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ABSTRACT

Objectives: **To describe the socio-demographic characteristics and clinical course and follow up of clients who have undergone voluntary surgical contraception (VSC) through minilaparotomy (mini-lap) under local anaesthesia (LA). Also, to evaluate the safety and method satisfaction, so as to forward recommendations for method utilisation in the Ethiopian context.**

Design: **A case series design where pre- and post-operative conditions of clients coming for voluntary surgical contraception via mini-laparotomy were systematically analysed.**

Setting: **Department of Obstetrics and Gynaecology, Gondar College of Medical Sciences, Gondar, Ethiopia.**

Subjects and methods: **Eighty two clients (median age of 33 years, range 25 - 40) who decided to use tubal sterilisation method of contraception from April 1993 to May 1995 were included in the study. A format prepared and distributed to VSC providing sites in Ethiopia by the Family Guidance Association of Ethiopia (FGAE) was used in collecting the necessary information, including informed consent of every client.**

Main outcome measures: **Previous knowledge of contraceptive methods, decision making for tubal sterilisation, size of incision, advantages of use of local anaesthesia in the local setting, duration of hospital stay, conditions on follow up.**

Results: **Eighty two (55.4%) women underwent tubal sterilisation through mini-lap. The mean number of the live children per client was 6.2±1.7, with parity ranging from two to eleven children. Mothers with five or more children were 70 (85.4%). Among 69 mothers (84.1%), the last pregnancy outcome were live births. The average length of the time since making a decision not to have any more children was 2.5±2 years (median of one year). The rationales given were economic, ill health and completed family size. Regarding the pattern of decision making, in 77 (91.9%) clients both the couples were involved in decision making. All except two underwent the procedure under LA and no complication was encountered during surgery. Follow-up attendance was 100% in one-year period and nothing serious was reported. All reported to be satisfied with the method.**

Conclusion: **The study showed that early decision making by involving both couples other than proper case selection minimises regrets. The authors believe that tubal sterilisation through mini-lap under LA is an ideal method in developing countries where access to family planning and other reproductive health services are not widely available and where there is population explosion, less than 10% contraceptive prevalence rate and high maternal mortality.**

INTRODUCTION

One third of pregnancy-related deaths in the world could be prevented by the use of safe and effective family planning methods(1). Hence, to curtail the high maternal morbidity and mortality on one hand and the rapid population growth on the other, provision of adequate health services with especial emphasis on family planning is of paramount importance(1).

Voluntary surgical contraception (VSC) is one of the most effective, safe and economical family planning (FP) method and it is believed to be permanent(2). The health benefits of VSC are especially evident in developing countries where temporary methods may be periodically in short supply or used less effectively, and where unwanted pregnancies carry a high risk of maternal deaths(2). Improvements in the quality of sterilisation services and increases in the number of institutions that can provide

mini-laparotomy under local anaesthesia have led to an increase in the acceptance of sterilisation(3).

VSC was introduced in Ethiopia in the late 1980's. Presently, VSC services are rendered at 18 sites (Personal communication, Dr. Taye Tokon, 1995, Family Guidance Association of Ethiopia). In Gondar, VSC service was started in April 1993.

Research in developing countries is essential for the evaluation of the safety, efficacy and acceptability of both new and already available contraceptives including VSC. But, there are no reports that address the experience of tubal ligation through mini-laparotomy under local anaesthesia in Ethiopia. Thus, as a first step, this record analysis is aimed at describing the socio-demographic characters, level of knowledge about and practice of other family planning methods, indications, the referral source, clinical evaluation, details of the procedure and findings during the follow-up of clients who have undergone VSC. It was also aimed at determining the proportion of clients who have undergone VSC out of all deliveries at the GCMSTH in the study period so that it could be used in future studies to assess the acceptability of the method.

MATERIALS AND METHODS

The principal author began performing Pomeroy tubal ligation through a mini-laparotomy incision under local anaesthesia(4) in April 1993 at GCMSTH. Until May 1995, eighty two operations were performed at interval, post-abortal and immediate postpartum period(5) after having obtained an informed consent. Hence, records of these operations were reviewed for this study. Sixty six tubal sterilisation through conventional laparotomy method were performed on women who did not fulfil the criteria(5-7) for tubal sterilisation through mini-laparotomy under local anaesthesia and at Caesarean section during the same period at the hospital.

The 82 clients were followed for a period of one year following operation and at the end of the first postoperative week. After one year of follow up, they were re-informed about the long-term complications of the procedure, and were told to come back immediately whenever problems are encountered.

Information about each client was documented in a format prepared and distributed to VSC providing sites in Ethiopia by the Family Guidance Association of Ethiopia (FGAE).

The information which was recorded before and after the procedure: socio-demographic characteristics of clients and their spouses; knowledge about and practice of other family planning methods; decision to undergo VSC, that is, the duration and who among the couples made the decision; the referral source; medical history and examination of clients; details of the procedure and; follow up.

