Surgical Equipment and Training in Reproductive Health

Proceedings of a Conference

JHPIEGO
The Johns Hopkins
Program for International Education
in Gynecology and Obstetrics

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Proceedings of a Conference

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Preface

JHPIEGO (The Johns Hopkins Program for International Education in Gynecology and Obstetrics) seeks to narrow the gap between the health care available in more affluent societies and that available in developing countries. Specifically, JHPIEGO works at improving knowledge and skills in obstetric, gynecologic and early infant care. New technology has revolutionized OB/GYN care; since 1974, JHPIEGO has urged leading doctors in developing countries to train in this new technology, especially the laparoscope. This training has provided an excellent opportunity to involve these professors in the improvement of local standards of medical practice.

The introduction of laparoscopy should probably be ranked as one of the most important advances in obstetrics and gynecology during the past 10-15 years. It provides specialists with a remarkable diagnostic tool for viewing the reproductive organs, as well as an agile therapeutic and surgical instrument for tubal ligations. The use of such an instrument and its applications as part of an educational program provides the necessary balance between fertility management and gynecology/MCH. We believe few medical teaching institutions can ignore the potential use of this instrument and its significant role in advancing reproductive health.

As of September 30, 1979, more than 1,800 physicians have been trained in JHPIEGO courses at U.S. and overseas centers. These trainees have come from 90 countries, representing more than 1,000 institutions. Additionally, JHPIEGO has shipped more than 650 laparoscopes and Laprocators* to approximately 350 institutions in 70 countries.

Beginning in January 1979, JHPIEGO began to distribute to training centers and their graduates a newly developed laparoscope—the Laprocator—which is an advanced endoscopic system of reduced cost which can perform most diagnostic and therapeutic laparoscopic procedures. The basic instrument system includes: a straight optic, combined with a single-incision Falope-Ring** applicator, with two-ring configuration; a compact insufflator for use with either an external gas source or a hand insufflator; a low voltage power source for illumination; and the basic surgical instruments to perform the procedure. The simplified straight-line optic is an important advantage—it comes in one piece rather than several, it easily separates from the applicator, and can therefore be replaced far more readily at less cost.

As a result of the development of the Laprocator, and the distribution of this instrument to JHPIEGO graduates, JHPIEGO organized a conference on Surgical Equipment for Reproductive Health, held in September 1979 in Key Biscayne, Florida. The conference brought together 79 individuals, including 43 physicians and maintenance technicians from 23 developing countries, to review their experience with the Laprocator, which at the time had been available for up to eight months. The meeting's objectives were to:

1. Review the current status of the Laprocator and recommend any revisions;
2. Review the anesthesia requirements for laparoscopy;
3. Review new advances or approaches to laparoscopy and reproductive health surgery, and recommend changes if needed to existing training approaches; and

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*Laprocator® is a registered trademark of KLI, Inc., Newtown, Pa. 18940, U.S.A.

**Falope-Ring® is a registered trademark of KLI, Inc., Newton, Pa. 18940, U.S.A.

4. Assess the status of equipment maintenance and repair and to recommend any improvements which reduce cost and increase utilization.

This volume presents the results of the deliberations and recommendations of Conference participants. It is hoped that these proceedings will be useful in improving the delivery of health care to women and children in countries all over the world.

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Welcome

Theodore M. King, M.D., Ph.D.
President, JHPIEGO
Chairman, Department of Gynecology and Obstetrics
Johns Hopkins University School of Medicine
Baltimore, Maryland

I would like to welcome you all to Florida and to this conference on surgical equipment for educational programs in reproductive health.

The reason we are here is our desire to continue to expand our efforts in fertility management, education and services. Our focus is on permanent surgical contraception, but the broader context is the improvement of maternal health and thereby the improvement of reproductive health for families.

It is easy to become discouraged in our family planning efforts when we witness in each of our countries the many continuing challenges. But if we would all look at what we have accomplished in such a very short time, it would be impossible not to have confidence and not to believe that we will be successful ultimately.

This equipment conference has long been needed but it is only now that we have had sufficient experience to allow us to focus on further resolution of the problems with surgical equipment that has been so successfully utilized in our countries. I am confident that the deliberations of today and tomorrow will result in a further improvement in our educational efforts.

Goals and Objectives of the Conference

Ronald T. Burkman, M.D.
Director, JHPIEGO
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One of the objectives of this conference is to evaluate the status of the Laprocator. This instrument has been in existence for a little over a year and it is believed to be simpler and easier to maintain than other equipment of its nature, but still able to function in a dual role for both surgical storilization and diagnosis. Most of you have completed questionnaires that will help us gain insight about the effectiveness of this instrument.

Another topic that we wish to address is the overall issue of repair and maintenance of equipment. Your suggestions will help improve services and will guide us in formulating our policies for the future.

Another objective of the conference is for all of us to examine new techniques that may have a role in present or future training programs, such as the use of air for pneumoperitoneum or the use of open laparoscopy.

We also need to examine various aspects of our educational programs with the goal of really improving the training of physicians around the world. Aspects of this subject include: the team approach to training physicians and nurses in surgical sterilization, use of films and training manuals, changes in the use of anesthesia, and so on. Your suggestions will help physicians and health care providers to better utilize newer technology.

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Finally, I think an overall goal of the conference is also to examine any problems you feel have surfaced over the years in your experience with surgical training or equipment. I also hope all of you will get an opportunity to exchange ideas with each other which will be helpful in your own programs.

A Decade of Laparoscopy

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Sterilization has certainly come a long way in the last decade. It has proved to be a successful marathon runner. But we have seen too many other methods stumble, and this is a key reason for holding this conference: what problems with equipment are there now that need attention if voluntary sterilization is to proceed and additionally flourish in the years ahead?

As I reflect upon all that has happened in the last decade, the dissemination of sterilization has been accomplished with remarkable speed. At the end of the 1960's, it had been demonstrated that voluntary sterilization could be performed by outpatient laparoscopy. We held a conference in Virginia in December 1971—some of you were there—focusing upon what needed to be done to improve the technology of laparoscopic sterilization, and decided the most urgent need was a non-thermal means of tubal interruption. Then, with remarkable speed, the Falope-Ring and a variety of tubal clips were developed and rapidly tested and used.

We were also aware that if this technology were to be disseminated rapidly and well, a powerful training program was needed, and in 1972, we created the JHPIEGO program at the Johns Hopkins University—a program that most of you have participated in. Although like most actions we have engaged in, it has had its problems, in

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looking back, it is clear that this training program has been indispensable for the rapid dissemination of laparoscopic technology. There are very few countries in the world that have not somehow been affected in this extraordinary training and technology—dissemination action.

We were also confronted with the fact that the laparoscope as it existed at that time was large, clumsy, very expensive and difficult to maintain. In 1976, after having had considerable experience with the old laparoscope and its backup unit, we drew together a small group of people to focus on what could be done to simplify the equipment. Within weeks a manufacturer, KLI, Inc., had produced a prototype, and within a few months, the working model, of what became the Laprocator.

We were interested in eliminating the CO_2 unit, and thereby the big backup unit; and I am pleased with the progress that has been made toward this simplification.

From a programmatic point of view, one has to be concerned with simplicity and cost as well as precaution. When considering time, money and training, one has to ensure that everything that is done is truly justifiable and necessary, otherwise it is an encumbrance upon the greater use of that method. Programmatically, we have to be concerned not only with errors of commission, such as an occasional death due to sterilization, but we must also be concerned with errors of omission—those millions of women who will not be served if the method is too complex and too costly to be available everywhere. To date, errors of omission are causing far more deaths in the world of voluntary sterilization than errors of commission.

Consequently, we were delighted when the simplified laparoscope or Laprocator emerged. In 1978, AID purchased a thousand of these which have been disseminated to many countries. But we do not yet have full feedback information from this action, which is a main purpose of this meeting.

We know there have been some problems: that the Falope-Rings sometimes break, that there are failures. We need to learn how these can be prevented. Our goal is zero mortality and zero failures, and we must somehow get very close to that. If one band on each tube is insufficient, had we best use two? Should this procedure be regularized as a fail-safe approach to the application of tubal

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bands? Why not? Does it cause other problems? Does it solve the one percent or a half of one percent failure rate? We have to consider such possible solutions. We must do all we can to perfect the equipment and procedures to reduce failures to the irreducible minimum.

The Role of Surgical Training in Reproductive Health Programs

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Ladies and gentlemen, it is a pleasure and an honor to be asked to address this distinguished audience.

It is easy for this conference to deal too much with the technical aspects of equipment and training, and to forget what our work is all about. Our goal is *reproductive health*, and equipment and training are only a means to an end, not ends in themselves. I would like to put this subject in its proper perspective, and first I will review with you briefly the status of reproductive health in our world today.

Let us consider what the world's "table of accounts" for human reproduction would say for the last 24 hours. In the past 24 hours, one million human conceptions occurred. During these same 24 hours, half a million *previous* conceptions ended unsuccessfully, terminating spontaneously in abortion, miscarriage, or stillbirth. The table of accounts also records that during this day, 150,000 couples ended their undesired conception by induced abortion, while 350,000 conceptions ended today in a live birth. Of these live births, one-half were not wanted or were not planned (that is, did not occur at the optimal time). Almost 20% of the live births occurred to women below the age of 20 or after the age of 35.[1]

What is the message of these figures? They indicated that much of human reproduction is wastage. Almost one-

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half of the conceptions prove unsuccessful. Of the remaining half, one-third are not wanted and are ended by induced abortion, and another third is unwanted but carried to term. Only one-sixth of all the conceptions therefore end in a wanted child. Human *over*-reproduction occurs in order to compensate for this apparent reproductive wastage.

Let us study the table of accounts further and see what is forcast for the 350,000 infants born in the world today. Almost 15% are premature or immature and have little chance for survival or normal growth. Ten percent or more of the children born today will not see their first birthday. Another 15% are not going to reach adulthood. About 5% have some major congenital abnormality or defect, which may hinder development or may necessitate sophisticated care. About 3% are born with some degree of mental retardation which is probably going to last throughout their lives. Thus would that table account for almost 50% of the births today—all additions to the wastage of human reproduction.

If we turn another page into the table of accounts we will see what it says about mothers. Today at least 500 women were reported killed in the process of reproduction. They were killed before the termination of gestation, during parturition or after. But that is only the tip of the iceberg. No less than 75,000 today have been affected with some serious illness as a complication of pregnancy or childbirth and a large number have started to suffer from some chronic condition—malnutrition, infection, anemia —which may have a long-term debilitating effect on their lives.

What is the message? Breeding may be fun, but it is not without danger. Of all the human sports, sex is one of the most hazardous, and of the conditions that are sexually transmitted probably conception is the most dangerous. So the two lessons that we learn from reading the world's table of accounts for today are first, that much of human reproduction is wastage, and second, that human reproduction is not without serious hazards. What can we, members of the medical profession, do about this?

We definitely cannot do everything for two main reasons. The first is our ignorance; we simply do not know enough about the processes of human reproduction. Second, much of what is needed is closely related to socio-

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economic conditions over which we do not have control. But there is definitely much which we *can* do. Improving the quality and availability of medical care will certainly do much to improve reproductive health, but we have learned the lesson that curative medicine, however important it may be, is not the most cost-effective method for improving health. Preventive medicine will be more effective, and this is as applicable in reproductive health as elsewhere. Of the preventive measures we may think of, fertility regulation is a most effective and most efficient means for improving reproductive health. The ability of men and women to determine when and whether they will have children is a most important factor in promoting reproductive health. We have all known that this is true in our practice, and it is now documented in several studies including a recent major study conducted in ten countries in Latin America, Asia and Africa by the World Health Organization (WHO).[2] The study dealt with the relationship between family formation patterns and family health, and the researchers investigated the effect of certain factors such as the age of mothers, the spacing of children, and birth order on outcomes such as pregnancy wastage and fetal mortality, maternal morbidity and mortality, and the physicial and intellectual development of the child. This study has documented that family formation patterns are a definite factor in family health, and influencing that pattern is the most cost-effective means of improving the reproductive health of our people.

Where does surgery fit into reproductive health? Surgery has become the number one fertility control method in the world today. I do not need to go into the advantages of surgical contraception over other means of fertility control, because the battle is already over. People have already made their choice, and whether they live in a skyscraper in New York or a cottage in a remote area of Asia, more people have chosen surgical contraception for fertility control than any other method.

