterus and a week or so later the uterine lining will be shed in menstruation. The lining of the uterus is built up under the influence of hormones produced by the ovaries, oestrogen and progesterone, to provide a suitable environment for implantation and nurturing of the fertilized ovum. The process of the menstrual cycle is controlled by a critical and complex interrelation and feedback system between hormones produced in the hypothalamus and pituitary glands of the brain, and ovarian steroids.
The ovum and spermatozoan undergo fusion in the fallopian tube. The principle in sterilization is to prevent that contact taking place by blocking off the access of the spermatozoa to the ovum. It can be done either following delivery (post-partum) or as a separate procedure (interval).

In the next section first the methods of approaching the fallopian tubes surgically will be described, followed by methods of tubal occlusion.

4 - SURGICAL PROCEDURES

Methods of Access for Sterilization (5)

1. Laparotomy: A midline, vertical incision from below the navel or a transverse horizontal incision near the pubic hair line, several inches long, is made to facilitate easy access to the abdominal or pelvic organs. This is a major surgical procedure, requiring hospitalization and general anaesthesia, with higher risk of post-operative complications, such as infections and bleeding. This method is usually used when combined with some other operative procedure such as caesarian section or other abdominal surgery.

2. Mini-laparotomy: This is the method used most frequently in developing countries since it can be done using local anaesthesia and therefore be done on an outpatient basis. A small transverse incision (2-3cms) is made just above the pubic hair line, down to the peritoneum. The uterus is elevated using a vaginal instrument, until it is against the abdominal wall and the tubes can be grasped and occluded externally. The complication rate is low. For post-partum sterilization, the incision is made just below the navel because the uterus is enlarged following pregnancy and the tubes are high in the abdomen.

3. Laparoscopy: An endoscopic instrument is used to visualize the tubes.
The long thin laparoscope is inserted through a tiny incision (2cms) near the navel; the instruments for occlusion may be introduced through the laparoscope, or else through a second small incision made in the lower abdomen. This method requires specialized training and special equipment (including electricity) but can be used quickly and easily, and on an out-patient basis.

4. **Colpotomy**: An incision is made in the posterior area of the vaginal canal behind the cervix, the uterus is manipulated so that the fallopian tubes can be reached and each tube is pulled through the incision and occluded. It is usually carried out under general anaesthesia, but may be done under local anaesthesia on an outpatient basis. It is undesirable as a method in areas with a high prevalence of vaginal infections and where follow-up care is inadequate. Post-operative complications include bleeding from the vaginal incision, wound infection, pelvic inflammation and abscess.

5. **Culdoscopy**: The culdoscope is a long thin viewing instrument similar to a laparoscope, and is introduced through an incision in the posterior fornix of the vagina, the tubes are visualized, grasped, delivered through the incision and occluded. Many of the problems associated with colpotomy apply with this method also, but it causes less discomfort and requires a shorter recovery time.

6. **Transcervical**: Some methods of occlusion, such as cautery or chemical application, are attempted via the transcervical route, but are not very successful due to the difficulty of locating the entrance to the tubes through the uterus. In hysteroscopy, a viewing instrument is introduced into the uterus through the cervix and instruments for occlusion of the tubes introduced through it. Since no incision is used in this method, complications of bleeding and infection are avoided. This can only be performed as an interval procedure.

7. **Hysterectomy**: This method provides 100% effectiveness, but is a major surgical procedure and may be emotionally traumatic for the woman.
Methods of Tubal Occlusion (5)

1. **Madlener technique**: First reported in 1919, this technique involves the lifting of the tube into a loop, the midsection is crushed with a clamp and the crushed area is ligated. This method has a higher failure rate than the following methods.

2. **Pomeroy technique**: The tube is picked up near the midsection to form a loop, the base of the loop is ligated with absorbable suture, the top of the loop is then cut off. As the suture is absorbed, the ends of the tube pull apart. This technique involves minimal interference with the broad ligament or ovarian blood supply, but also provides the best chance of reversal.

3. **Fulguration**: This method involves burning a section of tube using electrocautery to coagulate the tube, or using a stronger current, to cut the tube and seal the ends. The major problems associated with this method are those of burns from sparks or misplaced instruments. Even using low voltage current or bipolar instruments which have greatly reduced the hazards, some of the risks of burns are still retained. Electrocoagulation is a quick and effective method but the potential for reversal is limited since often too much of the tube is destroyed, especially with use of the unipolar cautery method.

5. **Bands and rings**: The Yoon band or Falope ring, made of silicone, less than 1 mm inner diameter, is stretched and slipped onto an applicator, a loop of fallopian tube is pulled up into the applicator, the ring is slipped round the base of the loop of tube. The constricted tube becomes ischaemic and eventually forms scar tissue. Occlusion of this type can be used through a laparoscope, culdoscope or with a mini-lap incision.

6. **Clips**: These are easy to apply to occlude the tube, except that, as with bands and rings, they may be applied to
the round ligament by mistake. Tantalum clips made of a non-
tissue reactive metal, and spring-loaded plastic and metal clips
are the most often used at present despite the relatively high
failure rate.

7. **Chemicals**: These are under experimentation at present and
include quinacrine, liquid silicone, and may be inserted either
transcervically or through the fimbria. Solid plugs of silicone,
polyethylene, porous ceramic, Dacron and Teflon are also under
investigation.

Bangladesh Sterilization has become an increasingly important
component of Bangladesh's National Family Planning Programs.
The annual number of tubectomies performed increased from
The government's second Five Year Plan for 1982-86 calls for
almost 3.4 million sterilizations, rising from a target of 257,000
in 1980-81 to 965,000 in 1984. If this goal is met, steriliza-
tion will account for 43% of contraceptive use in 1989. Tubec-
tomies accounted for approximately 75% of sterilizations in 1980-81
and 85% in 1984-85.

A study done by Haas et al. in 1987 with 1,226 sterilized
women showed that 60% of them had used any contraception
prior to sterilization (15% oral contraceptives, 27% IUDs or
0.52 injectables, 10.5% other methods). A 1977 estimate of
63% of tubectomized women using some form of contraception
with 73% in this study of 1,000 suggest that the women form
an increasing proportion of recently sterilized women. In
1978 54% of families in Bangladesh were planning to have an
additional child. Agricultural income was critical with 40% of the
government programs providing nutrition, education and funds to
the surgeon and to the patient.
This study aims to examine the possible association between female sterilization and menstrual problems, particularly menorrhagia, with special reference to women in South Asia. South Asia, formerly referred to as the Indian sub-continent, is made up by Bangladesh, India, Pakistan and Sri Lanka.

Bangladesh: Sterilization has become an increasingly important component of Bangladesh's National Family Planning Programme. The annual number of tubectomies performed increased from 11,076 in '75-'76 to 83,865 in '78-'79 and to 159,208 in '79-'80. The government Second Five Year Plan for 1980-85 calls for almost 3.4 million sterilizations, rising from a target of 407,000 in '80-'81 to 968,000 in '84-'85. If that goal is met, sterilization will account for 43% of contraceptive use in 1985. Tubectomies accounted for approximately 75% of sterilizations in '78-'79 and 85% in '79-'80. (8)

A study done by Measham et al in 1982 with 3,220 sterilized women showed that only 16% of them had used any contraception prior to sterilization (13.2% oral contraception, 2% condoms, 0.5% injectables, 0.5% other methods). A 1977 estimate of 63% of tubectomized women coming from landless families compared with 73% in this study of 1982 suggests that the landless form an increasing proportion of recipients of sterilization. In 1978 54% of families in Bangladesh which has a predominantly agricultural economy, were classed as landless(8). The Government programme provides an incentive payment to the recipient, the surgeon and to the motivator.
India: Voluntary sterilization was introduced into the Family Planning Programme in 1956 with 7,000 operations performed that year of which 76% were female. In 1960 64,338 sterilizations were performed, with increasing emphasis on male sterilization (58%) which continued until the mid-seventies (1973 - 83.7%, 1974 - 42.8%) when female sterilization predominated once more (except for 1976 during the Emergency) (9). The cumulative number of sterilizations up to 1976 were 5 million tubectomies and 13.6 million vasectomies (10). Here too financial incentives were used and Moni Nag described one study in which 43% of vasectomized respondents (n=297) stated that their "sole motivating factor" for adoption was the incentive. In terms of age and marital status 36.7% of these respondents need not have been vasectomized for purposes of family limitation (9).

Pakistan: Post-partum sterilization has been available for a limited number of women since the 1950s and interval sterilization has been provided in the last few years. For the period 1965-69 4,909 tubectomies and 56,150 vasectomies were performed. There has been a trend reversal recently so that 12,353 tubectomies and 2,389 vasectomies were performed in 1975 and 15,121 tubectomies and 2,082 vasectomies were performed in 1976. Sterilizations now form 5% of total contraceptive usage (1,10).

Sri Lanka: Voluntary sterilization has been available since the late 1960s with female sterilization predominating (1974: 83% were female). The cumulative numbers were 3,000 in 1966, 4,300 in 1971, and 39,400 in 1975. A survey in 1975 showed that 8.1% of married women of reproductive age had been sterilized (1).
There are some general areas of difficulty in studies of this nature, some which are unavoidable if the researcher lacks time and resources.

1. Many of the studies performed are retrospective*. This usually because they are cheaper, easier to do and require less time and fewer subjects. Since much of the information gained from interviews and questionnaires was based on recall, sometimes over several years, it is less likely to be accurate than that gained from a prospective study. A case-control study is often a useful starting point in order to assess the possible association between cause and effect. A cohort study would become economic if one knew that the effect under investigation was quite frequent. If this can be first established using the case-control approach, a prospective cohort study can then be undertaken.

2. The question of controls follows from the last point. Many of the studies described did not use controls. The women who had been sterilized were surveyed for side-effects but as there were no comparisons to matched women it was difficult to assess the findings.

In some studies the controls were not appropriate, for instance if they were pregnant, lactating or using oral contraception, factors affecting menstruation itself and thereby distorting comparisons.