All the data were then entered into and analysed by a computer using EPI INFO version 5 software. Descriptive and analytic statistical methods were used. Frequency distributions of all variables were calculated. The odds ratios (OR) and 95% confidence intervals (CI) were used to analyse the 2 x 2 tables. Two or more means were compared using t-tests and one way analysis of variance (ANOVA), respectively. The Chi-square test was used to compare proportions. For continous variables, correlation and regression analysis was performed. $P<0.05$ was considered significant.

RESULTS

A total of 148 women underwent VSC, 82 (55.4%) through mini-laparotomy and 66 (44.6%) through conventional laparotomy or at Caesarean section, at the GCMSTH from April 1993 to May 1995. During this period, 2978 women delivered at the hospital. Hence, the proportion of tubal sterilisation was 5 per 100 deliveries. Out of these, mini-laparotomy accounted for 2.8 per 100 deliveries and tubal ligations through conventional laparotomy was 2.2 per 100 deliveries.

Socio-demographic characteristics and past reproductive performance of clients: The socio-demographic characteristics of the clients are shown in Table 1. Mean (± SD) number of live children per client was 6.2±1.7. The mean gravidity per client was 7.4±2.0 pregnancies, ranging between 4 and 12. Parity ranged between 2 and 11, the mean being 6.4±1.8 births.

Table 1

The socio-demographic characteristics of VSC clients (n=82)

Characteristic	Frequency	%
Age (years)		
25-29	11	13.4
30 - 34	40	48.8
35 - 39	27	32.9
40-44	4	4.9
Address		
Urban	64	78.0
Rural	18	22.0
Marital status		
Married	77	93.9
Separated	2	2.4
Divorced	3	3.7
Educational level[1]		
No schooling	31	38.8
Primary	25	31.2
Sec. or higher	24	30.0
Occupation		
House wife	62	75.6
Government employee	14	17.1
Daily labourer	2	2.4
Farmer	1	1.2
Merchants	2	2.4
Others	1	1.2

[1] Information about two clients was missing

There were twelve (14.6%) multiparous and 70 (85.4%) grand multiparous clients. In 69 (84.1%), the last pregnancies ended up in live births, in seven (8.5%) still births and in six (7.3%) early neonatal deaths. Out of the 82 women, 64 (78%) were breast feeding and 18 (22%) not at the time of procedure.

Knowledge and practice of clients towards family planning: Concerning previous knowledge of other FP methods, 26 (32.5%) knew none, 23 (28.8%) new one and 31 (38.8%) two or more of family planning methods. The most commonly known FP method was the oral pill by 53/80 (66.3%) followed by the IUD 23/80 (28.8%).

Information about FP (knowledge on both the family planning methods and their uses) of two clients was missing. Of the 80 women reporting, 32 (40%) had used at least one of the FP methods in the past. Orals were used by 24 (30%) and IUD by six (7.5%) (Table 2).

Table 2

Last method used before VSC by the clients

Type	Freq. (No.=80)	%
None	48	60.0
Orals	24	30.0
IUD	6	7.5
Injectable	3	3.4
Condoms	1	1.3
Foam, jelly	1	1.3

Totals exceed 100% due to multi-method users by a single client.

The average time since clients decided not to have any more children was 2.5±2.0 years, the median being one year. The main reasons for not wanting to have any more children were economic conditions in 31 (38.8%), health problems in 28 (35%), and completed family size in 21 (26.3%) clients. The average time since clients decided to have VSC was 11.8±14.3 and median of nine months. Twenty (24.4%) decided one month before undergoing VSC. The decision was made by both the client and spouse in 77 (91.9%) and clients alone in five (8.1%). The referral sources of VSC were the clients themselves for 29 (35.3%), the clients and spouses together for 19 (23.5%) and others such as health workers, sterilised clients, etc., for 34 (41.5%) cases.

Pre-operative assessment, clinical course and follow-up: The medical history of clients revealed that one had hypertension, three respiratory illnesses and two had anaemia. On clinical evaluation and laboratory investigations one had leg deformity and another one a simple goiter, but none of the other aforementioned reported medical problems.

The average weight of clients was 52.8±8.3 kgs. There were three (3.7%) clients with weight greater than 70 kgs. The uterus was enlarged in 39 (47.7%) of the 82 clients, as they were postpartum and due to recent birth.

Concerning the timing of the surgery, 40 (48.9%) were not pregnancy related (interval), 39 (47.6%) immediately post-partum (within 12 -48 hours) and three (3.5%) were post abortal. In all, except two, the procedure was done under local anaesthesia. In two clients, tubal ligation under local anaesthesia was difficult and general anaesthesia was required. One of these was an obese woman and the other with omental adhesions to the uterus. In these cases, since the procedure became difficult due to the reasons just mentioned, general anaesthesia was given and the tubal ligations were performed. But these cases were excluded from further analysis.