We must try to see the implications of this choice and the magnitude of the task before us. No one would have imagined a few decades ago that surgery would have such an extensive role in human reproduction, or that surgery would be used in preventive rather than curative medicine on such a large scale. Surgery means equipment, but more than that, it means training. I think that training

has probably been de-emphasized. There is the glimmer of new equipment and new technique, but what is not realized is that this new equipment and new technique, if not accompanied by proper and adequate training, will probably be worse than the old equipment and old technique which we already have. When I am asked by my students what instrument is best or what technique is best, my answer is usually, "the best technique is that which you can do best, and the best instrument is that which you can handle best." Last year, there was a very important publication from the International Fertility Research Program. Laufe and McCann[3] investigated the role of training in the delivery of surgical contraception and various other techniques of fertility control. This significant study showed that what we consider to be more simple, safe and efficient techniques can be more risky and less efficient when initially introduced in a program, especially if not accompanied by adequate training. They also showed that the variability of physician skill may account for differences in the success of different techniques more than differences inherent in the techniques themselves. A significant correlation was found between the complication rates and the professional experiences of the people performing these procedures. This all goes to emphasize the importance of training, and it was gratifying to all of us to see such a prestigious institution as Johns Hopkins taking on this tremendous task of organizing training in the new methods of fertility control through the JHPIEGO program.

But the task is not easy. A few years ago Dr. Ravenholt calculated what facilities and personnel would be needed in the developing world in order for sterilization to reach a prevalence level of 25%, for which the demand is certainly there.[4] In the developing world, excluding China, there would be a need to set up ten thousand clinics acting full-time performing surgical contraception, and there would be a need to establish 400 training centers in the developing world to teach the operative personnel. This is the real challenge which we have, and which JHPIEGO has, but we have to accept this challenge if we want to make human reproduction not a sorrow but a joy—a joy that is wanted and planned.

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Open Laparoscopy

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Five years ago, during a national meeting of the American College of Obstetricians and Gynecologists, I observed Dr. Harith Hasson of Chicago demonstrate a curious and apparently cumbersome method of entering the abdominal cavity in order to perform laparoscopy. Instead of making a small incision and thrusting in a needle followed by a sharp trocar, this man was actually taking the trouble to perform a subumbilical minilaparotomy incision under direct vision.

After carefully dissecting the subcutaneous fact, he elevated the fascia with small Kocher clamps and incised it transversely. Having widened the fascial incision with a Kelly clamp, he placed a #1 chromic suture through the upper and lower fascial edges, and held each suture with a clamp. Then, after inserting his Baby Deaver retractors through the fascial incision, he exposed the peritoneum and perforated it with the gentle thrust of a small straight hemostat. He then introducted a cannula of his own design, with its blunt obturator and adjustable outer cone, and attached the fascial sutures to two tiny steel hooks on opposite sides of the upper part of the cannula. With the fascial edges held taut against the outer cone to maintain a gas-tight seal, a satisfactory pneumoperitoneum was rapidly accomplished.

When I first witnessed this technique, I was intrigued.

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But, at that particular time, I was satisfied with conventional needle and trocar entry as pioneered by Palmer, Frangenheim, Wheeless and others. I had experienced no problems with these sharp instruments, so why should I change to the Hasson method which seemed so cumbersome?

One year later, the answer to this question became clear after a study of major blood vessel injuries during laparoscopy.[1]

Major vessel injury from needle or trocar insertion is a rare event in the hands of a competent gynecologist. Nonetheless, well over one hundred aortic or iliac artery injuries have been reported to me during the past three years, approximately thirty of them with detailed written documentation and the rest by word of mouth. A great many more such injuries from around the world have occurred but are usually not reported. While most accidents are experienced by beginning laparoscopists, there are documented cases in my files of major vessel lacerations occurring in the hands of well-qualified gynecologists who have performed many hundreds of such operations.

How can aortic or iliac artery injuries occur with closed abdominal entry if all the proper precautions are taken? Several circumstances may predispose to injury. For instance, deviations from the normal patient position on the operating table may go unrecognized. The surgeon may lose awareness of the position of the needle or trocar—an error not totally preventable when performing a blind procedure. It is even possible that a physical peculiarity of the patient may disguise the exact anatomic relationship of the aortic bifurcation to the anterior abdominal wall.

Even the most skilled gynecologist cannot guarantee to his patient that major vessel injury will not occur during conventional laparoscopy. Even if he is certain that he can avoid striking the aorta or the iliac vessels with his needle or trocar, he cannot be certain that he will not lacerate a large mesenteric or omental vessel, and thus produce intra-abdominal hemorrhage.

It is principally because of the unavoidable risk of major vessel injury from the needle or the trocar that increasing numbers of laparoscopists are abandoning closed or conventional laparoscopy in favor of open laparoscopy; a technique which eliminates the needle and trocar, and involves scalpel and hemostat entry into the ab-

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dominal cavity under direct vision. Open laparoscopy, therefore, is a technique which eliminates the possibility of major vessel injury.

An airtight seal is just as easy to maintain in open laparoscopy as it is with conventional techniques. Because of the adjustable outer cone of the Hasson cannula, the fascia "tents up" and produces an airtight seal around the cone collar (Figure 1). There is no significant leakage of gas because the fascial incision is smaller than the maximum diameter of the cone.

After the surgeon has done fifteen or twenty of these operations, he will find that they are no longer cumbersome, and that only one or two minutes additional time is required for direct incisional entry into the abdominal cavity.

There are other surgical complications that open laparoscopy avoids, such as gas embolism, failed entry, bowel laceration, and formation of abdominal wall hematomas. Open laparoscopy has the additional advantage of reducing the chance for postoperative hernias, because the fascia is sutured during wound closure. This is important in the light of ten separate studies in the English literature which refer to postoperative subumbilical herniation through fascial tears caused by the sharp trocar.[8-11]

It has been suggested that open laparoscopy is a useful operation in special cases such as in patients with suspected postoperative adhesions. I would go further and suggest that open laparoscopy, because it is a safer operation than conventional closed laparoscopy, is to be preferred in all cases.

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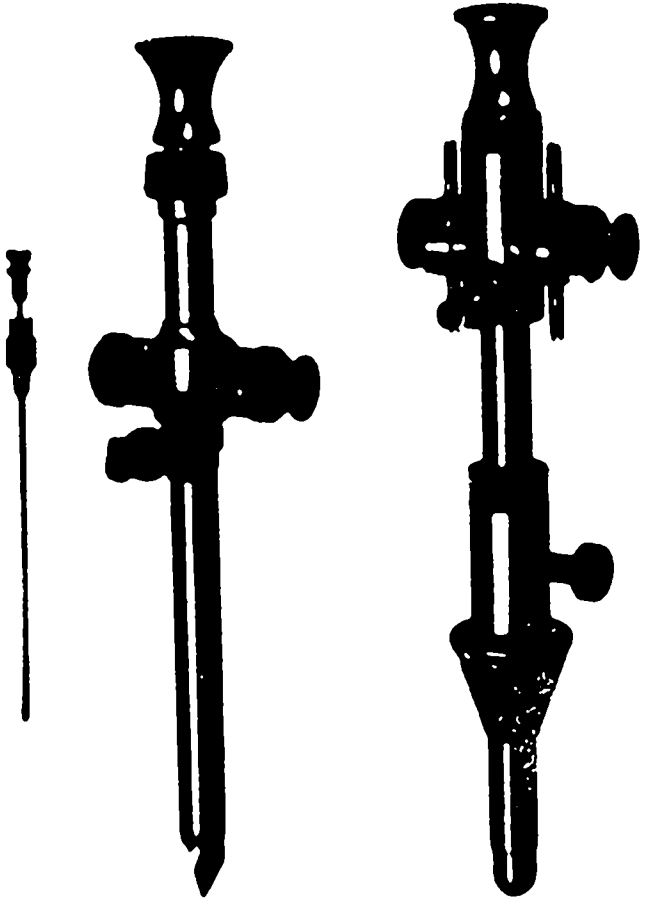

FIGURE 1.—The Hasson Cannula for Performing Open Laparoscopy

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Air for Pneumoperitoneum

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Using air in endoscopic procedures is not new. Abdominal endoscopy began in the 1930's, when it was called peritoneoscopy. By 1957, Dr. Ruddock[1] reported on more than 5000 cases of diagnostic peritoneoscopy with the use of air without any problems. Every surgeon who opens an abdomen exposes the patient to air. A whole specialty—cystoscopy—was built on air. The first attempt to use something other than air should be credited to Dr. Zollikofer[2] who, in 1924, used carbon dioxide because he wanted to decrease absorption time of the medium with the hope of minimizing patient discomfort.

As laparoscopy techniques improved, and particularly with the advent of electrocoagulation, surgeons began to use gaseous media other than air, usually carbon dioxide or nitrous oxide. There were many reasons for this trend. The use of electrocoagulation within the pelvis was perceived as raising the possibility of an explosion. People were also worried about air embolism, and there were anecdotal reports of death due to embolism, which were never confirmed by autopsy. Nevertheless, in their perseverance to find the safest and most effective means of accomplishing pneumoperitoneum for laparoscopy, surgeons used gases other than air.

Three years ago when we considered how to simplify endoscopic procedures and how to disseminate the tech-

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nology to get more people involved, three critical suggestions were made. First, another medium besides nitrous oxide or carbon dioxide was needed because these are expensive and in short supply, or unavailable, in the developing world. Second, it was proposed to eliminate the concept of an offset lens system in order to reduce cost. Hence, the development of the Laprocator. The third development was that research[3] through the International Fertility Research Program (IFRP) and the Johns Hopkins University[4] proved that the use of the silastic ring was an efficacious method of tubal occlusion for voluntary female sterilization. This eliminated the use of electricity within the pelvic cavity.

In 1978, IFRP initiated four major studies which will evaluate the use of air for pneumoperitoneum, the Laprocator itself, and the Hasson technique of open laparoscopy. These studies are ongoing but the preliminary data collected from the collaborating centers can be presented.

The air insufflation system being used in these studies is the KLI air insufflator and Laprocator console. Insufflation is accomplished by using a small hand bulb, nothing more than a blood pressure bulb, which inflates the reservoir balloon, and then slowly delivers air under low pressure into the peritoneal cavity. There is a gauge on the front of the console which tells the clinician the amount of pressure that is being generated.

In these studies, we asked our contributors to use the Laprocator with the standard laparoscopic approach in their first 100 cases, and then to perform the next 300 cases by open laparoscopy. In all cases, air insufflation was used. From the pooled data thus far, we have 192 standard laparoscopy procedures and a little over 600 open laparoscopy procedures.

The very low rate of surgical difficulties speaks to the skill of the contributors (Table 1). In 98% of all cases there were no surgical difficulties. Every one of these patients had their occlusion performed by the Falope-Ring, but only one mesosalpingeal injury occurred (Table 2). The complications and minor complaints that occurred during the procedure are shown in Table 3. Pelvic pain is apparently more related to the application of the ring than it is to any other part of the procedure (Table 4). Although all doctors were instructed to express as much of the air as

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TABLE 1

SURGICAL DIFFICULTIES ENCOUNTERED USING ROOM AIR BY TWO APPROACHES

Surgical Difficulties	Standard Laparoscopy (N = 192) N	%	Open Laparoscopy (N = 605) N	%
None	184	95.8	600	99.1
Entering peritoneum	1	0.5	1	0.2
Grasping tubes	4	2.1	1	0.2
Occluding tubes	0	0.0	2	0.3
Visualizing tubes	0	0.0	1	0.2
Change of technique: difficulty grasping tubes due to enlarged tubes				
Cauterization	2	1.1	0	0.0
Ligation	1	0.5	0	0.0

TABLE 2

SURGICAL INJURIES ENCOUNTERED USING ROOM AIR BY TWO APPROACHES

Surgical Injuries	Standard Laparoscopy (N = 192) N	%	Open Laparoscopy (N = 605) N	%
None	192	100.0	603	99.8
Tubal or Mesosalpingeal injury without bleeding	0	0.0	1	0.1
Uterine perforation	0	0.0	1	0.1

TABLE 3

COMPLICATIONS AND MINOR COMPLAINTS EXPERIENCED USING ROOM AIR BY TWO APPROACHES

	Standard Laparoscopy (N = 192)		Open Laparoscopy (N = 605)	
During Initial Recovery*	N	%	N	%
None	53	27.6	114	18.8
Pelvic Pain	117	60.9	457	75.5
Shoulder Pain	6	3.1	42	6.9
Other Pain (headache (6); Backache (4); coxitis (1); wound stings (3); chest (2)	12	6.3	4	0.7
Other (nausea/vomiting (14); gas (2); dizziness (3); dyspnea (1))	5	2.6	15	2.5
Urinary Tract Infection	0	0.0	1	0.2
Vaginal Bleeding	55	28.6	46	7.6
During Later Follow-up				
None	149	77.6	430	71.1
Pelvic Pain	14	7.3	18	3.0
Shoulder Pain	3	1.6	11	1.8
Other Pain (backache (5); wound stings (6); headache (1); chest (2); coxitis (2))	8	4.2	8	1.3
Other (gas (2); dizziness (2); nausea/vomiting (6); vaginal bleeding (1))	2	1.0	9	1.5
Unknown	16	8.3	159	26.3
Urinary Tract Infection	0	0.0	1	0.2
Vaginal Bleeding	20	10.4	3	0.5

*More than one complaint may be recorded for each patient.