* A retrospective study is backward looking in that it starts with the effect and goes back to the postulated cause. A prospective study starts with the cause and goes forward to the effect. Both are longitudinal in that they are based on data referring to more than one point in time(11). Alternatives are the terms 'case-control' instead of retrospective, and 'cohort' instead of prospective, with retrospective cohort being a study based on existing records (12).
In some studies, the women were used as their own controls with comparison made of their menstrual patterns before and after the sterilization. In such cases the effect of time is neglected which may be important when examining long-term effects spanning several years. One can not separate the effects that are due to the operation which may take a while to emerge from the effect of being x years older.

In other studies women who had been sterilized were matched with women whose husbands had been sterilized, so that there was an assumed termination of fertility in both sets of women. Care has to be taken that women are well matched on other criteria and that selection of method itself is not indicative of other differences. However, these are probably the best controls to use.

3. Losses to follow-up were often neglected, with an assumption that they were random samples of the original group. As Doll and Hill (12) showed, those lost to trace may be special in themselves in that having the effect may lead to non-attendance or non-response. Women who developed menorrhagia may have been too ill to attend the clinic, or as a result of illness, felt antagonistic to the centre where they were sterilized. Poorer women may not have been prepared to miss work to attend the clinic but may have been in a higher risk category. The converse is that women who developed the effect may have continued to visit the clinic for treatment whereas those who did not, could not see the advantage of giving up time with the inconvenience of losing work and arranging child-care and dropped out of the study. The results are distorted in each case.

4. With some studies, especially the older ones, a distinction was not made between those women who had been sterilized for contraceptive reasons and those for medical or obstetric reasons. Previous uterus surgery like caesarian section, for fibroids, or medical problems of thyroid disease or cardiac failure may in themselves cause menstrual problems.
5. Similarly it was not always clear if sterilization was performed as a post-partum operation. If it was and the women involved were lactating (in the case of Third World areas lactation may take place for 18 months) this would cause variations in menstruation even after the initial amenorrhoea. These women should be kept in a separate category if the follow-up is done six months or one year after sterilization and not combined with non-comparable interval sterilization cases.

6. Hysterectomy is used as an indicator of the prevalence of menorrhagia. However, women who develop heavy bleeding but do not present for treatment will not be included in those statistics.

A review of the literature

Williams et al (1951) studied the development of subsequent pelvic disorders in 200 patients who had been sterilized in the period 1926-48 in the USA and compared them to data from records of 3,222 obstetrical patients and also to 1,994 gynaecological patients hospitalized during 1942-48. He found 'significant abnormal bleeding' in 16.5% of the 200 post-sterilization cases, compared to 19.1% in the gynaecological cases and 5.1% in the obstetrical cases.

The controls were not appropriate for this study and did not cover the same time period. Sterilizations in that time were usually done for medical or obstetric reasons and not ostensibly for reasons of contraception and so there would be other pre-disposing factors involved. The authors acknowledge this, but suggest that hysterectomy would have been a better alternative as primary surgery in view of the 'high percentage' of subsequent abnormalities, explaining that, "procedures short of hysterectomy preserve only the menstrual function of the uterus and leave an organ that is, as far as is known, not only worthless but potentially dangerous". (13)
Lu and Chun (1967) wrote to patients who had post-partum sterilizations in Hong Kong between 1957-62. They got a 34% response rate: 1,055 women were interviewed out of 3,092 invited. Of these women, 14% had been sterilized for medical or obstetric reasons. Some menstrual changes were noted in 51.8% of patients either in length of cycle, duration of flow or amount of loss. In only four women was there menorrhagia of such severity as to require hysterectomy. The authors explain that 30% were in the pre-menopausal age group of 35-45, a time when functional disturbances are common, and in their opinion the menstrual disturbances found in their study were not significantly more frequent than in unoperated women of a similar age group.

The authors of this study were also investigating other lay beliefs that were making women apprehensive of sterilization as a means of contraception, including that sterilization caused adiposity, "makes the temper worse, causes deterioration of the memory, renders the patient less fit and thus lowers her ability for work". Curiously, 45.3% of the women felt that their memory had become worse and 30.1% felt their tempers had become worse since the operation!

This study used retrospective recall and no controls. (14)

Phatak (1969) described a long-term follow-up study done in India on a sample of 277 women who had been sterilized. The post-operative study period ranged from 6 months to 5 years. Menstrual abnormalities were reported in 21% of the 194 women studied for this. The number of patients who reported for follow-up decreased as time went by, but the proportion of women complaining of menstrual difficulties increased. There were no controls in this study and it seems as though the increasing proportion of women with problems could be explained by selection bias in those who persisted in returning for follow-up. The author concluded, "long-term follow-up indicates that there is definite hazard of potential infection of the
apparently normal fallopian tube. This topic needs further study on a larger scale." (15)

Muldoon MJ (1972) looked at the post-sterilization history of at least 10 years of 374 of the 410 (91%) women who had been sterilized at two Dundee teaching hospitals during 1955-60. The author felt that as 43% required further gynaecological treatment and major gynaecological surgery was needed by 25%, there seemed a good case for the selective use of hysterectomy as a method of sterilization. The commonest symptom was menstrual disturbance and more than 90 women were treated for this (24%) with 13% requiring hysterectomy for control. Most of the patients needing further major surgery were either highly multiparous or had had surgical wounds in the uterus for instance from caesarean section. 19.3% of the women had been sterilized for medical or obstetric reasons.

There were no controls used in this study. (16)

Alderman (1975) conducted a prospective study in Liverpool of 596 women in whom tubal occlusion was performed as an elective procedure. Details of menstrual patterns and information about total number of pads or tampons used per menstruation were recorded before the operation and 2-3½ years afterwards. At the time of operation any abnormalities of the uterus or ovaries were noted. After exclusion of patients in whom a possible causative factor could be identified such as recent pregnancy, previous contraception, abnormal findings at operation, there remained 6.5% of women for whom there was no apparent cause for increased menstrual loss. However, there also remained 7.6% of women whose menstrual losses appeared to have decreased since the operation. The author concluded that tubal occlusion did not influence subsequent menstrual loss. (17)
Neil et al (1975) designed a retrospective study in which women sterilized by laparoscopy with diathermy or by abdominal tubal ligation in Southampton were compared with women whose husbands had been sterilized. The response rate was 77% for the cases (350 out of 454) and 72% for the controls (143 out of 198). The authors reported 39% complaining of more menstrual loss after operation for the laparoscopic method, 22% for interval laparotomy and 13% for vasectomy. Both differences are statistically significant at p<0.005. The follow-up time covered ten to twenty-eight months. In all 10 women from the cases and one from the control group required hysterectomy. The study was done by questionnaire, did not take previous contraception or pre-existing menstrual problems into account. (18)

Letchworth and Noble (1977) who were co-authors in the above study re-examined their data and concluded that their findings remained statistically significant when corrected for the effects of discontinuing oral contraception or removal of intra-uterine devices (IUD). They reviewed the patients in their study, now 3-5 years from the time of sterilization, and traced only two-thirds of them, but found a highly significant difference in frequency of hysterectomy. (19)

Chamberlain and Foulkes (1975) in a questionnaire survey of 200 women who had had laparoscopy sterilization 2 years previously in London, found that 34% reported longer periods and 32% reported more days of heavy menstruation. A breakdown by previous contraceptive practices showed that many of the symptomatic patients came from groups previously using oral contraceptives or IUDs. Similarly the 10% increase in dysmenorrhea after sterilization was almost entirely from those women who had previously been on the Pill. After exclusion of this group there was no increase in dysmenorrhea in the 126 women who were not using oral contraception before surgery. (20)
Nag M. (1976) in her overview of India's sterilization programmes 1965-75, mentioned that sterilized women seem to have more physical complications than sterilized men, that immediate complaints were voiced by 50.6% to 80% of those sampled. She quoted from Chakravarty's paper of 1966 that menstrual disturbance and dysfunctional uterine bleeding seem to persist among some women even 2 years after sterilization. (9)

Kasonde and Bonnar (1976) presented a longitudinal study in which menstrual blood loss was measured by the alkaline-haematin method. 100 women from the waiting list for sterilization in Oxford were invited to take part, 32 of these were suitable for study, and 25 completed the course. Those who had been on previous oral contraception had two spontaneous menstruations before entering the study, and women who had been lactating or had an abortion or delivery in the preceding three months were excluded as were those who complained of excessive bleeding. Total blood loss was measured for three consecutive periods before operation and six consecutive periods after operation. In 10 women alternate periods were then measured until the twelfth post-operative period. The authors found no significant change in menstrual loss subsequent to sterilization. Curiously, although none of the women complained of heavy bleeding, one was found to have a loss of up to 260 mls (menorrhagia is considered over 80 mls). (21)

Wig et al (1977) studied 405 tubal ligation cases in India, pre-operatively and then followed-up after 6 weeks, 6 months and 18 months post-operatively by a combined psychiatric and gynaecological team. Of the women 120 lived in rural areas and 285 in urban areas. Detailed verbatim records of symptoms and relevant history of any complaints of ill-health due to the operation were assessed by joint meetings of the senior investigators. About 27% of the women complained of some physical, psychological or menstrual
symptoms pre-operatively, 22.7% mild, 3.7% moderate and 0.3% severe symptoms. There was no breakdown given of menstrual symptoms separately which makes comparison difficult. Follow-up at 6 months was 92.5% and at 18 months 88%. At the second follow-up there were 9.9% complaining of menstrual problems and at the third follow-up there were 7.8%. 8 cases complained of menorrhagia and 6 diagnosed as dysfunctional uterine bleeding. The authors concluded that about 5% of the women had moderate to severe psychological or menstrual problems, but cautioned that as 77% of the sample comprised of post-partum cases, the evaluation of a change in menstrual pattern requires consideration of various factors like the period of lactation and the time taken to re-establish menstruation after the delivery. No controls were used in this study. (22)