The average (mean) size of the incision was 2.3±SD 0.6 cm (range between 2 - 5 cm). The mean duration of surgery was 22.3±SD 5.7 and median of 20 minutes. Thirteen (16.3%) complained of mild abdominal pain, four (5%) dizziness and vomiting, and two (2.5%) developed nausea and headache persisting for few hours out of the 80 reporting clients. The hospital stay after the procedure was two hours for post abortal and interval procedures, and for post-partum cases it was the same as for other non-sterilised normal post-partum cases, that is, 24 hours.

All clients were given appointments for follow-ups. All the follow up visits were attended by the principal investigator, and no post-operative complications were observed. Ten (12.5%) clients reported that the operation caused some or moderate pain, whereas 70 (87.5%) had little or no pain. All were completely satisfied with the method. Except two non-respondents, all would advice others to undergo the procedure. All considered VSC to be a permanent method. No method failure or request for reversal was encountered during the first year of the follow-up and until the time the data was analysed.

On bi-variate analysis, the highest parity was observed among the 40 - 44 years ($F3 = 3.778$; $p=0.01$) and among the illiterate ($F2 = 6.537$; $p=0.003$). The highest number of alive children was found among 35 - 39 years group ($F3 = 4.736$; $p=0.005$). Knowledge of family planning methods was strongly associated with FP practice (OR = 35.9; 95% CI = 4.5,774). The size of skin incision was strongly correlated with the duration of surgery, that is, the smaller the incision, the shorter was the duration of surgery ($r = 0.73$; 95% CI = 0.61,0.82).

DISCUSSION

According to recent data, maternal deaths could be reduced by one third each year if all women used contraception once they did not want any more children(2). By the time the woman is 25 to 35 years old, there are many occasions when couples need effective protection against unwanted pregnancies(2).

Worldwide, approximately 16% of the women in the reproductive ages have undergone a sterilisation procedure(9) and studies(6-8) have shown that tubal sterilisation through minilaparotomy under local anaesthesia is a convenient and cost effective procedure. The same findings were observed in this study.

VSC is offered as part of health and family planning service because for many men and women, it is an appropriate choice compared with other family planning methods or continued exposure to the risk of pregnancy(2).

In this study, most of the clients came from urban areas mainly Gondar town where the GCMS hospital and the Gondar Health Centre are located. These women are supposed to have better exposure to family health education. This may show why a considerable proportion (68%) had knowledge of family planning. However, the finding may be worrisome for the fact that the health services provision in general and family planning coverage in particular is far from reach to the needy majority of the rural population.

Some of the reasons for not wanting to have more children were economic and health problems as well as completed desired family size. Similar findings were reported elsewhere(10).

VSC via mini-laparotomy under local anaesthesia is medically safe, whether performed early post-partum (within 48 hours of delivery) or at interval. Yet it is highly stressed that the role of screening before carrying out the procedure is vital. The main, yet rare, concerns due to sterilisation especially post-partum procedures are infection, bleeding, surgical injuries and thrombosis(8,11). It is also effective with regard to the low method failure rate in the first year ranging between 0 and 0.8%, with a mean of 0.4%(5). The finding in our study is the same. There were no major complaints and manifestations during the procedure and follow ups, and the continuation rate for the first year was 100%. But in two cases (2.4%) tubal ligation through mini-laparotomy under local anaesthesia was not possible, since one was obese and the other with omental adhesion to the uterus. This suggests the need to improve our preoperative selection of clients(6- 8).

Long term complication such as risk of pregnancy and menstrual disturbances are less likely especially in interval than post-partum procedure(12). The very short follow up period in our situation restricts comments in this issue.

A strong correlation observed between the size of incision and operation time with no immediate complications may justify the overall advantage of mini-laparotomy over sterilisation via laparotomy. The other explanation may also be that clients are easier to operate in cases such as less obese and better counselled ones. It may also require less time to operate on.

Regret after sterilisation can occur(13-15), which is commoner in post partum than interval procedures. In this study, up to the time of reporting, regrets were not reported (though not actively pursued). The reason for this may be that most of our clients had a stable marriage, large family size, and the couple made decision or clients and all knew that the method is permanent.

VSC is rapidly becoming widespread, even in rural areas of developing countries where other forms of surgery are seldom performed. Therefore, it is the belief of the investigators that tubal sterilisation through mini-laparotomy under local anaesthesia is an ideal procedure in properly screened clients in Ethiopia, because temporary methods are periodically in short supply or used less effectively. We therefore, recommend that larger studies be conducted to confirm its safety and acceptability and evaluate the efficacy so that tubal ligation through mini-laparotomy under local anaesthesia can be promoted further.

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