TABLE 4

PRIMARY SITE OF PAIN EXPERIENCED USING ROOM AIR BY TWO APPROACHES

	Standard Laparoscopy (N = 192)		Open Laparoscopy (N = 605)	
During Procedure*	N	%	N	%
None	143	74.5	409	67.6
Pelvic	44	22.9	189	31.2
Shoulder	3	1.6	2	0.3
Other Sites (chest (1); back (1))	0	0.0	2	0.3
Unknown	3	1.6	5	0.8
During Recovery Period Before Discharge				
None	54	28.1	119	19.7
Pelvic	121	63.0	457	75.5
Shoulder	11	5.7	32	5.3
Other Sites (chest (4); back (2))	3	1.6	3	0.5
Unknown	3	1.6	6	1.0

*More than one site of pain may be identified for each patient.

possible prior to closure of the incision and removal of the cannula, there was still some transitory discomfort for the majority of these patients. Most of the pain was pelvic which we believe is related to the application of the ring rather than the use of air for the pneumoperitoneum. The incidence of persistent shoulder pain which one would expect to find using the air was not so high as to justify avoiding the use of air. As for the severity of pain, there was very little that could be categorized as incapacitating to the patient. Every patient in this series who had any discomfort was well handled by simple analgesics, such as aspirin. The number of patients still complaining about

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TABLE 5

PAIN INTENSITY EXPERIENCED USING ROOM AIR BY TWO APPROACHES

	Standard Laparoscopy (N = 192)		Open Laparoscopy (N = 605)	
During Procedure	N	%	N	%
None	144	75.0	410	67.8
Mild	11	5.7	132	21.8
Moderate	34	17.7	47	7.8
Severe	0	0.0	11	1.8
Unknown	3	1.6	5	0.8
During Recovery Period Before Discharge				
None	58	30.2	127	21.0
Mild	109	56.8	337	55.7
Moderate	15	7.8	125	20.7
Severe	7	3.6	10	1.6
Unknown	3	1.6	6	1.0

severe discomfort prior to leaving the clinic was only 3.6% in the standard laparoscopy procedure cases and only 1.6% in the open laparoscopy group (Table 5).

Of the other major complications, there were no overt infections with either positive cultures or abscess formation, only one urinary tract infection and a few cases of vaginal bleeding, probably attributable to the use of the uterine elevator. Complications seen at follow-up (occurring from seven to twenty-one days in these cases) were very minimal and compare favorably to any other laparoscopy or endoscopic series which have been published (Table 6).

We believe that these 800 cases are just the beginning of documentation which will prove that air is a safe, effective

TABLE 6

COMPLICATIONS ENCOUNTERED AT FOLLOW-UP USING ROOM AIR BY TWO APPROACHES

Incision Complications	Standard Laparoscopy (N = 192) N	%	Open Laparoscopy (N = 605) N	%
None	166	86.6	433	71.6
Inflammation	1	0.5	3	0.5
Serious Discharge	7	3.6	8	1.3
Bleeding	0	0.0	1	0.2
Pain	2	1.0	0	0.0
Incomplete Dehiscence	1	0.5	2	0.3
Complete Dehiscence	1	0.5	0	0.0
Unknown	16	8.3	158	26.1

and worthwhile medium to use for pneumoperitoneum in endoscopic procedures in voluntary sterilization programs. We clinicians should not be afraid to employ air; we can save time, effort, and the resources of our countries in so doing.

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Anesthesia and Analgesia for Laparoscopy: An Overview

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Since the introduction of laparoscopy in gynecologic surgery, a wide variety of analgesia-anesthesia methods and agents, ranging from general endotracheal anesthesia to hypnosis, have been used to provide analgesia and sedation during laparoscopy.

Regardless of what method or agent is used, it is essential that the patient has a reasonably comfortable and pain-free state. This provides a quiet operative field and good abdominal relaxation for the operator who needs to have the freedom of being able to manipulate the pelvic organs. The method has to be simple, easy and quick to administer with low cost.

Analgesia-anesthesia for laparoscopy is somewhat different from that for other operative procedures in that the creation of a pneumoperitoneum, the steep Trendelenberg with lithotomy position and good abdominal relaxation required for laparoscopy present complex problems due to major changes in respiratory, cardiovascular and gastrointestinal functions.

The changes in respiratory function include: reduction in tidal volume from the pneumoperitoneum and the Trendelenberg position, decrease in lung compliance, decrease in arterial oxygen tension, increase in the pulmonary shunt, rise in airway pressure and rise in the arterial carbon dioxide tension from hypoventilation and absorp-

tion of CO_2 in the peritoneal cavity (if CO_2 is used as the insufflating gas).[1,2,3,4,5]

Reduction in venous return due to pneumoperitoneum with decrease in cardiac output, hypotension, cardiac dysrhythmia and reflex bradycardia are some of common changes in cardiovascular function during laparoscopy.[8,10] Venous CO_2 embolism from inadvertent intravenous CO_2 insufflation has also been reported.[6]

In addition to this, compression of the stomach from pneumoperitoneum increases the intragastric pressure, predisposing the patient to regurgitation and aspiration of the stomach contents.

General anesthesia provides the best possible condition for the patient and the operator. It provides complete analgesia and amnesia and eliminates anxiety of the patient. It provides a quiet operative field with good abdominal relaxation. At the same time, we can control the ventilation and thereby control carbon dioxide tension by means of hyperventilation.

Disadvantages of general anesthesia relate to its high cost, the need for special equipment and trained personnel, a possibility of vomiting and aspiration, more cardiovascular depression from general anesthetic and increased postoperative discomfort from intubation (sore throat, nausea, vomiting and muscle pain produced by fasciculations from succinylcholine).

When general anesthesia is used, it is recommended that the patient be oxygenated for about three minutes before induction of anesthesia and that 3 mgs. of curare be given intravenously approximately two minutes before the succinylcholine injection to prevent fasciculations that cause postoperative muscle pain. One should refrain from giving positive pressure ventilation before intubation to avoid air being pushed into the stomach. For that reason, oxygenation is best accomplished utilizing the patient's spontaneous respiration. This procedure also serves to wash out the nitrogen in the lungs and to provide adequate oxygenation before intubation. It is mandatory to intubate the patient with a cuffed endotracheal tube in order to provide a safe, unobstructed airway and also to prevent possible aspiration of the gastric contents. If there is any question of the stomach being inflated by air, a nasogastric tube should be inserted to deflate the stomach before insertion of a needle or a trocar into the

peritoneal cavity.[2,9,11] Mild hyperventilation also should be employed to prevent hypercapnia during the course of laparoscopy.[1,4,8]

Regional (spinal and epidural) anesthesia can also be used and does have some advantages. It provides good abdominal relaxation, provides analgesia without systemic sedation, and almost completely eliminates the possibility of aspiration. Conversation can be maintained with the patient so that one can always detect any early signs of an impending complication.

However, the disadvantages of regional anesthesia outweigh its advantages. To eliminate the discomfort of pneumoperitoneum, a high level of blockade is necessary. This high level of block along with the effect of pneumoperitoneum on the cardiovascular system can easily lead to severe hypotension. Furthermore, the paralysis of respiratory muscles can cause added difficulties for respiration already strained from the pneumoperitoneum and the Trendelenberg position. Post-anesthesia headache is one of the common complications following spinal anesthesia. Although the incidence of major neurologic complications is quite small, when it happens, it can be catastrophic.

Regional anesthesia should be administered only by well trained anesthetists with a knowledge of the pathophysiology and pharmacology of spinal and epidural anesthesia. This knowledge is essential in order to treat the complications and any untoward reaction from the local anesthetic as well as the problems of high level blockade. There are numerous reports of death from spinal and epidural anesthesia following administration by untrained personnel. Furthermore, regional anesthesia does not offer real advantages over local anesthesia for laparoscopy.

Local anesthesia with systemic sedation is by far the most popular and frequently used analgesia method today. It is well accepted by the operator and the patient, the cost is less, it reduces the anesthesia and the recovery time, and also decreases postoperative discomfort. Under local anesthesia, one can maintain verbal contact with the patient to detect any pending complications.

However, there are some limitations to the use of local anesthesia. The operator must employ a precise, gentle and speedy surgical technique. Pain and discomfort from

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the pneumoperitoneum and the manipulation of pelvic organs is not completely abolished under local anesthesia and the operator may sometimes encounter difficulty in performing the desired procedure due to inadequate relaxation and increased anxiety of the patient.[3,5,7]

The operator must also pay strict attention to the total dosage of local anesthetic administered in order to minimize the incidence of toxic reaction from high blood concentrations of local anesthetic. This is obviously directly related to the amount of local anesthetic used and whether or not there has been a significant intravascular spill. It is also essential to take a careful history from the patient to avoid the rare but possible allergic or hypersensitivity reaction to local anesthetic. In selecting the agent and the dosage for systemic sedation, care must be taken to avoid oversedation and respiratory depression. A trained anesthetist stand-by is recommended if available, to monitor and maintain normal cardiorespiratory function of the patient.[7]

As for additional preparation and equipment needs, it is essential to have intravenous fluid running and the minimum resuscitative equipment such as an Ambu bag, laryngoscopes, endotracheal tubes and resuscitative medications available nearby. Staff who have experience in resuscitation should also be available.

In conclusion, when selecting the proper analgesic or anesthetic method and agent, one should consider the desires and needs of the patient, the availability of a trained anesthetist and special equipment, the cost to the patient and the skill and experience of the operator. Whether or not the patient has any systemic disease also influences the choice. No single anesthetic method or agent is suitable for every patient in every situation. Regardless of what method or agent used, the primary goal is to maintain the safety and comfort of the patient.

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Reversibility of Tubal Sterilization

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The pattern of contraceptive utilization is shifting toward tubal ligation. The reasons for this change are numerous and interesting, but beyond the scope of this discussion. The fact that more and more younger women of lower parity are choosing sterilization means that more women may have reason to regret choosing a permanent method of contraception. Thus the question of restoration of fertility following tubal sterilization is a new problem in gynecology.

Studies by Gomel[1] and others have shown that the preponderance of patients seeking sterilization reversal were, at the time of their sterilization, under thirty years of age, had two children or less, and were often undergoing a life crisis or were in an unstable marital relationship (Table I). Reversal requests come mainly in the first year or two after sterilization; therefore, though it is important that counseling and patient selection be of good quality for *all* patients undergoing sterilization, particular attention must be paid to the younger, low-parity women. Proper counseling and case selection will minimize the number of patients who later regret their surgery, will counter criticism that sterilization is being promoted or indeed even coerced in certain individuals or groups, and will prevent patient dissatisfaction. In spite of good counseling, however, requests for reversal will undoubtedly continue and we must recognize this need.

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TABLE I

REASONS FOR REQUESTING REVERSAL OF STERILIZATION

Reason	Patients (Number)
Change in marital status	63 (63%)
Crib-death of newborn	17 (17%)
Desire for more children (marital status same)	10 (10%)
Psychological	6 (6%)
Tragedies	4 (4%)
Total Number of Patients	100 (100%)

In: Reversal of Sterilization, Sciarra, J. J.; Zatuchni, G. I.; Speidel, J. J. (eds). Proceedings of a Workshop, Harper & Row, Publishers, Hagerstown. Table 24-1, Pg. 196. 1977.

How Should We Provide for Sterilization Reversal?

Is a new technique of reversible sterilization of value or are current techniques of tubal sterilization adequately reversible? There is in fact no method clinically available which can be termed a reversible sterilization. The three methods under study are the hysteroscopically-applied tubal plug of Hosseinian[2], the laparoscopically-applied ampullary plug-clip system of Steptoe[3], and the hysteroscopic injection of polymerizing silastic monomer to produce a tubal plug as proposed by Erb.[4] It will be several years at least before any of these methods could become routinely available because of the number of cases and duration of follow-up needed to test three criteria: the adequacy of fertility control, success of reversibility after removal of the device, and risks of ectopic pregnancy. Only the technical feasibility of these methods has been established. Trials are being conducted with each of these systems but it is too premature to make any statements about their clinical utility.