Stock (1978) analyzed pre- and post-operative questionnaires on women attending a private practice in Washington, USA. Of the 268 women who underwent sterilization during the study period, 87% returned the post-operative forms. Only 63% sets of pre- and post-operative forms were available, so in order to minimize selection bias, additional material was obtained from clinical records and operative reports. 68% of their clients had been using oral contraception for an average of 6 years. 36% of laparoscopy cases were found to have altered pelvic pathophysiology at time of operation. The author considered that when prior contraceptive history of the women, gynaecologic history and operative findings are taken into account, the long-term prevalence of menorrhagia, pelvic pain and subsequent gynaecologic surgery are markedly fewer than have been claimed previously. His own adjusted figures were 6% for menorrhagia, 6% for pelvic pain, 4% for subsequent surgery. (23)

Lieberman et al (1978) presented a prospective study of women in Britain in which assessments were made before, six months and one year after the
sterilization (using spring-loaded clips) about the amount of menstrual bleeding, the degree of dysmenorrhoea, the number of days of menstruation and the length of cycle. 56 of the original 504 women were lost to follow-up at 6 months and 104 one year after the operation. Their study showed that women who used the Pill or IUD before laparoscopic sterilization with plastic spring-loaded clips, reported changes in menstrual patterns within 6 months of operation. No changes were reported by women who used other methods. No changes were reported in the second 6 months except by women who used the Pill. A similar trend was noted in the case of dysmenorrhoea. The authors argued that their findings strongly suggest that a causal relationship does not exist between their method of sterilization and menstrual disturbances in the first post-operative year. They were conducting a 3 year follow-up study at the time of writing this paper.

The authors suggested that a possible reason for absence of menstrual changes is that the spring-loaded clip does not interrupt the vascular anastomosis between the ovarian and uterine arteries. Diathermy coagulation of the fallopian tubes may damage a significantly larger segment of the tube and probably the terminal branch of the uterine artery supplying the ovary. (24)

Ali et al (1978) surveyed the research literature in developing and industrialized countries and presented some data on menstrual side-effects following tubal ligation. This is a summary of some of the findings they quote:

1. Senawal (1958-59) - 85% of the respondents felt their health was unchanged, 5% reported some menstrual changes.

2. Gunk (1971) - 60% had no physical symptoms, menorrhagia (27.4%) backache (10%), weakness and giddiness (7.23%), leucorrhoea (16%)

3. Das Gupta et al (1970) - 39% reported menstrual disorder

4. Verma and Boparai (1974) - 52.8% reported no physical complaints 18% menstrual irregularity
5. Sikand et al (1968) - 47% reported chronic fatigue

6. Hasalkar (1976) - 87.23% no change, 7.96% irregular menstruation
   11.5% intermittent bleeding with abdominal pain

The authors pointed out that most of the studies they reviewed were retrospective in design, without any pre-operative data for comparison. Secondly all these studies lacked controls and age was not considered a confounding factor. (10)

Rubinstein et al (1979) in California assessed 147 women pre-operatively on four parameters: days of bleeding, days of interval between menstruation, amount of flow and episodes of intermenstrual bleeding. They repeated this assessment at 2 weeks after the operation then at 12-28 months after surgery. Information was collected by interview pre-operatively and then by questionnaire post-operatively. Their results showed no significant differences in the duration of menstruation or the length of interval after sterilization. There was a slight increase in the number of women reporting heavy menstrual flow after surgery, especially among previous users of oral contraception, and also of barrier methods, but individual comparison of pre- and post-operation menstrual flow for each woman revealed no demonstrable pattern of increased or decreased flow. Statistical analysis showed no significant over-all changes in menstrual flow. The authors recommended the use of careful pre-sterilization menstrual histories rather than matched women as controls, though this neglects the effect of time on menstruation patterns. (25)

Lawson et al (1979) attempted to review 566 women in Edinburgh 6 months after sterilization. 377 women were interviewed in a clinic and the remaining 153 answered questionnaires, giving a follow-up of 93.6%. Of these, 235 had been sterilized by diathermy and 295 by silastic bands. However there was no significant difference between them either in the nature or prevalence of menstrual problems. At 6 months, 40% of all women
reported that their periods were heavier and 26% reported that they were more painful. There was "unexpected discrepancy" between women who previously used barrier methods and those who used no contraception in that a higher proportion of the latter reported heavier and more painful periods. 27% of those complaining of heavier bleeding were past oral contraceptive users. The authors point out the subjective nature of this assessment in that only about 9% (excluding IUD users who were 2%) stated that their periods were more bother than before sterilization. There were no controls used in this study. (26)

Whitelaw (1979) attempted to survey all the women who had been sterilized in Dunfermline between 1965-74 and achieved a 88.7% response rate with 485 women interviewed and examined. Extensive efforts were made to keep losses to follow-up at a minimum. No woman was interviewed unless she had been sterilized at least 2 years earlier. 11.8% of the women subsequently had to have another gynaecological operation, 3.7% required hysterectomy (2.1% of these for irregular or heavy menstruation). 59 women complained of symptoms: 37 of irregular vaginal bleeding (7.6%), 5 of menorrhagia (1%), 4 of dysmenorrhoea. Pelvic examination showed that 83 women had some pelvic disorder such as small symptomless fibroids, of which the person was unaware. Prior to sterilization 104 women had experienced some disorder of menstruation and nearly a third of them had had a curettage. This study was retrospective and did not use controls. (27)

Poma PP (1980) in the USA reviewed the records of 514 consecutive women who had elective sterilization in the two years 1970-71 and evaluated their readmission records for a minimum period of 7 years. These were compared with 514 consecutive women of similar parity who delivered at the same institution during the same period. There were more cases in the older
age groups than the controls. Menstrual irregularities requiring hospitalization 3-6 years after the beginning of this study occurred in 22 cases and 2 controls (p<0.01). Almost half the cases (47% of 36) readmitted for gynaecologic complaints had hysterectomies during the follow-up period. Three controls (14% of 22) also had hysterectomies 4-5 years after the study started.

65% of the controls were readmitted for vaginal deliveries during the study period which makes their validity as controls less reliable. Also there were more readmissions amongst the cases for medical and surgical reasons, indicating that the study population may have been less healthy. There is no indication as to what proportion of women were lost follow-up since only those who returned to the original hospital were included in the follow-up data, thereby introducing possible selection bias. Previous menstrual patterns were available to some extent from clinical notes, but previous contraception was not accounted for in the analysis even though about half were using oral contraception until sterilization. (28,29)

Bhatt et al (1981) used the standard India Fertility Research Programme protocol to follow-up 2,053 women enrolled over 1973-79 in Baroda through the hospital and camp sterilization units. Patient characteristics, medical and menstrual histories at time of sterilization were noted. Cases were used as their own controls. Only women undergoing sterilization for birth control were included. Also only those who had been seen for one or more follow-up visits at least 2 months post-operatively were included. All those who had used systemic contraception or IUDs during 3 months prior to sterilization were excluded. Follow-up visits were at 6 months, 12 months, 18 months and 24 months, with data available on menstrual patterns for 28%, 31%, 36% and 91% respectively. Information is not given in the paper on why the numbers for the first three follow-ups is so low, whether they were
selected and if so, on what basis. At 24 months 89% reported no change, 5.1% reporting an increase and 5.9% reporting a decrease in menstrual flow. 81.2% reported no change in duration of menstrual flow with 7.5% reporting an increase and 11.3% reporting a decrease (increase to decrease $p<0.01$). 94.7% reported no change in regularity with 4.1 reporting an increase and 1.2% reporting a decrease (increase to decrease $p<0.01$), 83.7% reported no change in dysmenorrhoea with 5.6% reporting an increase and 10.7% reporting a decrease (increase to decrease $p<0.01$). 0.9% of women had hysterectomies by the 24 month stage, about half of whom had complained of menstrual problems. There is no indication in this study what proportion of women were post-partum cases. (30)

Alder et al (1981) took a random 50 cases from their register, excluding women who had previous gynaecological problems, a baby in the year preceding the sterilization or concurrent termination of pregnancy with sterilization. These cases were matched with 57 controls who were wives of men who were sterilized, by age, parity, social class. They were interviewed 2 years after sterilization, with a response rate of 90% for cases and 79% for controls. They were asked "to rate periods now and as they had been before the operation when not using either the pill or intra-uterine device."

<table>
<thead>
<tr>
<th></th>
<th>Cases n = 45</th>
<th>Controls n = 42</th>
<th>$X^2$</th>
<th>$p^*$</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. who thought clots worse</td>
<td>10</td>
<td>4</td>
<td>2.59</td>
<td>0.107</td>
</tr>
<tr>
<td>No. who thought menstrual loss worse</td>
<td>15</td>
<td>5</td>
<td>5.63</td>
<td>0.018</td>
</tr>
<tr>
<td>No. who thought menstrual loss less</td>
<td>13</td>
<td>8</td>
<td>1.15</td>
<td>0.28</td>
</tr>
</tbody>
</table>

The author concluded that there was a tendency for sterilized women to observe a change in either direction. (31)
Sen Gupta et al (1981) reviewed 298 cases of hysterectomy performed from 1974-79 at one unit in Calcutta, India. Of these, 36 women had previously had tubal ligation sterilization. Clinical data pre- and post-operatively was available for study along with histopathological reports, so that findings of post-ligation hysterectomy could be compared to non-ligation cases. Ligation-hysterectomy interval was found to be less than 5 years in 3 cases, between 5-10 years in 12 cases, between 11-15 years in 10 cases, and between 16-20 years in 10 cases, with only one case of more than 20 years. Those that attended within 8 years came with symptoms of uterine prolapse, excessive white discharge per vagina, and in two cases with hydrosalpinx. In only one case the person attended with menorrhagia from multiple fibroids, otherwise menorrhagia was a late symptom in most cases. However, 69.4% of post-ligation women presented with menorrhagia as compared to 34.3% of controls, and 16.6% presented with dysmenorrhoea as compared to 9.6%. Age-specific rates of hysterectomy show that in the 35-40 group there is a significantly higher proportion of cases (36%) than controls (10.6%) implying that hysterectomy had to be performed at a younger age in post-ligation women than in controls.

The histopathology reports showed a significant increase among the cases in fibroids (cases 55%, controls 22.5%) endometriosis (cases 33% controls 3.4%) hydrosalpinx (cases 41.6% controls 1.5%) polycystic ovary (cases 42% controls 7.6%) endometrial polyp (cases 14% controls 2.2%). Dysfunctional uterine haemorrhage is said to have occurred in 19.4% cases and 1.9% controls.

There is no distinction made between women who had been sterilized for contraceptive purposes or those who had been sterilized for medical or obstetric reasons. The high prevalence of pathology in the cases indicates that they were from a less healthy population than the controls, and many of those complaints would have lead to menorrhagia. There is no way of
knowing because of the shortage of this kind of data, whether these women would have developed these pathologies even if the sterilizations had not taken place. (32)

Savage (1982) reviewed the case notes of all the women (309) who had been sterilized by her in New Zealand during the period 1973-76, then administered a questionnaire to 222 of those women and gathered data on 96 cases from postal questionnaires, general practitioners, family planning or public health nurses. Information was available on 80% of the cases. Comparison was made with women whose husbands had been sterilized. She compared the cases in two groups: group 1 included all those operated on via vaginal and abdominal routes in association with gynaecological operation, termination of pregnancy or as an elective procedure; group 2 consisted of women sterilized in the puerperium or in association with caesarian section. There was no significant difference between cases and controls, with about a quarter of each group complaining of longer and heavier periods. There appeared to be no difference between the contraception groups in their subsequent menstrual patterns, but interestingly, there were 18% more previous pill-users in the vasectomy group and group 2 than in group 1.

The author suggested that one reason for absence in her study of the "post-sterilization syndrome" is that the tubes were divided without damage to the terminal branch of the uterine artery. (33)

Templeton and Cole (1982) used record linkage data derived from Scottish hospital discharge summaries and admissions to gynaecological units. The study group, women aged between 30-39 who were sterilized in 1973, was linked to gynaecological discharge summaries for each of the subsequent years 1974-77 inclusive. Women of the same age-group delivered of a live or stillbirth
in 1973, and who were not subsequently sterilized or pregnant in the study period, were used as a control group. This provided 6260 cases and 7612 controls. A total of 12,117 women had been sterilized from 1967 to 1973.

There were more cases than controls in the older age-group, fewer women from social class I and II among the sterilized women, and of 1431 women who were sterilized in the post-partum period on whom only data about previous pregnancies were available, the cases were more highly parous than the controls.

Age-specific and pregnancy-specific rates for hysterectomy following sterilization showed a highly significant difference between cases and controls. The average annual hysterectomy rate was 9.3 in sterilized women and 2.5 in the controls (per thousand women). The average annual gynaecological admission rate per thousand women was 43.7 in sterilized women and 21.5 in controls.

The authors emphasized that these results should be used with caution: the controls were women who had been pregnant in 1973 and then did not have another pregnancy for 4 years, so were probably using some form of contraception in that time. Oral contraception would diminish symptoms of heavy bleeding, thus reducing the risk of hysterectomy. There may have been other differences between the cases and controls. However the authors stated that this study demonstrated an "undoubted association" between sterilization and subsequent risk of hysterectomy. Whether this effect was due to the sterilization procedure itself or characteristics of the women seeking sterilization was not clear, but "in epidemiological terms it may not be important whether sterilization actually produces increased menstrual problems or not. It has the effect of producing an increased demand for hysterectomy." (34)
The Indian Council of Medical Research (1982) undertook a multicentric, nationwide study following up women who had been sterilized at 13 teaching hospitals. A total of 32,177 women had been sterilized from Sept. '76 to June '78 and of these only 11,688 (36.32%) were available for follow-up. The commonest menstrual abnormality encountered was menorrhagia with overall prevalence of 5.1% in comparison to a pre-operative prevalence of 1.3%. This study is described as a prospective one but there is no description of the methodology in the report. The loss to follow-up is too substantial to be ignored and there is no indication of the time interval between sterilization and follow-up. (35)

Pachauri and Jamshedji (1982) working with the India Fertility Research Programme, Hyderabad India, followed up 3,466 women who had undergone sterilization during 1973-79 at 8 institutions participating in 15 studies, applying the standard protocol of the IFRP. Data on patient characteristics, medical and menstrual history and clinical aspects of procedure were reported at the time of sterilization and early complications and complaints reported at the first follow-up 1-3 weeks after surgery. Further follow-ups took place at 6, 12 and 24 months. Data on menstrual patterns at these follow-ups were only available for 42%, 36% and 59% respectively.

Women who had used systemic contraception or IUDs during the 3 months previous to ligation were excluded form this study. The cases were used as their own controls, with changes evaluated by comparing selected parameters on each visit. The analysis only included those women who were seen for one or more follow-up at 2 months after ligation.

At 24 months 88.3% reported no change in amount of menstrual flow with 5.7% reporting an increase and 5.9% reporting a decrease in amount of flow. 81.2% reported no change in duration of flow, with 11.1% reporting an increase and 7.7% a decrease (increase to decrease \( p < 0.01 \)). 94.2% reported no change in regularity with 1.5% reporting an increase and 4.3% reporting a decrease (increase to decrease \( p < 0.01 \)). 82.8% reported no
change in dysmenorrhoea with 5.7% reporting an increase and 11.4% reporting a decrease (increase to decrease p<0.01).

1.2% of women followed had had a hysterectomy by the 24 month stage.

The authors conclude that there is no change for the majority of women following sterilization. The losses to follow-up are substantial. (36)

Bhiwandiwalla et al (1982) presented a study using a data set collected at five institutions in five countries, looking at menstrual pattern changes in 1,025 women, following laparoscopic sterilization by two techniques, electrocoagulation and tubal rings. After controlling for prior contraception, the two techniques were compared with respect to cycle regularity, cycle length, flow duration, amount of flow, dysmenorrhoea and intermenstrual bleeding. Approximately 10-50% of the menstrual pattern changes seen within the 6 months following sterilization could be attributed to the discontinuation of oral contraception or removal of IUD at time of sterilization. The authors were testing the theory that sterilization causes menstrual changes by disturbance of the utero-ovarian vascular anastomosis and that as the degree of destruction would be greater with unipolar electro-coagulation, so would be the subsequent menstrual pattern disturbance using that method. The authors consider that this study renders that theory invalid. (37)

Riedel and Semm (1982) insisted on the opposite in their paper, "in 1981 we proved that a clear relationship exists between the extent of destruction of circulation and nervous system within the mesosalpinx and the occurrence of menstrual disorders as well as menopausal symptoms". They argued that as two-thirds of the ovarian blood supply passes through the ramus tubarines of the uterine artery, destruction of large areas of mesosalpinx would lead to striking disturbances within ovarian metabolism.
The authors described animal experiments in which the effects of mono and bipolar high frequency techniques, endocoagulation and carbon dioxide laser coagulation methods were examined. They recommended the latter two methods as producing the least tissue damage. (38)

Cooper (1983) used data from the Oxford Record Linkage Study to examine whether the risk of hysterectomy was greater in women who had had tubal sterilization than would be expected among all women at risk in a defined population. Abstracts of all hospital discharges and all deaths in a population of about 365,000 women in Oxfordshire and W. Berkshire from 1963-70 were linked and analysed, with corrections made for variations in incidence with age, losses through death and migration, and the varying periods over which women were at risk. Over the eight years, 588 women had had tubal sterilization and 8150 had had a hysterectomy, of which 20 rather than the expected number of 9 had a hysterectomy following sterilization. All these hysterectomies were for dysfunctional bleeding, only 4 women were over 40 years old, and the time interval between sterilization and hysterectomy varied from 6 months to 6 years.

The author concluded that, "the results seem to provide prima facie evidence that the risk of hysterectomy for menorrhagia may be doubled after tubal sterilization." It is further noted that the association is unclear and the recommendation made that an intensive prospective study be undertaken in which the pre-operative characteristics of women seeking sterilization are clearly defined and objective measurements of menstrual blood loss before and after surgery, made. (39)

Bhiwandiwala et al (1983) reported again on their pooled data set, this time on 10,004 cases collected by collaborating investigators at 64 institutions in 27 countries. They explored whether four occlusive techniques:
electrocoagulation, tubal rings, prototype spring-loaded clips, and the Rocket clips differed with respect to subsequent menstrual patterns. From this they wished to determine, along the lines of their previous study, whether menstrual pattern changes were attributable to sterilization procedures. Data was collected prospectively at the time of admission and then at 6, 12, and 24 month follow-up visits. Of the 10,004 women for whom they had 6 month follow-up data 62% returned for the 12 month follow-up, and only 20% for the 24 month follow-up. Women were not asked about menstrual changes rather they were asked about specific menstrual parameters for their last three cycles: cycle length, cycle regularity, menstrual flow duration, amount of flow, dysmenorrhoea, and intermenstrual bleeding.

The women were used as their own controls, comparing changes which took place in the period 6-12 months to the changes reported in the period 0-6 months, on the assumption that any changes due to contraception would have occurred prior to the first follow-up visit at 6 months, and that sterilization did not cause any menstrual changes.

The authors concluded, "the majority of women reported no menstrual changes subsequent to sterilization. When changes are experienced they occurred in equal proportions in opposite directions. Depending on the parameter, from 15% to 79% of the menstrual pattern changes seen within 6 months after sterilization in women who were using oral contraceptives or IUDs at the time of sterilization could be attributed to the discontinuation of those methods....... there were no significant differences between the several occlusion techniques with respect to the proportion of women who reported changes in their menstrual patterns after sterilization." Age was not found to be a confounding factor. They also found that there was no cumulative effect: the proportion of women who experienced change did not increase over time.