Since none of the methods of reversible sterilization are clinically available, results with the reversal of current

techniques are important to consider. The reports of the 1960's indicated that term pregnancies following tubo-tubal anastomosis occurred in about 25–30% of cases. The techniques to achieve these results generally employed 2–0 and 3–0 catgut sutures. Often tubal splints were used. Tissue handling was rough by today's standards. Pre-operative evaluation probably did not include endoscopic appraisal.

The results for tubo-tubal anastomosis today are very good. Winston[5] has reported a 75% pregnancy rate after isthmo-isthmic anastomosis in 14 patients (Table II). He has found that the greater the length of tube following anastomosis, the better the result. He and others have also found that isthmic repair is usually more successful than repair to other segments of the fallopian tube. The nature of the damage caused by the original sterilization may be important—diathermic damage is more destructive than suture, bands or clips, particularly to blood vessels and supporting tissue. More recently, however, Winston[6] has stated that isthmic diathermic cauterization is satisfactory for reversal provided an excessive length of tube has not been damaged. Nevertheless, this method can be more unpredictable in the amount of damage produced and should be used carefully in young women of low parity.

With this information in mind and faced with a woman under 30 years of age with two or less children, tubal sterilization should be performed on the isthmic segment of the tubes with no more than a 1 cm segment of tube sacrificed. This should provide a satisfactory level of contraceptive effectiveness while giving a surgeon who may later be faced with a tubal anastomosis the best chance to perform a successful reversal.

Should Patients Seeking Sterilization be Told that Reversal is Possible?

This is a very difficult problem because on the one hand it could sway the patient who is not entirely certain that she wishes to terminate reproduction into accepting sterilization. On the other hand, the patient who has had a dramatic change in circumstances such as divorce or loss of children and who regrets the sterilization may not be

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TABLE II

SUCCESS OF STERILIZATION REVERSAL IN HUMAN FEMALES ACCORDING TO SITE OF JOIN

	Cornu	Isthmus	Ampullary-Isthmic Junction	Ampulla
TOTAL	20	8	10	12
Pregnant	13	6	6	4
	65%	75%	60%	33%

(Overall 58%)

In: Reversal of Sterilization, Sciarra, J. J.; Zatuchni, G. I.; Speidel, J. J. (eds). Proceedings of a Workshop, Harper & Row, Publishers, Hagerstown. Table 23–6, pg. 193. 1977.

aware that reversal is possible if she is told the operation is permanent. Without trying to confuse the original choices of the patient, it is my belief that the operation should be described as permanent but that in some circumstances should the need arise, a medical investigation may show that surgery for reversal is possible. Thus, the patient is made aware of the potential for reversal but not left with the impression that sterilization is equivalent to other forms of contraception which are easily reversible. Clearly, the counseling is the key and it is becoming a more complex task as sterilization techniques become more varied and gain even more widespread acceptance.

What is the Role of the Operating Microscope in Sterilization Reversal?

With the remarkable improvement in results of tubal anastomosis using microsurgical techniques, the future is unclear. The data of Winston[5], Gomel[1], and others using the operating microscope have been strikingly good. Unfortunately, the results have not been shown to be directly and specifically related to the factor of the magnification achieved with the operating microscope. The other factors in addition to optical magnification, such as fine nonreactive sutures, gentle tissue handling, and case selec-

tion have yet to be sorted out in affecting the overall improvement in operative results. Clearly the microsurgical methods are valuable, but the cost, skill and time demanded by the operating microscope make a careful comparative evaluation of these techniques very important. Better case selection, and endoscopic evaluation are certainly two key factors in recent improved results with the surgery or damaged tubes.

What is the Role of Reversal in a Tubal Sterilization Program?

It seems appropriate that centers for reversal should be available if one is to offer a sterilization program. Such centers should not be publicized nor emphasized during counseling, but they should be available so that when legitimate need arises for reversal of tubal sterilization, the patient will have access to a facility where such work can be done competently. In this way, when a woman decides to undergo sterilization as her choice of a family planning method, the service provided will be truly complete; the patient will have confidence that the tubal blockade itself will be done well, and that back-up services will be available should the unexpected occur and she once again finds childbearing desirable.

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*Risks and Benefits of Laparoscopy and Minilaparotomy**

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Introduction

Family planning and health organizations are frequently called upon to provide sterilization services. In a recent publication, Dr. Benjamin Viel estimated that the demand in Latin America closely exceeds one million cases.[1] It is therefore appropriate to consider the types of sterilization that should be encouraged in order to meet this accelerating demand.

Because laparoscopy provides interval sterilization without major abdominal surgery, this procedure has played the major role in promoting acceptance of female sterilization. Colpotomy and culdoscopy have been the other primary options, but these procedures are performed by very few physicians. Minilaparotomy, a sterilization procedure popularized in Asia, is gaining recognition as a possible alternative to laparoscopy and is becoming the preferred procedure for many physicians throughout the world.

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*This presentation is based entirely upon a previously published paper by Margaret F. McCann and Pouru Bhiwandiwala entitled, "Is Minilaparotomy Appropriate in the United States"? (Advances in Planned Parenthood *14(1)*:1-12, 1979).

The Technique of Minilaparotomy

Because laparoscopy techniques will be discussed by other speakers, let me briefly cover some aspects of the "minilap" technique.

Minilaparotomy sterilization is performed through a 3 cm wide transverse suprapubic incision. By using an instrument inserted through the vagina to manipulate the uterus, the fallopian tubes are brought into position for direct visualization through the incision. Several modifications of this technique have been described, but no one technique is superior; the choice is a matter of individual preference.

The indications for minilaparotomy are the same as for any sterilization procedure. Contraindications to this approach include pelvic infection, adhesions producing uterine immobility, endometriosis and the presence of a mass. Relative contraindications are obesity and previous bladder surgery; in cases of previous bladder surgery, higher placement of the incision is preferred.

Local anesthesia, supplemented by analgesics or tranquilizers, is generally used and provides the patient with minimal discomfort. Some patients and physicians may prefer a short-acting, general anesthetic if proper facilities and personnel are available.

The patient is placed in the lithotomy position, and a pelvic examination is performed. A sterile uterine manipulator may be inserted and the patient draped so that it is available to the sterile field. A 3 cm transverse incision is made 2 to 2.5 cm above the pubic symphysis and below the pubic creases, although some physicians prefer a higher incision to minimize the risk of bladder injury.

Retraction may be provided by a pair of simple right-angle retractors or by one of several specially designed self-retaining retractors. The uterine elevator is manipulated to bring the fundus and proximal portion of each tube, in turn, to the incision. Each tube is grasped either with the fingers, with a blunt hook, or with atraumatic forceps. Interruption of tubal patency may be accomplished by any standard technique, including mechanical occlusion using rings or clips.

Ligation techniques, particularly the Pomeroy method,

are effective and only require readily available suture material. Mechanical occlusive devices are advantageous because they can be applied while the tube remains in the pelvis, thus minimizing patient discomfort and tubal trauma. Following tubal occlusion, the incision is closed in layers.

The postoperative regimen is a simple one. Patients may be discharged as soon as they feel fit. No restrictions are placed upon daily routine or sexual activity. Oral analgesics are the only medications generally indicated.

Instruments for Minilaparotomy

One of the major advantages of minilaparotomy is that it requires only simple, routinely used surgical instruments, but the increasing popularity of this procedure has generated a variety of special instruments.

For uterine elevation, the instrument must have a guard to prevent the possibility of excessive uterine insertion and perforation. A Rubin cannula with tenaculum is the most effective instrument, and the Vitoon elevator is the least complex of the specially designed elevators. Other, more expensive instruments include the Hulka tenaculum, Valtchev uterine manipulator with interchangeable tips, vacuum uterine manipulators (which are attached to the cervix by suction), and Hasson balloon cannula, a disposable self-retaining uterine manipulator with a curved handle, which obviates the need for the patient to be in the lithotomy position. Instruments still in the developmental stage include a magnetic system and a suction cup with a rigid or malleable handle that can be applied to the uterine fundus per the abdomen.

A pair of small, right-angle retractors can be used to facilitate vision through the small incision, but self-retaining instruments, including the Laufe retractor, Madrigal-Goldsmith[3] incisional speculum and standard short or modified proctoscope, obviate the need for a surgical assistant. If the tube is not easily accessible, digitally or with forceps, various tubal hooks may be helpful.

Among the commonly used occlusive devices, the tubal ring and spring-loaded clip are most promising. The tubal

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ring, made of silastic, is applied to a knuckle of the tube and the spring-loaded clip, consisting of two plastic toothed jaws that lock together, is applied across the tube. Special applicators for occlusive devices have been designed for minilaparotomy, including a tubal ring applicator with a built-in light source.

Minilaparotomy Versus Laparoscopy

Risks and benefits of minilaparotomy and laparoscopy can be assessed on clinical, psychological and economic criteria and judged from the interlocking vantage points of the patient, physician and institution.

Clinical Criteria. Both minilaparotomy and laparoscopy can be performed on an outpatient basis, in freestanding facilities, and under local anesthesia. However, the convalescence period and type of anesthesia selected are dependent upon the preferences of the patient and physician and upon hospital or clinic policies.

Requirements for facilities, staff (other than physicians), and backup equipment are similar for both sterilization techniques, but the more complex laparoscopic equipment particularly if electrocoagulation is utilized requires special staff training in inspection and maintenance.

Criteria for the selection of patients are similar for the two procedures. Obesity is not an absolute contraindication, although the explanation often given by some physicians for not adopting minilaparotomy is that the thick abdominal wall in the average women in their country is greater than that found in women in Asia where minilaparotomy has been most widely used.

Laparoscopy, or "open" laparoscopy as described by Hasson[3], may be preferable for moderately obese patients; any procedure would be difficult in extremely obese patients. Similarly, the presence of adhesions resulting from a previous laparotomy or pelvic inflammatory disease is also a possible contraindication because it tends to make both sterilization techniques difficult to perform.

Data have been collected on both minilaparotomy and laparoscopic sterilization by the International Fertility Research Program (IFRP). Analysis of more than 4,000 minilaparotomies and 16,000 laparoscopies using a

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variety of occlusive techniques* performed for women who underwent sterilization at least six weeks after termination of their last pregnancy is presented below. Only one mortality was reported in the laparoscopy series: death occurred during the recovery period in a patient with a pre-existing cardiac condition. There were no deaths among the minilaparotomy patients.

Surgical injuries were reported for 1.4% of minilaparotomies and 1.7% of laparoscopies (Table I). These rates were not significantly different ($p > 0.10$). Injury to major blood vessels, the most immediately life-threatening complication, occurred only during laparoscopy (4 cases). Bowel injury, which can become life-threatening if not detected and repaired immediately, was more frequent among laparoscopy patients (17 cases), although it occurred during minilaparotomy as well (2 cases). Bladder injury (8 cases) was reported for a higher proportion of minilaparotomies, presumably because of the site of the incision.

Injury to the tube or mesosalpinx was associated primarily with the tubal occlusion technique and was highest for the tubal ring, applied via either procedure, and for laparoscopic electrocoagulation. Uterine perforation was reported for the same proportion of cases in both procedures. Electrocoagulation, attempted occlusion or ligation of a structure other than the tube occurred only via laparoscopy, as did cervical laceration.

The rate of all surgical injuries varied by tubal occlusion technique, occurring in 1.1% of the Pomeroy sterilizations and 2.3% of applications of tubal rings at minilaparotomy, and ranged from 0.7% to 3.1% among the cases of laparoscopic tubal occlusion.

Laparotomy was required (Table II) in a significantly large proportion of the laparoscopies ($p < 0.05$)—0.03% versus 0.1% for the minilaps. The need for laparotomy in these cases was evenly split between management of complications and proper accomplishment of tubal occlusion.

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*Among the minilaparotomy patients, 3,380 patients were sterilized by Pomeroy ligation and 998 by the Falope Ring. Among the laparoscopy patients, 9,811 were sterilized by electrocoagulation using unipolar forceps and various types of electrosurgical equipment, 1,517 by the Hulka-Clemens prototype spring-loaded clip, 587 by the Rocket of London modification of the spring-loaded clip, and 4,464 by the Falope Ring.