In order to assess possible cultural variations in reporting practices
the prototype spring-loaded clip data was split into two groups, 43% of the cases from the USA and Europe, and the other 57% from the "developing world". The differences between these two groups were found to be pronounced with respect to all parameters except cycle regularity.

Rank ordering of the occlusion techniques showed that overall, the proportion of women who reported menstrual changes was least with the tubal ring, followed by electrocoagulation, the prototype spring-loaded clip and finally the Rocket clip, indicating therefore that in fact the more destructive technique, unipolar electrocoagulation, did not lead to the most change.

In this study an assumption was made that losses to follow-up were not related to menstrual problems, which may not be the case. Certainly very little can be based on the 24 month follow-up for which 80% of the women were lost to trace. Therefore the follow-up period for which one can accept the results extends only to 12 months which is not long enough to assess the long-term effects of sterilization. (40, 41)
I decided to design a small pilot study in order to experience at first hand the issues and problems related to collecting and analysing data about menstrual problems associated with sterilization by tubal ligation. I had a month in which to do a short field study which I decided to do in Bangladesh which has an active sterilization programme. I made arrangements to work in a primary health care project some 20 miles from Dhaka, which had a reputation for well-trained paramedical workers and good record-keeping.

In preparation for this study I drew heavily for advice on a book edited by Shamima Islam called, "Exploring the Other Half: field research with rural women in Bangladesh" (42) and also on my own experiences with primary health care in India.

Carrying out research on a population such as rural Asian women can be a very one-sided process. The researcher is eager to gain information on certain topics of particular interest. This material may eventually benefit the people in question. The interviewees, especially women in rural areas, may be confused, suspicious, amused by the research attention they are suddenly getting. As Florence McCarthy has written:

"Most western research methodologies assume that the sample population knows what research is or at least has some idea about it. Second, it is assumed that asking questions is a universal and approved form of eliciting information, and third that people know how to answer questions. What I realized in the first few weeks of my reconnaissance work was that these assumptions were totally inappropriate to the village context at that time.........anyone asking questions had some hidden intent and must be from the government...... to seek information for its own sake was foreign
and it made no sense for a foreign person to come all the way to their village just to talk to women." (42)

An interviewer, especially an outsider cannot simply walk into a village and start asking questions. This is particularly the case if questions are of an intimate nature. One has to become known to the villagers, to gain their confidence, trust and respect, and to be willing to spend time in reassuring them. It may be best to actually live in the village during the study, so that they get used to having a stranger around. Foreign women can be confused by village women asking personal questions about marriage, children, husbands, often touching their clothes or hair. This is usually because they are trying to establish common ground, sharing common symbols. It is also a partial exchange of information, they are finding out about the researcher's life as she is trying to find out about theirs. This process closes the unfamiliarity gap and so is constructive. However, it can be very time-consuming especially if it has to be repeated with each woman or group of women being interviewed.

An unmarried woman travelling alone or working with men may so shock the village women that a rapport becomes impossible. For instance, Saleha Begum described how village women in her experience considered that young unmarried or unaccompanied women did not come from good families since they were allowed to travel around alone and work with males who were not relatives. They warned her that these women would find it difficult to get married since "no decent parents would want their sons to marry them". (42)

Other researchers have found that their legitimacy increased if they brought their children with them, or if their husbands visited while they were in the village. Villagers sometimes believe that well-educated people work in offices rather than in the field. I have often found this impression of doctors: a real 'MBBS' doctor works in private practise, usually in the cities.

Travelling alone in India I was frequently surprised when people
asked each other if I was a man or woman. This was usually because I had short hair, wore kurta and pyjama and was unaccompanied, characteristics not associated with being a woman in rural terms. Even Asian researchers would have to be sensitive to the urban/rural divide, that their social and cultural values and behaviour may not be shared by the villagers. I have found that being Asian is sometimes a handicap in that villagers may accept eccentric behaviour from foreigners but not from fellow nationals. They often disapprove of city women who do not observe taboos on menstruation, pregnancy and childbirth, who do not serve their husbands and who are familiar with non-related men.

Mumdani also emphasized this in his critique of the Khanna Study, "The Myth of Population Control", "All efforts had been expended to ensure that the fieldworkers were all Punjabis and that the American supervisors had considerable familiarity with India. But the staff, though Punjabi, were all members of the urban, educated middle class. What they shared with the directors was a bourgeois culture. What plagued the study was not a national bias, but a class bias. This bias pervaded its staff as well as its directors, without distinction of race, religion or 'culture'". (43)

There are many problems associated with trying to administer a questionnaire in the village context. There are the usual problems of the season. If it is the rainy season the village may be inaccessible. If it is harvest time the women would be too busy to answer 'senseless' questions. Even at other times, it would be difficult to see the women on their own, between all their domestic chores. Privacy is largely unknown to them. To insist on seeing each person alone would probably make her nervous and her family suspicious. The hierarchy within the female community needs to be respected, especially if there are many wives of one man, and the consent of the mother-in-law is essential. The men would have
to be convinced that the researcher is not a threat, an agent trying to coerce their women to accept contraception or sterilization. They will often listen to conversations, sometimes secretly, until their doubts are dispelled, and may interfere, challenge or seek to dominate the discussions. The women would be very cautious in their presence.

It is difficult to restrict the conversation to the research topic and one would have to pick up the information and clues in somewhat casual conversation, sometimes completing the questionnaires after the visit. Notebooks make the subjects nervous: "note-taking never does us any good". (42)

If it becomes known that the researcher is a health professional, especially a doctor, that person can become a source of advice and influence with the attendant consequences. The act of carrying out research without providing services is very controversial and should be resolved at the outset. To be told that the research may ultimately benefit them may not convince them. I was told, "You people come and go, and in the end what difference does it make for poor people like us?"

Finally, one has to consider the quality and integrity of the data collected. As I have indicated, if one has developed a warm and co-operative relationship with the women one is working with, the information one gains is more likely to be reliable. It must be clear in the researcher's mind whether the aim is to collect any data, or whether the aim is to collect good data that is truly representative of the situation. This is particularly the case when dealing with issues which reflect the effectiveness of a policy or problems arising from it that have political implications. Family planning or population control is such an arena.

Shamima Islam in her book on indigenous abortion practitioners in Bangladesh describes the delicacy with which she obtained information on a topic normally never discussed with outsiders. (44). She also described how women would deny any knowledge or experience of abortion, both for
religious and legal reasons, but would affirm the opposite when a closer association between them had formed later. Another woman who voluntarily talked about her health and family planning status said later that she had lied initially about her husband's awareness of the matter. (42)

Again Mamdani has a good example in his critique of the Khanna Study, "... it took years of work and persistent failure before the study staff would admit that there was a great difference in numbers between those who were in favour of contraception in principle and those who would accept contraception when offered; between those who 'accepted' contraceptives and those who admitted to 'using' them; and finally, between those who said they were 'using' contraceptives and those who in fact used them. Why would a villager accept contraceptives without intending to use them? And furthermore, why should they say they were using them when in fact they weren't? .......in brief, there was only one reason for such behaviour: politeness. As one of the villagers explained to me: Babuji, someday you'll understand. It is sometimes better to lie. It stops you from hurting people, does you no harm, and might even help them."

In designing my study, I was very aware that I was not going to be able to establish the kind of relationship I would need, in the short time available. Acceptance was easier if one could explain the background and importance of the research, but in the case of this study, I would be examining the association of menstrual problems with sterilization, and knowledge of that possible association might create a bias. Nor did I wish to create anxiety in the women who had been sterilized and possibly jeopardize the future of such programmes. Further I did not wish my identity as a doctor to encourage them to over- or under-emphasize their symptoms.

The best plan seemed to be to enlist the help of project paramedical workers in administering the questionnaires. The advantages of this were that they would be working with women they were well known to, asking the questions in the normal course of their work. In many cases the women
questioned would have been sterilized through the project itself and were being followed up by the health workers anyway. The paramedics would be collecting data on their own clients and so would have a further incentive to increase their knowledge of those women.
Methodology: 1. Case-control study using questionnaires

2. Information from the record cards

1. The questionnaires were designed in English and then translated into Bangla. They were checked by representatives of the study population to ensure that the language was appropriate to them. Each questionnaire consisted of two forms: A and B; A was for application to all respondents and B was for sterilized women only.

At the primary health care project in Bangladesh, a meeting was held of all the paramedical workers currently undergoing training there. With the help of the doctor and family planning supervisor of the project, I explained the purpose of the study and the planned procedure. I requested female volunteers from the group and continued working with them. We repeated the same process in a sub-centre of the same project in another district. There were four paramedics in each district working on the interviewing, making eight in all.

Each paramedic was give a list of instructions as well as having detailed discussions in the groups as to the procedure. Each paramedical worker had a list of her own clients and records of those who had been sterilized and dates. Each paramedic systematically drew out of the lists the names of those who had been sterilized five or more years ago. Only when there were not enough on the list to make up the number required, were women who had been operated on less than five years ago included. We were attempting to collect at least fifty cases and controls.

To avoid bias by specific mention of the sterilization when asking about menstrual problems, the paramedics were asked to write next to the relevant question (no.18) the number of years since sterilization, before
the interview was started. In this way specific discussion about the sterilization was reserved for form B only.

The paramedics were asked to select controls on the basis of age, parity, abode and subjective assessment of socio-economic status. They quickly pointed out to us that they could not match on both age and parity since women who had not been sterilized would have remained fertile and could have continued having children in the same time period. After discussion it was agreed that matching should concentrate on age, but with matching on parity where possible.

The questionnaires were administered by the paramedicals in their own catchment area. After collection, they were translated into English for analysis. Some of the questionnaires were translated by two independent people to ensure the consistency of the data.

2. Record cards: The women who had been sterilized through this primary health care system were followed up at a certain interval after the operation. I collated the details from approximately 100 records, the first one selected at random, the rest numbering systematically from it.

The sterilizations performed in this area, both at the project and in the Government centres, were mini-laparotomies, usually under local anaesthetic with modified Pomeroy ligation and resection.
1. Questionnaire case-control study:
The data collected in Bangladesh was transferred to Britain and translated, then analysed manually and using the Statistical Package for the Social Sciences (SPSS) programme on the computer.

Altogether there are 154 completed questionnaires, after discarding 5 forms which were incorrectly filled in. Of these completed forms, 85 were for the cases, women who had been sterilized at least two years earlier, and 69 were for controls, women who were matched to the cases on age, parity where possible, abode, and by subjective assessment of social class. Predictably the cases were in greater number because they were easier to identify in the limited time available.

Most of the data were in the form of closed questions which could be coded directly. In some cases, such as for village, occupations, lists were drawn up and then coded. With open questions, the replies were allocated to categories which were then coded.

A summary of the main demographic characteristics of the cases and controls, is given in table 2. and in figures 1. and 2. There were no significant differences between the cases and controls with respect to either age or parity.

The occupation listings were more difficult to interpret. 52% of controls and 45% of cases came from families involved in farming, but there was no record of how much land they owned, or if they were sharecroppers working on other people's land. 4% of controls and 11% of cases were involved in fishing and 13% of controls and 16% of cases came from families involved in business. Again there is no breakdown of what this means, so socio-economic status is difficult to assess. The rest of the women had
### Summary of demographic characteristics of women in the case-control study

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<th>Cases</th>
<th>Controls</th>
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<tbody>
<tr>
<td><strong>Mean age</strong></td>
<td>32.9 (3.9)</td>
<td>32.5 (4.2)</td>
</tr>
<tr>
<td><strong>Education</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>none</td>
<td>87%</td>
<td>87%</td>
</tr>
<tr>
<td>primary</td>
<td>11%</td>
<td>13%</td>
</tr>
<tr>
<td>secondary</td>
<td>1%</td>
<td>0</td>
</tr>
<tr>
<td><strong>Literacy</strong></td>
<td>13%</td>
<td>13%</td>
</tr>
<tr>
<td><strong>Religion</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Muslim</td>
<td>74%</td>
<td>83%</td>
</tr>
<tr>
<td>Hindu</td>
<td>26%</td>
<td>16%</td>
</tr>
<tr>
<td><strong>Mean age at first marriage</strong></td>
<td>12.5 (2.6)</td>
<td>12.7 (4.2)</td>
</tr>
<tr>
<td><strong>Mean number of children born</strong></td>
<td>5.1 (1.7)</td>
<td>4.9 (1.9)</td>
</tr>
<tr>
<td>(b)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Mean number of children died</strong></td>
<td>0.8 (1.06)</td>
<td>0.78 (1.09)</td>
</tr>
<tr>
<td>(a)</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Crude mortality a/b</strong></td>
<td>16%</td>
<td>16%</td>
</tr>
<tr>
<td><strong>Mean number of living male children</strong></td>
<td>2.3</td>
<td>2.1</td>
</tr>
<tr>
<td><strong>Mean age of youngest child</strong></td>
<td>6.2 (2.7)</td>
<td>3.8 (3.0)</td>
</tr>
<tr>
<td><strong>Use of contraception in the past</strong></td>
<td>34%</td>
<td>30%</td>
</tr>
</tbody>
</table>

(standard deviation in brackets)
### FIGURE 1. AGE DISTRIBUTION IN CASES AND CONTROLS

<table>
<thead>
<tr>
<th>Age group (yrs.)</th>
<th>Controls</th>
<th>Cases</th>
<th>Totals</th>
<th>(X^2) *</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>25-29</td>
<td>14</td>
<td>15</td>
<td>29</td>
<td>0.174</td>
<td>0.67</td>
</tr>
<tr>
<td>30-34</td>
<td>29</td>
<td>32</td>
<td>61</td>
<td>0.306</td>
<td>0.58</td>
</tr>
<tr>
<td>35-39</td>
<td>17</td>
<td>31</td>
<td>48</td>
<td>2.486</td>
<td>0.11</td>
</tr>
<tr>
<td>40-44</td>
<td>9</td>
<td>6</td>
<td>15</td>
<td>1.552</td>
<td>0.21</td>
</tr>
<tr>
<td>45-49</td>
<td>0</td>
<td>1</td>
<td>1</td>
<td>0.817</td>
<td>0.37</td>
</tr>
<tr>
<td>Totals</td>
<td>69</td>
<td>85</td>
<td>154</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

\(X^2\) linear trend = 0.16
\(p = 0.68\)

*for one degree of freedom
FIGURE 2. PARITY DISTRIBUTION IN CASES AND CONTROLS

<table>
<thead>
<tr>
<th>No. of births</th>
<th>% of Women</th>
<th>Controls</th>
<th>Cases</th>
<th>Totals</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 - 2</td>
<td>2.4</td>
<td>7.2</td>
<td>2</td>
<td>7</td>
</tr>
<tr>
<td>3 - 4</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5 - 6</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7 - 8</td>
<td>10.6</td>
<td>11.5</td>
<td>51</td>
<td>52</td>
</tr>
<tr>
<td>9 - 10</td>
<td>7.1</td>
<td>7.2</td>
<td>8</td>
<td>9</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>69</td>
<td>85</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>No. of children born</th>
<th>Controls</th>
<th>Cases</th>
<th>Totals</th>
<th>$X^2$</th>
<th>p</th>
</tr>
</thead>
<tbody>
<tr>
<td>1-2</td>
<td>5</td>
<td>2</td>
<td>7</td>
<td>2.10</td>
<td>0.147</td>
</tr>
<tr>
<td>3-4</td>
<td>31</td>
<td>32</td>
<td>63</td>
<td>0.84</td>
<td>0.358</td>
</tr>
<tr>
<td>5-6</td>
<td>20</td>
<td>36</td>
<td>56</td>
<td>2.94</td>
<td>0.067</td>
</tr>
<tr>
<td>7-8</td>
<td>8</td>
<td>9</td>
<td>17</td>
<td>0.04</td>
<td>0.841</td>
</tr>
<tr>
<td>9-10</td>
<td>5</td>
<td>6</td>
<td>11</td>
<td>0.002</td>
<td>0.968</td>
</tr>
<tr>
<td>totals</td>
<td>69</td>
<td>85</td>
<td>154</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

$x^2$ linear trend = 0.735

*for one degree of freedom
husbands working in occupations including carpenters, labourers, porters, potters and barbers. The majority of women (91% of controls, 89% of cases) said they looked after the household, with 3% of both working as domestic servants and 4% of both working as potters.

Previous contraception was not used at any time in 70% of the controls and in 63% of the cases. 25% of controls and 26.7% of cases had used oral contraception at some stage, 1.7% of controls and 3.8% of cases had used an IUD, 13.3% of controls and 10.2% of cases had used injectable contraception, and one woman acknowledged having had an abortion. None of these differences in usage of contraception are statistically significant.

No details were given of any of the barrier or 'natural' methods such as rhythm or withdrawal.

Menstrual cycle questions revealed that the average length of menstruation at the present time for controls was 4.3 days and for cases 4.0 days. The range was 2 - 8 days for controls and 1 - 9 days for cases. 89.6% of controls and 86.3% of cases had a cycle* of 26 - 34 days. 4.1% of cases had periods irregularly once or twice a month, 1.5% of controls and 4.1% of cases had cycle lengths regularly less than 25 days, 6% of controls and 1.4% of cases had cycle lengths of more than 35 days and one woman from the controls had a cycle of more than 150 days.

* a cycle consists of the number of days from day 1 of a period to day 1 of the next.
The following table shows the response to the question, "Have you ever had any problems with your periods?" (the categories were suggested)

Table 3.

<table>
<thead>
<tr>
<th></th>
<th>Cases No.</th>
<th>Cases %</th>
<th>Controls No.</th>
<th>Controls %</th>
<th>$\chi^2$</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>No problems</td>
<td>31</td>
<td>36.5</td>
<td>45</td>
<td>65.2</td>
<td>12.59</td>
<td>0.0004</td>
</tr>
<tr>
<td>Bad pains</td>
<td>46</td>
<td>54.1</td>
<td>20</td>
<td>29.0</td>
<td>9.8</td>
<td>0.0017</td>
</tr>
<tr>
<td>Heavy bleeding</td>
<td>27</td>
<td>31.8</td>
<td>14</td>
<td>20.3</td>
<td>2.57</td>
<td>0.11</td>
</tr>
<tr>
<td>Lasts many days</td>
<td>10</td>
<td>11.8</td>
<td>2</td>
<td>2.9</td>
<td>4.17</td>
<td>0.041</td>
</tr>
</tbody>
</table>

*2 of the controls had amenorrhoea

The following table shows the responses to the question, "Has there been any change in the last x years?"

Table 4.

<table>
<thead>
<tr>
<th></th>
<th>Cases No.</th>
<th>Cases %</th>
<th>Controls No.</th>
<th>Controls %</th>
<th>$\chi^2$</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Yes</td>
<td>45</td>
<td>74.5</td>
<td>13</td>
<td>25.5</td>
<td>18.86</td>
<td>&lt;0.00005</td>
</tr>
<tr>
<td>Increased bleeding</td>
<td>18</td>
<td>21.2</td>
<td>2</td>
<td>2.9</td>
<td>11.26</td>
<td>0.0008</td>
</tr>
<tr>
<td>Decreased bleeding</td>
<td>12</td>
<td>14.1</td>
<td>8</td>
<td>11.6</td>
<td>0.22</td>
<td>0.65</td>
</tr>
<tr>
<td>Increased pain</td>
<td>14</td>
<td>16.5</td>
<td>2</td>
<td>2.9</td>
<td>7.53</td>
<td>0.006</td>
</tr>
<tr>
<td>Decreased pain</td>
<td>4</td>
<td>4.7</td>
<td>2</td>
<td>2.9</td>
<td>0.33</td>
<td>0.56</td>
</tr>
<tr>
<td>Increased regularity</td>
<td>2</td>
<td>2.4</td>
<td>2</td>
<td>2.9</td>
<td>0.05</td>
<td>0.83</td>
</tr>
<tr>
<td>Decreased regularity</td>
<td>11</td>
<td>12.9</td>
<td>0</td>
<td>0</td>
<td>9.6</td>
<td>0.002</td>
</tr>
<tr>
<td>Increase in length</td>
<td>6</td>
<td>7.1</td>
<td>0</td>
<td>0</td>
<td>5.07</td>
<td>0.024</td>
</tr>
<tr>
<td>of menstruation</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Decrease in length</td>
<td>5</td>
<td>5.9</td>
<td>1</td>
<td>1.4</td>
<td>2.00</td>
<td>0.16</td>
</tr>
<tr>
<td>* of menstruation</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ambiguous symptoms</td>
<td>7</td>
<td>8.4</td>
<td>1</td>
<td>1.4</td>
<td>3.56</td>
<td>0.059</td>
</tr>
</tbody>
</table>

*Ambiguous symptoms (weakness, dizziness, burning, fever etc.)
The women were asked what, in their opinion, had caused these changes (if any) of the eight controls who gave a reason, 4 said their previous contraception had caused it, one said it was 'habit', one blamed it on her illness, one explained it by the birth of her child, one said the change resulted from her discontinuing oral contraception.