TABLE I

SURGICAL INJURIES OF STERILIZATION VIA MINILAPAROTOMY AND LAPAROSCOPY, POOLED IFRP DATA

Surgical injury	Minilaparotomy				Laparoscopy							
	Pomeroy (n = 3,380)		Tubal ring (n = 998)		Electro-coagulation (n = 9,811)		Hulka clip (n = 1,517)		Rocket clip (n = 587)		Tubal ring (n = 4,464)	
	No.	(%)	No.	(%)	No.	(%)	No.	(%)	No.	(%)	No.	(%)
Injury to major blood vessels	0	(0.0)	0	(0.0)	2	(<0.1)	1	(0.1)	1	(0.2)	0	(0.0)
Bowel injury	2	(0.1)	0	(0.0)	10	(0.1)	1	(0.1)	6	(0.1)	0	(0.0)
Bladder injury	7	(0.2)	1	(0.1)	6	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)
Injury to tube/mesosalpinx	16	(0.5)	16	(1.6)	102	(1.0)	2	(0.1)	1	(0.2)	77	(1.7)
Uterine perforation	8	(0.2)	2	(0.2)	12	(0.1)	4	(0.3)	5	(0.9)	10	(0.2)
Cervical laceration	0	(0.0)	0	(0.0)	10	(0.1)	0	(0.0)	0	(0.0)	0	(0.0)
Electrocoagulation/occlusion/ ligation of inappropriate structure	0	(0.0)	0	(0.0)	6	(0.1)	1	(0.1)	1	(0.2)	5	(0.1)
Other injury	5	(0.1)	4	(0.4)	4	(<0.1)	1	(0.1)	4	(0.7)	9	(0.2)
Women with one or more surgical injuries	38	(1.1)	23	(2.3)	152	(1.5)	10	(0.7)	18	(3.1)	100	(2.2)

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TABLE II

FAILED PROCEDURES OF STERILIZATION VIA MINILAPAROTOMY AND LAPAROSCOPY, POOLED IFRP DATA

Planned technique	Laparotomy required		Alternate technique required		Tubes not occluded		Total failed procedures	
	No.	(%)	No.	(%)	No.	(%)	No.	(%)
Minilaparotomy								
Pomeroy (n = 3,380)	4	(0.1)	26	(0.8)	1	(<0.1)	31	(0.9)
Tubal Ring (n = 998)	0	(0.0)	19	(1.9)	1	(0.1)	20	(2.0)
Laparoscopy								
Electrocoagulation (n = 9,811)	25	(0.3)	9	(0.1)	34	(0.3)	68	(0.7)
Hulka clip (n = 1,517)	7	(0.5)	10	(0.7)	0	(0.0)	17	(1.1)
Rocket clip (n = 587)	1	(0.2)	0	(0.0)	0	(0.0)	1	(0.2)
Tubal ring (n = 4,464)	8	(0.2)	32	(0.7)	6	(0.1)	46	(1.0)

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An alternate tubal occlusive technique was required more often during minilaparotomy. The alternative was generally a simple ligation, while the alternative in laparoscopy involved additional equipment. In a significantly larger proportion of the laparoscopic procedures ($p < 0.01$), however, one or both tubes could not be occluded at all by any of the methods available at the time (0.2% versus less than 0.1% for minilap).

The resolution of the complications and technical failure must also be considered. Injuries occurring during minilaparotomy are readily detected and are usually repaired through the same incision. Conversely, these events, notably electrosurgical burns, are less likely to be noticed during laparoscopy. Such a situation markedly increased morbidity. Once a laparoscopic injury is detected, laparotomy may be required, or in the case of injury to the tube, alternate equipment for tubal occlusion may be necessary. Because of concern about injury to the major blood vessels inherent in a "blind" procedure such as laparoscopy, Penfield and Madrigal, pioneers in the performance of laparoscopy in a freestanding facility, now perform only minilaparotomy and open laparoscopy in their clinics but insist upon hospital operating rooms for doing laparoscopies.[4]

Knowledge and skill of the surgeon, together with the availability of alternative equipment, are other factors determining treatment of surgical injuries. For example, tubal transection with the tubal ring applicator can be resolved by the application of additional rings if the surgeon is familiar with this option; otherwise, electrocoagulation or even laparotomy may be necessary to control bleeding.

With one exception, pregnancy rates following sterilization were similar for occlusive techniques via minilaparotomy and laparoscopy in the IFRP data; the 12-month lifetable pregnancy rates per 100 women were significantly higher ($p < 0.10$) for the prototype Hulka clip than for any of the other procedures.

The risk of pregnancy varies primarily with the tubal occlusive technique, but the same technique performed via minilaparotomy may have a lower pregnancy rate because direct vision helps ensure adequate tubal occlusion. The high pregnancy rate with the prototype Hulka clip can be attributed in part to the difficulties in tubal

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visualization with the single-incision laparoscope or culposcope used in clip application. Pregnancy rates associated with the most widely used occlusive techniques (Pomeroy ligation for minilaparotomy and electrocoagulation for laparoscopy) are very low.

Psychological Criteria. Psychological factors influencing the choice between minilaparotomy and laparoscopy are more tenuous than clinical factors. The attraction of physicians and, to a lesser extent, of institutions to the laparoscope cannot be denied. The excitement surrounding this technology and its promotion by the manufacturers have been important in gaining the interest of medical personnel responsible for providing sterilization services, thus contributing to the rapid increase in the availability of such services in recent years. However, a physician's fascination with the laparoscope and ancillary gadgetry should not interfere with rational consideration of the risks and benefits of alternative procedures. Conversely, some surgeons argue that minilaparotomy is intrinsically appealing because of the psychological and clinical advantages of direct vision. If a certain amount of technology is essential to the acceptance of a procedure, perhaps various manipulators, retractors and tubal occlusive devices associated with minilaparotomy will suffice.

From the patient's point of view, both minilaparotomy and laparoscopy are appealing because of convenience. The selection of one procedure over the other may be influenced in part by preferences about the size and location of the scar, the physician's attitude and the availability of the procedures. Because laparoscopy is not an open surgical procedure, psychologically, some patients may be less likely to consider it an operation and consequently more willing to select this sterilization procedure.

Economic Criteria. Economic criteria for the two procedures closely parallel clinical criteria. Since both procedures can be performed on an outpatient basis and under local anesthesia, the cost is minimized. Operating time is similar for both, although this can vary greatly according to the surgeon's skill. Total time for setting up, maintaining and sterilizing the equipment is greater for laparoscopy, however. In addition, the initial cost of the laparoscope and ancillary equipment and the recurring cost for maintenance and repair are considerably greater than for surgical instruments used for minilaparotomy.

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The fact that less specialized physicians can perform minilaparotomy is a critical element in its favor, since their services are usually offered at a more moderate cost and their training period for developing proficiency in minilaparotomy is shorter. The provision of sterilization services by less specialized physicians also permits greater availability to the patients, an important goal in itself.

Morbidity associated with sterilization has economic as well as clinical implications. Major complications require a high degree of medical and surgical treatment, including personnel and backup equipment, which tends to be both expensive to maintain on a standby basis and costly when used. Standby capacity is necessary for both types of sterilization procedures, but is utilized less frequently for minilaparotomy.

Conclusion

Minilaparotomy and laparoscopy are appropriate procedures for female sterilization, with the choice of procedure being dependent on a variety of clinical, psychological and economic factors. Greater availability of minilaparotomy services should be encouraged because of the simplicity of the procedure and the potential for decreased risk of major complications. Laparoscopy should be reserved for hospitals where a large number of laparoscopic procedures, both operative and diagnostic, make the purchase and maintenance of the equipment cost-effective and where the larger number of patients help ensure the maintenance of the surgeon's skills.

For selected patients, particularly those who are obese, standard laparoscopy or open laparoscopy may be preferred to minilaparotomy. Laparoscopists, however, should be sufficiently familiar with minilaparotomy to employ it in selected cases of surgical injury.

In summary, minilaparotomy can be offered practically, safely and effectively to the greatest number of women and is, therefore, a procedure that should be provided by family health programs.

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Evaluation of the Laprocator System

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Introduction

The Laprocator system has been available through programs financed by the U.S. Agency for International Development (AID) for approximately one year. The Laprocator was developed in response to a need for a laparoscope system which was less costly and which could be more readily maintained when used in developing countries. This report presents the results of an initial evaluation of the Laprocator to test its success in actual use. These results are based on questionnaires received from 32 different surgical programs in Africa, Asia and Latin America.

The Laprocator

The Laprocator system (Figure 1) is a single incision Falope-Ring laparoscope with several major modifications. The Laprocator consists of a straight-line replaceable optical system that is less complex than the conventional single incision system which contains two right angles. The Laprocator is also shorter with an overall length of 41 centimeters as opposed to 50.6 centimeters, and is adaptable for two-ring rather than only one-ring

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FIGURE 1.—The Laprocator System

application. However, there is some decrease in the visualization of the forceps tongs with the Laprocator, and the tong configuration is not adjustable as is the case with the standard Falope-Ring laparoscope. Finally, the Laprocator has a grip system different from the laparoscope.

The trocar provided with the Laprocator system uses a self-sealing valve rather than a piston valve. The console uses a mini-light source as opposed to a projector bulb/fiberoptic cable system. In addition, the Laprocator console allows the utilization of either a high pressure gas source such as carbon dioxide or a low pressure source such as room air. The Laprocator console does not contain a reservoir tank, however. Finally, a switch on the Lapro-

cator console allows one to choose between 220 and 110 volts—a feature that is not contained on the previous laparoscope models.

Survey Results

A questionnaire was distributed to skilled JHPIEGO laparoscopists who had used the Laprocator prior to their participation in the JHPIEGO equipment meeting. Questions were asked about the number of cases performed with the Laprocator, the types of cases, types of complications, and specific questions regarding difficulties with the light source, the forceps tongs, the pneumoperitoneum system, the trocar, and the instrument length. Also, there were questions dealing with the type of anesthesia and whether room air had been utilized for pneumoperitoneum. Suggestions regarding potential improvements in the Laprocator system were requested.

A total of 32 questionnaires were returned by operators representing 21 countries in Africa, Asia and Latin America. Although the vast majority of the almost 7,000 cases were completed for the purpose of sterilization, it should be noted that a number of patients had procedures for diagnostic indications that were successfully accomplished with the Laprocator (Table I).

Table II details the complications with the use of the Laprocator system. The most frequent problem noted was persistent pain following surgery. Other types of complications encountered included tubal transection and hemorrhage (usually described as umbilical bleeding).

TABLE I

NUMBER OF LAPROCATOR CASES BY INDICATION

(32 Operators)

Indication	Number	Percentage
Diagnostic Indications	463	6.7%
Sterilization	6408	93.3
TOTAL CASES	6871	100.0

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TABLE II

COMPLICATIONS WITH USE OF THE LAPROCATOR

Complication	Number	Rate Per 1000 Cases
Persistent pain following surgery	116	18.1
Tubal transection	54	8.4
Hemorrhage		
No hospitalization	29	4.2
Hospitalization required	3	0.4
Infection		
No hospitalization	21	3.1
Hospitalization required	1	0.1
Pre-peritoneal or omental emphysema	13	1.9
Slippage of fallopian tube off tongs	11	1.6
Other	6	0.9

Very few patients required hospitalization, however. The "other" category included instances of failure to complete the procedure, and cases of round ligament application of the ring where the ring was reapplied correctly.

Table III details the evaluation of particular parts of the Laprocator system. As indicated, the mini-light source was felt to be dimmer as compared to other systems. In many instances, however, it was felt that this could be

TABLE III

EVALUATION OF PARTICULAR PARTS OF THE LAPROCATOR SYSTEM

(32 operators)

Change Suggested	Number	Percentage
Increase forcep-tong angle	12	37.5%
Increase length of the system		
Particularly with obese patients	8	25.0
Unqualified	6	18.8
Mini-light should be brighter		
Unqualified	8	25.0
Particularly for beginners	4	12.5
Leakage of self-sealing valve system	6	18.8
Room air pneumoperitoneum system is too slow in filling	5	15.6

overcome once one became more experienced. There also was interest in increasing the angle of the forcep tongs and in having a longer system, particularly for use with obese patients.

Discussion

The Laprocator represents a simplied laparoscopic system which can be utilized both for diagnostic and therapeutic indications. As with any type of new equipment, it is not surprising that initial users have suggested several possible improvements. If one reviews the results of this preliminary evaluation by highly qualified operators, one can see that the equipment can be used successfully for both diagnosis and sterilization.

The complication rates clearly compare quite favorably to those encountered by operators using conventional forms of the laparoscope. For example, the complication rates with the Laprocator are not that dissimilar from those reported in the surveys of the American Association of Gynecologic Laparoscopists as well as the report of the Working Party of the Confidential Enquiry into Gynaecological Laparoscopy from the United Kingdom.[1,2] In fact, the complication rates are even less than those reported for minilaparotomy and laparoscopy by Dr. Goldsmith at this Conference. One might also anticipate that with increased familiarity with the system, there would be some decline in the number of complications encountered.

The evaluation of particular parts of the Laprocator system did indicate some interest in improving the system. It was felt that the mini-light system could be brighter, particularly for beginning operators. The majority of operators were still able to carry out the procedure without a great deal of difficulty, however. Some of these comments obviously result from operators who are used to using the brighter conventional fiberoptic laparoscopic system.

Increasing the forcep tong angle is a problem that was recognized early in the development of the Laprocator system. The Laprocators initially distributed included tongs at a 55° angle from the line of the optic. This angle has now been increased to 65° and preliminary evalua-

tions from the field indicate that this has sufficiently improved visualization.

When using room air for pneumoperitoneum, the pressure bulb system is apparently slower to achieve pneumoperitoneum as opposed to the high pressure gas system. Whether this is a major problem leading to a significant delay in surgery could not be determined from the questionnaire. A number of operators commented on the leakage of the self-sealing valve in the trocar. However, during seminar sessions at this equipment meeting, other operators indicated that the self-sealing valve had less leaks than other systems. It is important to stress that to avoid damage to the self-sealing valve, it must be lubricated with sterile water or glycerine.

Finally, several respondents suggested increasing the length of the Laprocator. This comment was particularly relevant to the performance of cases on obese patients. However, during additional discussions during the course of the meeting, a number of operators indicated that with modification of technique and more experience with the shorter length, there were few obese patients who could not have their procedures completed with the Laprocator.

In summary, the initial review of the Laprocator system indicates that the complication rates are not markedly different than rates with conventional laparoscopes. There are a number of suggestions for possible improvements of the Laprocator system, but most cases can be completed satisfactorily with the equipment as currently designed. The considerable reduction in the equipment cost probably compensates for some of the technical problems. If the reduction in maintenance needed is also realized, the overall benefits of the system probably will outweigh the disadvantages.

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Issues/Discussion

Minilaparotomy and Laparoscopy

During the discussion period, several physicians agreed with the contention that minilaparotomy techniques are an essential corollary to laparoscopy services. For example, minilaparotomy is preferred in Bangladesh because cultural inhibitions prevent male surgeons from inserting an instrument (the laparoscope) into the body. Paramedical personnel performing minilaparotomy in Bangladesh have actually achieved a complication rate lower than that of the physicians. One physician remarked that he was trained in minilap by a non-physician, but added that the feasibility of paramedical delivery of sterilization varied from country to country. Asia in general has well-trained paramedical health workers, while Latin America in general has few well-trained nurses and auxiliaries compared to the number of physicians.

In Indonesia, it was noted that the need for a simple sterilization procedure is great because there are only 200 obstetricians/gynecologists specialists in the country whose population numbers 135 million.

Dr. Goldsmith did not recommend laparoscopy as an immediate postpartum procedure though it is safe and effective in the hands of very experienced surgeons. A Mexican physician added tnat even after 15 years of experience with laparoscopy, he still feared the blind entry of trocar and needle, and hoped that open laparoscopy might be the answer.

Anesthesia

The question of the danger of overabsorption of the local anesthetic was raised. It was acknowledged that lidocaine absorption varies from patient to patient, but there is considerable leeway. The general guideline is 7 mg. of lidocaine absorbed per kilogram of bodyweight, which allows for the absorption of 400–500 mg. in the average patient. The usual maximum total of lidocaine injected for laparoscopy is 200 mg.

A Mexican participant stated that epidural anesthesia is preferred in his country. They have no problems with it; it provides a quiet operative field, and causes no patient discomfort. On the other hand, another participant pointed out that the possible disadvantage of more discomfort with local anesthesia can be overcome by assuring the patient that the pain is no worse than a severe menstrual cramp.

Reversibility

When asked about the success rate in diathermy patients, Dr. Neuwirth replied that in Dr. Winston's series, three out of the five diathermy patients succeeded in becoming pregnant. Thus, the assumption that diathermy occlusion cannot be reversed is not totally true.

As for the issue of informing patients about the availability of reversal techniques, this was thought by one participant to be inappropriate for developing countries. The sophisticated microsurgical equipment required is expensive and difficult to repair. This was not to imply that reversal should not be attempted when feasible in appropriate circumstances.

Insufflation Technique

Considerable support for the use of air for pneumoperitoneum was expressed during the discussion period. Many participants felt this was the answer for insufflation in developing countries where the availability of gas is limited. As for the concern about infection, it was pointed out that surgeons have exposed the peritoneal cavity to

air for decades with little risk. The major concern is whether the insufflation bulbs with time become significantly contaminated, thus increasing the potential for infection. The requirements of good technique and achievement of a good seal apply equally to use of air and gas, and will result in equal utility. A participant pointed out that a bacterial filter is available if desired. The amount of air tolerable in the circulation is 5 m. per kilogram of bodyweight, or an average total of 300 ml. Dr. Lim stated it would be unlikely that one would ever reach that level. The margin of safety with CO_2 is much wider however (25 ml/kg).

Several participants suggested that an extension of the philosophy of simplifying these procedures would be to eliminate insufflation completely whenever possible, such as using the Laprocator through a minilap incision. It was reported that IFRP is researching "suprapubic endoscopy" which will eliminate the trocar and the need for insufflation or electricity. In this procedure, the Laprocator is used with the blunt Hasson obturator, a steep Trendelenburg position and a uterine elevator. This may be the optimal compromise between laparoscopy and minilaparotomy.

Open Laparoscopy

It was emphasized that the potential for major complications such as vessel injury is greatest among beginning laparoscopists. One participant suggested that open laparoscopy might be useful to learn initially with later "graduation" to the closed technique. Another participant suggested that major vessel injury was so rare that the additional expense for specialized cannulas perhaps was not warranted.

Country Report: Colombia

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The laparoscopic sterilization program of the Colombian Government was initiated earlier this year and therefore it is too early to present conclusions, but I would like to describe the projected program for surgical techniques in family planning. As with every Latin American country, it was not easy to obtain official permission to begin such a project, with opposition ranging from religious groups to "leftist" political groups. But despite these obstacles we developed a program that would take a total approach to maternal and child care in a manner different from that of existing private programs.

In Colombia, we have seen a rapid drop in fertility since 1970. We competed with Mexico for the highest birth rate in 1964–65, with a rate of 44 to 45 births per thousand. In 1970, we reached a rate of 39.0 per thousand and by 1975 we had dropped to a rate of 30.5 to 31 per thousand. The rate of population increase has fallen from 3.2% per annum in 1964 to 2.2% today. This trend, we feel, indicates that the country is reaching maturity insofar as family planning is concerned.

Recently, we have increasingly perceived a need among Colombian women for a more permanent method of family planning. There are potentially 250,000 women eligible annually for tubal ligation in Colombia. Our concept is that the entity that offers family planning ought to

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expand its services in order to include the two areas of permanent contraception and infertility treatment. The government decided that if we were going to have a sterilization program, we must also include a program of microsurgery for reversal of sterilization. Thus we must develop a national center for microsurgery in Bogota, the country's capital.

In order for us to determine which patients require tubal ligation or surgical intervention, we have developed a risk classification system which takes into consideration the family's socio-demographic factors, the woman's medical history and her clinical condition at the moment. This results in three types of patients: the patients of high reproductive risk, patients of average reproductive risk, and patients of low reproductive risk. In order to accomplish this classification, a point system has been devised during the last seven years. The variables are assigned a certain number of points which, when it is added at the end, determine the patient's reproductive risk.

In low risk cases, we advise the patient to use whatever family planning method she and her partner may care to use. There is little reproductive risk, and therefore any method will be satisfactory. In patients of average reproductive risk, we advise the patient to use the most effective methods of contraception. If the couple makes an informed decision on their own to seek a permanent method, we make those services available. In high reproductive risk cases, we advise the patient to use either very effective or permanent methods of contraception.

We are a poor country that must fully use every different level of health worker from the personnel in the communities, which we call *promotoras rurales de salud* or *promotoras urbanas de salud*, to clinics which are a little more sophisticated, to regional hospitals where we find experienced general practitioners or ob/gyn specialists. This structure gives us the opportunity to evaluate up to what point the obstetrician/gynecologist is needed or to what point the general practitioner can handle these surgical methods of family planning alone.

Our program has been developed with PROFAMILIA, the private family planning organization in Colombia, to train 108 local physicians, ob/gyns or general surgeons, and 108 nurses. These physician-nurse teams will then have the responsibility of training the rest of the per-

sonnel in their hospital—the "multiplier effect". It is essential that more than one doctor and nurse are trained in each hospital because of the equipment maintenance needs and the high rate of mobility of medical personnel throughout our country. Eight training centers have been established in each of the different capitals of the States of Colombia.

First, the physician-nurse team spends eight days with the PROFAMILIA trainer in the training center. Then, the PROFAMILIA surgeon travels to the hospital of the trained physician and performs 20 to 30 operations with the trainee.

Our sterilization training program also works closely with the country's universities. The university hospitals in each state are linked to the activities of the Ministry of Health through their cooperative maternal and child care programs. Working with the universities obviously helps to ensure the continuation of the training of the health personnel by the university hospitals. At the same time, the link to the university also provides us access to a complete system of the latest equipment and new technologies.

We are giving each institution one laparoscope, one Laprocator and a kit for minilaparotomy. We are giving them these instruments not only for family planning by tubal ligation but also for the diagnosis and treatment of gynecologic diseases. For this reason, the program is not entitled, "Tubal Ligation Program", but rather *Programa de Endoscopia Pelvica y Técnicas Quirurgicas*. We believe that with this system we can cover the country's surgical family planning needs, which is an important component of total maternal care.

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Country Report: Korea

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Introduction

In 1962, Korea adopted a population control program as a part of the national economic development plan, and implemented a national family planning program as a means of solving the population problem. The national family planning program in the past fifteen years has brought about a remarkable decline in Korean fertility. The crude birth rate in 1960 was 43 births per thousand of population, but declined to 24 in 1975; and the total fertility declined from 6.0/year in 1962 to 3.2/year in 1975. Of course, we do not ascribe this fertility decline to the national family planning program alone. Other contributing factors were changes in the value of children, growing numbers of induced abortions, and a rising age at marriage.

The government plans to reduce the total fertility rate to 2.9 by 1981. To meet this goal, a more effective and acceptable contraceptive method should be provided through a well-organized national family planning program. Fortunately, new female sterilization methods such as laparoscopy have been introduced recently in Korea and may provide just such a method. So far, public reaction to this sterilization method has been quite favorable. One major contributing factor to this favorable reaction is the quality training of surgeons provided by

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the Johns Hopkins PIEGO program since 1973. Another reason for the favorable public response and the resulting improvement in the female sterilization program is the government's decision to take on the burden of paying in full the fees of the physicians performing the sterilization.

Acceptance of Laparoscopic Sterilization

The number of women who had been sterilized through 1971 covered only one percent of the total married women of reproductive age. But that number increased to four percent in 1976 when the government began distributing laparoscopes and when privately purchased laparoscopes began to arrive. Every year, the number of female sterilization acceptors has increased rapidly: 4,793 women were sterilized in 1974; 14,532 in 1975; 38,000 in 1976; 181, 398 in 1977; and 193,398 in 1978.

Of all the female sterilizations performed in Korea in 1977, 81.3% were performed by laparoscopy, 18.2% by minilaparotomy and 0.5% by other methods. In 1978, laparoscopy comprised an even greater proportion—89.3% (Figure 1).

A major impetus to this rapid growth in the number of sterilizations was the government reimbursement of the sterilization fee, which increased from 5,000 won ($10) in 1974 to 15,000 won (more than $30) in 1977. The other major impetus was improvement in the sterilization technique and equipment, the continuous educational program provided by JHPIEGO, and the development of informational and motivational materials on laparoscopic sterilization. According to a recent survey, 96.4% of the eligible women answered that they think female sterilization is the most effective contraceptive method. The government has now revised its original female sterilization target for the next five years from 700,000 operations to 1,220,000 operations. If this target is achieved, a tremendous effect on fertility in Korea can be expected.