Of the 33 cases who gave a reason, 28 said the sterilization caused the change, one said her previous contraception had caused it, and 4 explained it as a result of 'age'.

Of the total 154 women, 107 complained of neither increase or decrease in pain or bleeding. Of the remainder, 9 women reported both increased pain and increased bleeding, while 6 reported both decreased pain and decreased bleeding. In order to assess whether the women complaining of increased pain and/or increased bleeding were those who had discontinued oral contraceptives during the year of sterilization, the changes experienced by those women were examined. Only 8 women had used oral contraceptives in the year of sterilization; of these 3 had no change in bleeding, 3 showed an increase and 2 showed a decrease in bleeding \( (X^2 = 2.936, p=0.087) \). Similarly, of those 8 women, 6 reported no change in pain and 2 reported an increase in pain \( (X^2 = 0.83, p=0.36) \).

(Discussion of these data is in the next chapter).

Data on the women who were sterilized:
The mean time interval since sterilization took place was 5.1 years (s.d. = 1.39) with a range of 2 - 9 years.

Half the sterilizations had been carried out at the primary health care project and the rest at government-sponsored centres. There were no significant differences between the side-effects reported by the women from the project or the government centres.
On being asked the reason for having the sterilization carried out
35% of the women said it was undesirable to have too many children, that
one could feed, clothe and look after a few children better. 20% mentioned
that poverty was the reason, with 19% stating that they did not have enough
land to be able to provide for their children. A further 24% gave 'financial'
reasons such as "only one wage-earner in the family with 8 dependents".
Only one woman directly referred to the incentive payment.
15% gave ill-health and obstetric difficulties as a reason for being
sterilized: one referred to repeated miscarriages, several women referred
to complications in pregnancy or labour, and another gave her husband's
ill-health as a reason. Three women gave fear of desertion as a reason
and three others said they were afraid of being ill-treated if they
refused. Two women described how they had been forced by their husbands
to be sterilized; in one case the woman had only had one child who had
died when one month old, but her husband already had several wives and
many children and tricked her into it.
The final question asked the women to describe how they felt at present
about having had the sterilization.
54% said they had no problems and/or felt better after the sterilization,
while 45% said they felt worse after the sterilization.
21 women said they suffered from weakness and giddiness; 9 said
they had headaches, insomnia, loss of weight and appetite, burning sensations
in their hands or feet; 4 women reported dyspareunia (one woman said she
could not walk for three days after intercourse); 9 women reported menstrual
problems; 8 women complained of pain in their abdomens especially when
working; 4 women said they felt uncomfortable and restless.
2. Record cards follow-up:

110 record cards of women who had been sterilized were drawn out and analysed. Each card was designed to match up with entries in a register of clients at the health centre. Information about age and parity was in the register and not on the cards, and since the register was not available for inspection, the information provided by the cards was quite limited. I was told that these women would be aged between 25-35 and that they would have a minimum of three children in order to qualify for sterilization at this centre.

Results:
The interval between follow-up and sterilization ranged from 2-43 months with a mean of 28.8 months (s.d. = 10.6).

The following table summarizes the data from the cards.

<table>
<thead>
<tr>
<th>Table 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Side effects immediately following operation:</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Side effect</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>none</td>
<td>76.4%</td>
</tr>
<tr>
<td>abdominal pain</td>
<td>0.9%</td>
</tr>
<tr>
<td>heavy bleeding</td>
<td>2.7%</td>
</tr>
<tr>
<td>weakness</td>
<td>4.5%</td>
</tr>
<tr>
<td>complications of wound infection</td>
<td>9.1%</td>
</tr>
<tr>
<td>fever</td>
<td>4.5%</td>
</tr>
<tr>
<td>other (joint pain, oedema)</td>
<td>1.8%</td>
</tr>
</tbody>
</table>

| Change in menstruation immediately after sterilization: |

<table>
<thead>
<tr>
<th>Change</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>none</td>
<td>67.3%</td>
</tr>
<tr>
<td>heavy bleeding</td>
<td>20.0%</td>
</tr>
</tbody>
</table>
Table 5 contd.

Dysmenorrhoea since sterilization:

<table>
<thead>
<tr>
<th>Present</th>
<th>Not Present</th>
</tr>
</thead>
<tbody>
<tr>
<td>22.7%</td>
<td>51.8%</td>
</tr>
</tbody>
</table>

Dyspareunia since sterilization:

<table>
<thead>
<tr>
<th>Present</th>
<th>Not Present</th>
</tr>
</thead>
<tbody>
<tr>
<td>10.0%</td>
<td>77.3%</td>
</tr>
</tbody>
</table>

Contraception prior to sterilization:

<table>
<thead>
<tr>
<th>None</th>
<th>Oral</th>
<th>Injectables</th>
<th>IUDs</th>
<th>Oral and injectables</th>
<th>Withdrawal</th>
</tr>
</thead>
<tbody>
<tr>
<td>50.9%</td>
<td>25.5%</td>
<td>1.8%</td>
<td>0.9%</td>
<td>4.5%</td>
<td>2.7%</td>
</tr>
</tbody>
</table>

Menstrual cycle:

<table>
<thead>
<tr>
<th>Regular</th>
<th>Irregular</th>
<th>Amenorrhoea</th>
<th>Heavy bleeding</th>
<th>Spotting</th>
</tr>
</thead>
<tbody>
<tr>
<td>81.8%</td>
<td>10.0%</td>
<td>2.7%</td>
<td>10.9%</td>
<td>1.8%</td>
</tr>
</tbody>
</table>

Length of menstruation:

| Less than 7 days | 65.5% |
| 7 - 15 days      | 26.4% |
| More than 16 days| 0.9%  |

Age of last child at time of sterilization:

<table>
<thead>
<tr>
<th>Born at or just before sterilization</th>
<th>24.5%</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 - 2 yrs</td>
<td>51.8%</td>
</tr>
<tr>
<td>3 - 4 yrs</td>
<td>11.8%</td>
</tr>
<tr>
<td>5 - 6 yrs</td>
<td>4.5%</td>
</tr>
<tr>
<td>7 - 12 yrs</td>
<td>3.6%</td>
</tr>
</tbody>
</table>

Women who had had abortions:

<table>
<thead>
<tr>
<th>None</th>
<th>One abortion</th>
<th>Two abortions</th>
</tr>
</thead>
<tbody>
<tr>
<td>70.9%</td>
<td>27.3%</td>
<td>1.8%</td>
</tr>
</tbody>
</table>

Abortions at time of sterilization: 76.4%
From the results of the case-control study (Set 1) the following points arise:

1. Table 2 and figures 1 and 2 show that the two groups of women were similar except in ages of their youngest children. A difficulty arises here which is that many of the controls continued to have pregnancies which would effect their menstruation patterns. It would be preferable to use controls who would not be getting pregnant but also not using contraception which would effect their menstruation. For this reason comparison with women whose husbands have been sterilized is a better option.

   From this data there is also an implication that the cases would possibly have had larger families if they had not been sterilized since they had the same average family size as the controls even though they had been sterilized approximately five years earlier.

2. The uptake of contraception is higher than the average for Bangladesh (16%) which is to be expected since these women were registered with the health project which provided contraceptive services.

3. A significantly higher number of cases reported "ever having "problems with their periods and the major differences were with painful periods and the length of bleeding. There was no significant difference between cases and controls as far as heavy bleeding was concerned. Interestingly, there is no significant difference between the average length of menstruation at the present time of the cases and the controls.

4. Table 4 shows that significantly more of the cases reported increased bleeding, increased pain, decreased regularity and increased length of menstruation. 33% of the cases attributed the changes to the sterilization.

5. Use of oral contraceptives in the year of sterilization did not contribute (as a result of withdrawal) significantly to the changes in menstruation. However the numbers involved were quite small, and for the injectables
and intra-uterine devices they were even smaller.

6. Many of the women who had been sterilized complained of ambiguous symptoms of weakness, loss of appetite, burning sensations and inability to work, which could be attributed to general poor health caused by anaemia, poor nutrition or infectious diseases.

Record card follow-up (Set 2)

The information from the record cards is more difficult to interpret as there were no controls or any past-menstrual history for comparison.

There is some information of interest which could not be obtained through the questionnaire, such as immediate post-operative complications and the number of women who had used abortion as a method of birth-control.

A comparison of data Sets 1 and 2 show that 16.5% of cases and 2.9% of controls in Set 1 reported increased pain after sterilization while 22.7% reported dysmenorrhoea in Set 2.

Also 10.9% of Set 2 complained of heavy bleeding in menstruation compared with 21.2% of cases in Set 1 who complained of increased bleeding since sterilization (table 4) and 31.8% of cases and 20.3% of controls who reported ever having heavy bleeding (table 3).