Local Distribution of Laparoscopes

According to the data collected by the Korean Association for Voluntary Sterilization (AVS), a total of 564 lapa-

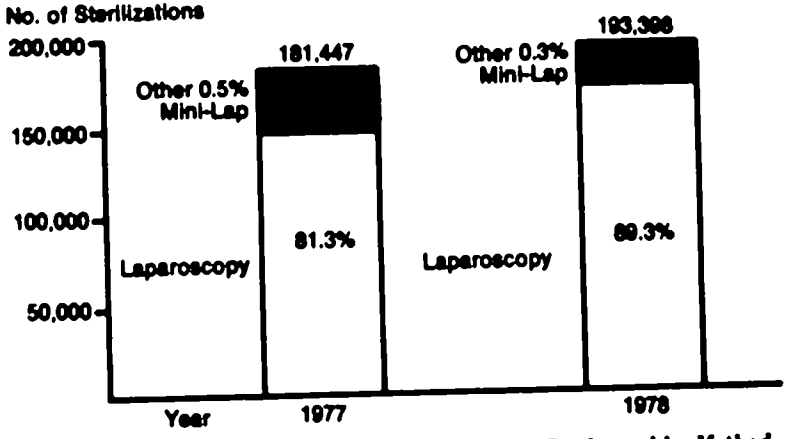

FIGURE 1.—Number of Female Sterilizations Performed by Method

roscopes have been imported into Korea as of December 1978. Of those, 82.3% were privately-purchased and only 17.7% were publicly-donated. As for the regional distribution of these laparoscopes, 59.2% (366 sets) were located in large cities, 23.0% (130 sets) in medium cities, and only 17.5% (98 sets) were dispatched to rural areas. Among the 138 counties in Korea, only 11 counties were supplied with laparoscopes from the government at the time of the survey. Therefore, we need more than one hundred additional laparoscopes in order to supply a minimum of one to each county.

Training

Laparoscopic sterilization was introduced in Korea through the training program conducted by JHPIEGO. In the beginning, four Korean physicians attended the course on Advanced Techniques for Fertility Management at the Johns Hopkins University. In 1975, JHPIEGO also conducted this training program in Korea with 120 obstetricians and gynecologists attending. This program was conducted in three phases—didactic sessions, practical training and field training. During the practical training, each trainee was assigned to one of five different training institutions and performed 15–20 laparoscopic

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procedures under close supervision. Upon completion of the practical training, trainees were given a set of laparoscopic equipment. During the field training phase, trainers from the five training institutions visited each trainee's hospital or clinic to check their performance and to install the equipment. Currently, there are 12 training institutions in Korea designated by the government for training in the advanced technology for sterilization.

Equipment Maintenance

In the first few years, we used to identify the equipment problems during the field training phase, and would then make an effort to replace the defective equipment in coordination with USAID/Korea. The Korean AVS has now established a Maintenance Center which carries out endoscopic equipment maintenance and repair activities. They perform routine preventive maintenance of all equipment every six months in order to identify and repair problems and keep all equipment in good working condition. One problem in equipment maintenance, however, is the fact that the Center cannot always acquire the necessary spare parts when needed.

Conclusion

With support of the Korean government and the JHPIEGO program, surgical contraception has contributed to the sharp drop in the Korean population growth rate in this decade. With regionalization of technical training and improved in-country equipment maintenance, laparoscopic sterilization will continue to be a significant component of family planning in Korea.

Country Report: The Philippines

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Population control in the Philippines prior to 1973 was largely accomplished through nonpermanent methods such as rhythm, condoms and diaphragms, spermicidal foams, tablets and jellies, pills and IUD's. Surgical sterilization did not receive much attention and support, and was carried out only upon the patient's request or in cases where the sterilization was medically indicated.

On June 1, 1973, the first sterilization clinic for men and women was inaugurated at Mary Johnston Hospital, funded by Family Planning International Assistance (FPIA). Many apprehensively awaited the repercussions it would bring, or the opposition it would create, considering that the Philippines is predominantly a Catholic country. As forecasted, the Roman Catholics showed their resistance by distributing "Mesalets", or preaching from pulpits about the sins committed by those who were involved in sterilization.

Questions on the gality of surgical sterilization were also raised. To clar.. this, the Philippine Commission on Population (POPCOM) sent a letter of inquiry on the legality of sterilization to the Secretary of Justice. In response, the Secretary of Justice declared that tubal sterilization and vasectomy are acceptable methods of contraception as long as the subject's consent thereto is given intelligently with full knowledge that the procedures are irre-

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versible. This declaration led to an increase in the number of acceptors of tubal sterilization. At the Mary Johnston Hospital alone, a total of 28,393 surgical sterilizations have been done (24,976 laparoscopies, 1,173 minilaparotomies, and 2,244 vasectomies).

Surgical sterilization in the Philippines owes its popularity to the laparoscopic technique. This was the method first utilized in the Mary Johnston Hospital sterilization program, and because this procedure was new, it created a big impact in the mass media. "Laparoscopy as a Surgical Sterilization Method" became a much talked-about topic on television and radio.

Many invitations to lecture and demonstrate the procedure came in, sent by medical societies, hospitals and other similar agencies. Consequently, more doctors were motivated to train at JHPIEGO in the United States. A similar training program was started at the University of the Philippines/Philippine General Hospital funded by the Association for Voluntary Sterilization (AVS) and Family Planning International Assistance. Fifty-seven laparoscopes were distributed throughout the country. The doctors who received this equipment were at first restrained in their enthusiasm by the maintenance problems—the equipment was expensive to repair and they did not know where to send the units in case of mechanical troubles. Aware of these problems, other funding agencies started promoting minilaparotomy instead, and some agencies in the Philippines today only provide minilap as the method for female sterilization. Even with minilap being offered in most places of the country, there is a continuous flow of patients to the Fertility Care Center at Mary Johnston Hospital for laparoscopic tubal sterilization. (Figure 1). The Center performs an average of fifteen cases a day, six days a week.

In answer to the persistent request for laparoscopic sterilization in other places in the country, we started a laparoscopic itinerant team officially called "Tilamsik". In the Philippine language, "Tilamsik" literally means "spark" or "splatter". The project, as its name suggests, provides outreach services—serving the patients who want to undergo laparoscopic sterilization but who cannot come to the clinic. This kind of project is difficult to undertake, calling for high endurance and commitment of the staff. It demands good coordination with the inviting

FIGURE 1.—Dr. Virgilio Oblepias Performing Laparoscopy with Patient

agency which takes care of motivating and recruiting the patients. On our part, it means bringing the clinic to the site of operation. Each trip may mean preparing and packing supplies two to three days beforehand for a trip that will serve one hundred patients or more. The trip may mean being on the road by dawn, and the staff may find it hard to keep awake this early and go on with their sleep during the trip. It may also mean going on a newly created road or through a forest, or even along the top of the mountain, suffering the discomforts of travelling along unpaved paths. Sometimes the team has to transfer to another means of transportation, as when we go out to the islands. Shifting the baggage from automobile to boat may be a problem considering the considerable weight of the equipment. But the advent of the lightweight Laprocator solved this problem. It is more handy, and even if laparoscopy must be done in places where there is no electricity, it is no longer a problem with the Laprocator.

A hospital or clinic may not be available to be the operative locale. Sometimes a classroom, a municipal hall office, or an ordinary house may be used. Whatever the setting,

on arrival the five-member team starts doing their duties. The social worker will start talking to acceptors, screening candidates for sterilization. Sometimes she gives group lectures or individual counselling to the patients waiting for their turn to be operated. The nurse and the driver, turned orderly and technician, prepare the "operating room" and laparoscopic equipment. The doctors meanwhile do the medical check-ups.

Everything is improvised—a simple table with one end elevated may be used as an operating table. The operating room is not often air conditioned and the surgeon will sweat. With two doctors operating in a small room with four improvised tables, the 100 or more patients waiting outside will all be served by dusk. Thanks to the "human patient stretchers" the turnover of patients is rapid. Patients are brought to a room where they stay on the floor with their own beddings. Patients stay in the recovery area for only one or two hours before leaving with instructions and medicines.

After the operation, the team packs up all the supplies used and unused, the instruments and the records. And again on the road the team will go, either back home or to another place where operations will be done the next day. Sometimes in very remote places, stores are not even available so we have to eat on the road, in the car. To quench one's thirst, we may have to make use of waterfalls or a small creek. These experiences show how remote the places are where we have gone so far.

Despite the remoteness of these locations, laparoscopy has proved to be very useful. The success of this technique has been shown: (1) unceasing invitations for the Mary Johnston Hospital Itinerant Team to do laparoscopy sterilization; (2) patients will travel to our clinic, spending the money for the transportation rather than submitting to another method of sterilization (even if offered for free); and (3) the preference for laparoscopy over other methods of sterilization.

In a certain area in the Philippines, an agency concerned with population control compared laparoscopy and minilaparotomy in terms of acceptability. The Mary Johnston Hospital Itinerant Team was invited to provide laparoscopic sterilization to one group of motivated patients, and another team provided minilap to another group of patients. The study[1] found that more women

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liked laparoscopy than minilap. Thus if patients have their choice, they will prefer laparoscopy because: (1) the procedure is faster, (2) the recovery is faster, and (3) the wound is smaller.

To meet the high patient demand, more laparoscopy centers should be established or reactivated. This can only be done with training and retraining of doctors. As an essential back-up support to a laparoscopy program there must be a good repair and maintenance service. Since May 1979, JHPIEGO hs funded our new training and maintenance efforts. I have high hopes that this will give my people more chance to choose the method of tubal sterilization they desire.

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Country Report: Tunisia

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To fully explain the Tunisian experience with laparoscopy would take many hours. In the short time that I have, I will try to bring up the most important points. Our experience with laparoscopic tubal ligation goes back many years. In the past, we had been using primarily the Palmer method of electrocoagulation with double incisions. But in August 1976, after several of us spent time training in Baltimore and Canada in the JHPIEGO program, we began to practice laparoscopic tubal ligations with the silastic ring.

To date, we have performed approximately 10,000 ligations in the principal family planning centers in Tunis, Sfax and Beja. We have now acquired enough experience so that we have been able to reduce the amount of anesthesia during the procedure, as well as hospitalization time, without increasing the number of complications. The population we serve varies greatly from center to center, but in general it is rural, very poor, with large family size. Our statistics show an average patient age of 35 years, with an average of 6 living children (Table I). A majority of the procedures (54.6%) are simple ligations performed on multiparous women. Over one-fourth of the procedures (26.5%) are performed at the same time as pregnancy terminations (in the case of undesired pregnancy). (Table II).

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TABLE I

PERCENTAGE OF LIGATIONS PERFORMED PER AGE GROUP

AGE	%
20–24 years	8.2
25–29 years	19.0
30–34 years	32.5
35–39 years	35.0
40–44 years	8.8
45–49 years	2.0

Anesthesia and Pneumoperitoneum

Every surgical center uses its own method of anesthesia. In Tunis and Sfax we use general anesthesia. In Beja we use the following procedure: the evening before the operation, the patient is administered a Nembutal suppository, and several hours before the procedure, 10 mg of diazepam and 0.25 mg of atropine intramuscularly. During the procedure, 100 mg of dolosal is slowly administered intravenously and procaine 1% is used for local anesthesia.

TABLE II

STATUS OF PATIENT AT TIME OF LAPAROSCOPY

Simple ligations on multiparous women:	54.6%
Tubal ligations at the same time as pregnancy terminations (unwanted pregnancy):	26.5%
Tubal ligations on women using IUD's:	17.2%
Tubal ligations for women using the pill:	1.7%

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Equipment

Laparoscope. The KLI single incision laparoscope has given us satisfactory results. Although the size of the trocar is imposing, after using this instrument one finds that it is easy to handle. The light source is very good and provides good vision. I have been able to avoid an extra step during the procedure by placing two silastic rings together on the instrument at the same time. By applying slight pressure on the handle, one ring can be placed on each tube at the same time without removing, reloading and re-inserting.

Laprocator. This unit, of course, is intended to have two rings applied with one insertion. This unit is smaller, lighter and easier to handle. The trocar is simplified but the scope is rather short, and it is insufficient for very obese women. The removable telescope, in my opinion, is a bit inconvenient, since after frequent use it risks the possibility of breakage or gas leakage. The mini-light source is not as bright and is not quite bright enough, especially for a beginner. Another problem with this instrument is that in cases involving slight hemorrhaging or enlarged tubes, another operative method has to be used to correct the problem (for example, electrocoagulation or laparotomy). We usually then have to resort to minilaparotomy since the Laprocator cannot adapt to these situations.