These can only be very rough comparisons since the questions asked were different for each set and would effect the answers, but also because there is no pre-sterilization data in Set 2.
General discussion:

Collecting reliable data on such areas as menstruation is very difficult. Much of it relies on women's recall of what their periods were like over long time intervals, and also when they may have had not only repeated pregnancies and lactation, but also possibly undiagnosed miscarriages or abortions. Post-partum sterilization cases present a particular problem in that the woman goes through a nine month pregnancy, followed by sterilization, then possibly a year of lactational amenorrhoea. Women have to prepare for menstruation roughly every month and so are aware of the time patterns and are usually sensitive to their own individual variations, but subjective variations between women are quite substantial.

A World Health Organization Task Force study in 1981 on "Women's Bleeding Patterns: Ability to recall and predict menstrual events", concluded that predictions of the length of the bleeding-free episode were more accurate than of the length of the bleeding-free interval or onset of the next bleeding episode (due to physiological variation in interval between bleeding episodes). Over two-thirds of the women in the study were unable to predict the onset of menstruation to within one day of its occurrence. The study also described how women confuse 'duration' and 'amount' of bleeding and what is termed as 'heavy' and 'light' bleeding is often associated respectively, with an increase or decrease in number of bleeding days.

The authors suggest that if recording menstrual events retrospectively especially with illiterate women, reference to the last period only obtains the most accurate information. (45)

Another way that researchers try to assess quantity of menstrual loss is by asking women about their periods, the number of sanitary pads or tampons used, and the duration of bleeding. Pelvic examination showing a bulky uterus is often regarded as confirmation of menorrhagia resulting
Study of menstrual blood loss
(Chimbira et al, 1980)

Relation between menstrual blood loss (in ml) measured during each of two consecutive periods in 92 women and the patient’s subjective assessment of menstrual blood loss (light, medium or heavy) (the bars represent the median values)

Relation between menstrual blood loss measured during each of two consecutive periods in 92 women and the number of sanitary pads and tampons used.
Figure 5.

Relation between 

menstrual blood loss (ml)

measured during each of two consecutive periods in 92 women and the duration of menstruation (in days). The bars represent the median values.
Study of menstrual blood loss
(Chimbira et al., 1980)

Figure 6.
Uterine weight (g)

Relation between mean menstrual blood loss (in ml) measured over two consecutive periods in 40 women and uterine weight (in g) at subsequent hysterectomy.

Figure 7.
Endometrial surface area (cm²)

Relation between mean menstrual blood loss (in ml) measured over two consecutive periods in 40 women and endometrial surface area (in cm²) at subsequent hysterectomy.
from myohypertrophy and the magnitude of blood loss related to the uterine weight and endometrial surface area. Chimbira et al (1980) described a study in which they measured these parameters in women complaining of menorrhagia for which no cause could be found. The graphs of their findings have been reproduced here as an illustration of the points they raised which are:

1. There was no relationship between parity and blood-loss.
2. The women's judgement of loss showed no correlation with measured loss with wide scatter of actual volumes against judged volumes of light, medium or heavy loss. (Figure 3.)
3. The women's judgement of loss showed no correlation with actual number of towels and/or tampons used per menstruation. (Figure 4.)
4. The duration of loss does not give an indicator of severity of loss. (Fig.5.)
5. Of those who subsequently had a hysterectomy (for menorrhagia) the uterus was weighed and endometrial surface area measured, and no correlation was found between uterus weight and blood-loss, or endometrial surface area and blood loss. (Figures 6. and 7.)

The authors conclude, "an individual woman can only assess the amount of blood loss in relation to her previous pattern, or her own preconceived ideas about menstrual blood loss...... it is worrying that some women in our study who complained of heavy periods, but in whom objective measurement of blood loss showed no evidence of heavy menstruation came to hysterectomy or were given medical treatment for a problem that did not exist."

The only study that compared pre- and post-sterilization blood loss objectively was that of Kasonde and Bonnar (21) and that showed no difference. However they only followed their cases for a year and many authors suggest that menstrual problems may take two or more years to develop. (29,32)

It would extremely difficult to make these objective measurements
in a Third World setting. There are strong taboos surrounding menstrual blood and women may be offended or anxious about research that involved keeping their soiled rags for collection. In some cases women do not use any sanitary protection at all and are segregated in menstrual huts (47) and in India impoverished women are known to use ashes, mud packs or paper from rubbish heaps (48).

However in industrialized countries where such measurements are more possible, a longitudinal study should be undertaken over at least two or three years in which women who are sterilized are matched with those whose husbands have been sterilized in order to monitor their menstrual losses, whether they do increase and if so, how severely.

The mechanism by which sterilization may lead to increased menstrual losses is not clear. A popular hypothesis at present is that damage to the tubo-ovarian anastomosis may lead to ovarian dysfunction and hormonal imbalance. Bhiwandiwala et al tried to compare different methods of tubal occlusion to assess whether the more disruptive methods lead to more menstrual problems. They concluded that there is no difference between methods.(37, 41)

Radwanska et al (1982) examined the hormonal patterns in 23 cases and 28 controls, and found characteristic cyclical patterns in all of the controls and in the 9 asymptomatic patients who had been sterilized. Among the 14 symptomatic cases, 4 had anovulatory cycles and 11 had mid-luteal progesterone deficiencies. The authors suggest that anovulation or poor progesterone production by the ovary may be responsible for the menstrual disorders occurring in some sterilized women, that the same problem may effect women who have had hysterectomies but is not manifest since bleeding can not occur. (49)

Beavis et al (1969) investigated hormonal status in women who had had hysterectomies and felt that their study group showed the same distri-
bution of ovarian function as in the normal population as assessed by age of onset of menopause.

This is another area that needs further investigation, not only because of the possibility of hormonal imbalance leading to menstrual problems, but because of all the other implications of hormonal imbalance in women aged 30+ years. (Vorherr et al attribute fibrocystic breast disease in some women to tubal sterilization)

In conclusion there are two areas in which further work needs to be done:

1. Objective measurements of menstrual loss before and after sterilization and compared to women matched for age, parity, social class and previous contraception, whose husbands have been sterilized. These women should be followed for at least two years if not more.

2. Hormonal assays of women who have been sterilized as compared to women whose husbands have been sterilized, or are using temporary barrier methods of contraception, matched on age, parity and social class. Data form several cycles would be required as hormone levels vary from cycle to cycle even in the same individual.

Until data from the above is available it is difficult to assess the extent to which there is an association between sterilization and menstrual problems. It may be that women notice a change in menstruation and consider their bleeding to have increased relative to before the sterilization, but it is objectively (i.e. by measurement) still within the normal physiological range.
11 - CONCLUSION

There is obviously a role for sterilization as a method of birth control both in the industrialized and developing countries. The risks involved in sterilization of women are less in the developing countries than those of maternal mortality (0.64 per 100 pregnancies in Bangladesh) and complications of oral contraception and injectables without supervision. However, there are areas described in this study which require further rigorous investigation. Many women in developing areas have poor health and sterilization is a life-event that they may date their problems back to. Sometimes their complaints get dismissed as "cultural" or "attention-seeking". It may be that sterilization gets blamed for what are in fact manifestations of poor nutrition, anaemia, repeated infections, anxiety and poverty. But it is vital that the desire for population control does not blind researchers to the possible side-effects to individual women. Further rigorous investigation may result in methods by which sterilization can be done safer, and the industrialized world has the technology by which this research can be done (hormone assays, alkaline-haematin assays, record-linkage systems, etc.). Or it could reassure that there are no significant problems associated with sterilization.

As a final conclusion, it must be said that vasectomy is after all a quicker and less complicated method of birth control, and so the recommendation is made that population control programmes should place their emphasis on male rather than female sterilization (especially since polygyny is more common than polyandry!).
REFERENCES


** Most of these references are available in the International Planned Parenthood Library in London.
1. Name: ____________________________ 2. Age: ____________________________

3. Village: __________________________

4. Marital Status: (tick in the box or boxes)
   single [ ] 1, married at present [ ] 2, widowed [ ] 3, divorced [ ] 4, remarried [ ] 5.

5. Education: none [ ] 1, primary [ ] 2, secondary [ ] 3.

6. Can you read and write?: Yes [ ] 1, No [ ] 2.

7. Religion: Muslim [ ] 1, Hindu [ ] 2, Other [ ] 3, specify: ____________________________

8. Husband’s occupation: ____________________________

9. Your occupation: ____________________________

10. Age at first marriage: ____________________________

11. Give details of children in the order they were born below:

<table>
<thead>
<tr>
<th>order of birth</th>
<th>sex of child</th>
<th>if living, age at present</th>
<th>if dead, age at time of death</th>
</tr>
</thead>
</table>

12. No. of miscarriages (if any): ____________________________

13. How long ago was your last child born?: ____________________________

14. What contraception have you used? (fill in details below):

<table>
<thead>
<tr>
<th>Method</th>
<th>When did you use it?</th>
<th>For how long did you use it?</th>
</tr>
</thead>
<tbody>
<tr>
<td>pill</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IUCD</td>
<td></td>
<td></td>
</tr>
<tr>
<td>injection</td>
<td></td>
<td></td>
</tr>
<tr>
<td>other</td>
<td></td>
<td></td>
</tr>
<tr>
<td>none</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

15. How often do you get your periods?: ____________________________

16. How long does the bleeding usually last?: ____________________________

17. Have you ever had any problems with your periods?:
   bad pain [ ] heavy bleeding [ ] lasts many days [ ]
   describe: ____________________________

18. Has there been any change in the last ________ years?:
   describe: ____________________________

19. If there has been any change, describe what you think the reason for this was: ____________________________
20. Have you had the sterilization operation?
   Yes [ ]  No [ ]

21. If the answer is Yes [✓] then answer the next questions.
    If the answer is No, then leave them.
    1. When was the sterilization done?
    2. Where was it done?
    3. What made you decide to have the sterilization done?

23. Describe your feelings now about having had the sterilization.

Interviewer's name