Complications

Statistics from the Ariana Training Clinic, where we have performed about 1,500 cases in 15 months, are shown in Table III. Most of the complications we have experienced are due to either operator- or manufacturer-caused problems with the silastic rings. The majority of failures have been caused by misplacing the ring on the round or broad ligaments.

Conclusion

The Tunisian experience in laparoscopic tubal ligation allows us to conclude that this method is simple and easy

TABLE III

COMPLICATIONS OF LAPAROSCOPIC LIGATIONS

I. Direct Complications	%
Transection of tube	0.5
Laparotomy	0.3
Hematoma	0.2
Unsatisfactory application of ring to tube	1.6
Inability to apply ring (enlarged tube)	0.2
Application to the round ligament	0.2
Application to utero-ovarian ligament	0.2
Tearing of mesosalpynx	0.2
Losing the ring	0.3
II. Indirect Complications	
Fractured ring	1.6
Uterine perforation	1.4
Preperitoneal emphysema	1.0
Equipment malfunction	0.5
Tear in cervix	0.4
Umbilical infection	0.1
Trocar failure	0.1

to perform, with minimal risk and without serious technical problems. This is due to the manageability and practicality of the equipment, and naturally assumes use by a well-trained operating surgeon.

Country Report: India

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Introduction

India, to the average visitor from overseas, consists of four major cities: Delhi, Bombay, Calcutta and Madras. One may form an opinion about the country after visiting these four major cities, but I want to impress upon you that India is much more—eighty percent of our population lives in the rural areas where the visitor is unlikely to go. These rural areas are also where our medical people are reluctant to go and settle and work.

From January to March 1979, I operated in several laparoscopy camps in these rural areas; I want to describe how we worked and how we used sophisticated laparoscopy equipment in a rural setting.

Most countries of the "third world" experience problems of excessive and unplanned fertility. India was the first country to initiate the "camp" approach for male and female sterilization. In the camp approach, a team of doctors and nurses visits rural areas to provide sterilization to people who do not have easy access to physicians and clinical facilities. Use of endoscopic sterilization in rural areas is controversial, and we have tried to evaluate laparoscopic Falope-Ring application in these settings through our experience with 5,287 such procedures performed within three months in the state of Gujarat.

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The operating team consisted of myself, three resident surgeons from my hospital in Baroda, and a nurse. We came to the villages as experts and operators only. The local physicians and nurses were responsible for organizing the camps, motivating and counseling local women, and ensuring that everything was ready for our arrival. Without this crucial local support, the program would not have worked.

The Setting

The operations were usually performed in one of three settings—district hospitals, primary health centers (PHC) or any local public building such as a primary school. Running water was not always available, and in some cases we requested the state government to provide a mobile water tanker. We could not always count on electricity being available either, and in areas without it we would rely on a kerosene stove to sterilize the speculum and similar instruments. The laparoscope was sterilized with xylene solution.

We did not always find a suitable operating table at the camp, so again we would improvise. If simple beds were available, we might put bricks underneath the feet at one end to improvise the Trendelenburg position. It was impossible to bring enough surgical gowns for each day's procedures, so we would only wear two each day—one for the morning session and one in the afternoon. Only the surgical gloves were changed after each procedure.

With one surgeon, three residents and a nurse, we were able to develop a system that enabled us to perform 80 to 100 laparoscopic sterilizations per day. On one particular day we actually performed 409 operations. We achieved this high rate by using three or four operating tables at a time and by dividing the tasks among the team members. One resident creates the pneumoperitoneum for all patients; the second resident is in charge of passing the uterine elevator and other vaginal manipulations. I then pass the trocar and sleeve, and then the laparoscope, apply the Falope-Rings, and move on to the next table where the first resident has already created pneumoperitoneum. In the meantime, the third resident is closing the

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first patient's abdomen with one subcuticular stitch. All four of us are thus working constantly at one table or another, and in this manner we can perform many operations in one session.

When we do so many procedures in one day, the government cannot provide us with enough attendants to transfer the patients. We find that the village people are very cooperative and volunteer to help take patients from the operating room to the recovery area. Patients are usually discharged 4 to 6 hours after the operation. The patients never come alone, so during the recovery period, their friends and family provide some food and water that they brought themselves. With all the people accompanying the patients, the camp takes on a festive atmosphere, and food vendors and craftsmen make good business among those waiting outside.

Laparoscopy has become so popular that patients do not wait for the government transport that will pick them up on the day of their operation. They want to be first on the list, so they may come the night before by foot or bullock cart and stay under a nearby tree where they will cook and sleep. In the rural areas we are never sure how many patients will come. Sometimes when we expect to see forty patients, there might be a hundred, and sometimes when we expect sixty there may be only ten. Much of the time the turnout depends upon group spirit. If a local woman leader comes to be sterilized, many women will follow. If someone changes her mind, others may say they will come another time, so the day's caseload is very unpredictable.

Preoperative Preparation

For preoperative screening, the nurse or technician takes the patient's history and checks the hemoglobin. Our standard for a permissible hemoglobin level is 8 grams percent (if we insisted on 11 grams percent, we would not be able to do many operations). Approximately 20 minutes before her scheduled operation, the patient is given intramuscularly 100 mg Percodan, 10 mg sequil and 0.6 mg atropine. Most patients will fall fast asleep within twenty minutes with these drugs and will have little discomfort during the operation.

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Pneumoperitoneum

We use room air for pneumoperitoneum—it is cheap, universally available and there is no discomfort since carbonic acid is not formed. We have found that carbon dioxide will combine with moisture in the peritoneal cavity and form carbonic acid which causes some discomfort for patients when local instead of general anesthesia is used. In addition, with room air there is no risk of cardiac arrhythmias, ventricular fibrillations or hypercarbia. We need to use very little air in most of our patients to achieve satisfactory pneumoperitoneum—usually about 1–1.5 liters. The disadvantages of air include the risk of embolism, postoperative discomfort due to slow absorption, and some difficulty in measuring intraperitoneal pressure.

The very simple device we have developed for instilling the air consists of a sphygmoscopy rubber bag, a plastic jar with a "T" tube, a suction pump used in reverse, and a small electric motor of the type used for aquariums. The sphygmoscopy bag will last for about a hundred pneumoperitoneums, and when it wears out, we throw it away and use a new one. Each bag costs less than the equivalent of U.S. $2.00.

Complications

A tabulation of patient characteristics, operative difficulties and complications is shown in Table *I* to *IV*. Total morbidity in this series of 5,287 patients was quite low and there were no mortalities. I want to stress that in any large series of laparoscopies the surgeon can expect to encounter several cases of pre-existing conditions that can complicate tubal occlusion. For instance, I encountered six cases of umbilical hernia in this series. It is important to record in the patient's file this finding on laparoscopy so it will not be considered a postoperative complication if discovered at follow-up. Congenital anomalies such as a bicornuate or unicornuate uterus were found in ten cases. One should be aware of the possibility of unicornuate uteri in order to prevent application of a ring to a nontubal structure.

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MOBILE ENDOSCOPIC CAMPS

TABLE I

CHARACTERISTICS OF LAPAROSCOPIC STERILIZATION PATIENTS

Total Cases	5287
Mean Age (years)	30
Mean Parity	4.3
Living Children	4

TABLE II

DIFFICULTIES IN FALOPE-RING APPLICATION

Omental Adhesions	2 cases
Abdominal Tuberculosis	1
Pelvic Mass with Adhesions	1
Tubes not Visualized	1

TABLE III

ASSOCIATED CONDITIONS WITH LAPAROSCOPIC STERILIZATION

Ovarian Cyst	8 cases
Fibroid	4
Hydrosalpinx	4
Umbilical Hernia	6
Congenital Anomalies	10

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TABLE IV

COMPLICATIONS OF LAPAROSCOPIC STERILIZATION

Uterine Perforation	54
Tube Transected	15
Bleeding from Mesosalpinx	5
Bleeding from Omentum	2
Bleeding from Abdominal Wall	1
Extra Peritoneal Air	10

As shown in Table IV, we had 54 uterine perforations in our series, for a rate of about 1%. Most of these were fundal perforations and required no special treatment. Because the standard uterine elevator we use extends about 5 cm beyond the stop, we must take extra care since the practice of prolonged breast feeding in rural India results in hyperinvoluted (3–3.5 cm) uteri in some of our patients. The other complications—transected tubes and bleeding—occurred only rarely. If no hematoma occurred during observation, we generally left them alone.

Conclusion

Someone might ask: is laparoscopy the final answer to the problem of female sterilization in India? At present, I would say no. The national target for 1979 in India is to perform 3.5 million sterilizations. Assuming that 80% of the operations are for females, and that one doctor can perform one thousand laparoscopies per year, we would need 3,500 trained laparoscopists to meet the national target. Obviously we have not yet trained that number, so for the time being, postpartum sterilizations will remain in the majority. Besides the training obstacle, we must also overcome the problems of high initial cost and maintenance problems with the laparoscopy equipment.

Though laparoscopy is most often considered an urban procedure, my team has demonstrated that laparoscopy

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can be successfully delivered in rural areas. The rural patients are very satisfied: one day when we had to offer conventional laparotomies instead, many patients said they would come back later when we had "the machine" working. They do not know what a laparoscope is, but they know they want to be operated on by "the machine".

In the immediate future, we must concentrate on training surgeons. It is no good to popularize the laparoscopy procedure among the people without having the personnel and equipment necessary to meet the demand. But with the help of JHPIEGO and others, we can train more physicians as the first step in expanding the availability of laparoscopy in India.

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Country Reports/Discussion

Cleaning and Sterilizing

How did the programs presented in these country reports accomplish the cleaning and sterilizing of equipment under often difficult circumstances? In the Philippines, the Tilamsik team used to use 10% formaldehyde, but now usually uses a 10 minute soak in Zephirin for sterilizing. Cleaning is done with simple soap and water, without disassembling the instruments. No infections have occurred in the series of several thousand cases. A physician from India also reported that they did not disassemble the instrument except after 40 to 50 procedures. Cleaning is done with tap water and a Xylex solution is used for sterilization.

Complications and Management

In response to questions about morbidity, Dr. Oblepias from the Philippines answered that the hospital or clinic which invited the Tilamsik team is usually responsible for patient follow-up. In their entire series of around 25,000 cases, they have had only one mortality, from typhoid. Only 6 cases required laparotomy for management. As a basis of comparison, the U.S. mortality rate for laparo-

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scopic sterilization cannot be cited precisely but is estimated at 8–10 per 100,000 procedures. Dr. Toumi from Tunisia reported that in his program, uterine perforations were usually simply treated with a 2–3 day course of tetracycline. It was pointed out that in the nonpregnant uterus, most perforations, if they occur, will be either in the fundus or the anterior wall which require no additional surgery. A laparotomy and suture would only be needed in the unlikely event of a lateral perforation into a uterine artery or vein.

India

Dr. Bhatt was asked several questions about his experience with laparoscopy camps in India. He estimated that if all of the demand for sterilization in the rural areas could be met, the proportion of women sterilized would reach 50%. But meeting such a demand would require a continually operating clinic in every local population center. As it is now, he is never able to fully meet the demand in one visit to a village. He has noticed that demand is highest from November to April, and lowest during the rainy season and during festivals.

When asked how he handled patients who were waiting to be sterilized and were also pregnant, Dr. Bhatt replied that if the woman was in the first trimester they would terminate the pregnancy and then use the silastic ring for tubal occlusion. In these patients, he has found that the postabortal tube is very vascular and therefore needs to be drawn into the ring applicator two or three times so that it will become small enough for the ring to slip over.

As for their equipment, Dr. Bhatt uses two operating units—one laparoscope and one Laprocator. While one is being used, the other is being sterilized in Xylex for 8 minutes. All other instruments and the linen are provided by the local health center. They use only one long sterilized sheet covering the patient from head to toe, with a hole cut for the operative field.

Follow-up of patients served by Dr. Bhatt's program is being handled by three research associates and six social workers. They will review the initial histories taken at the time of the operations and locate the patients to determine complications and other complaints. The

government will review this information to determine if the laparoscopic camp approach can be used on a large scale.

Laprocator

Several of the participants added their experiences with the Laprocator, all of which were generally very positive. The instrument was praised for its simplicity, efficiency and low cost. It was pointed out that the complete Laprocator unit sells commercially for about U.S. $8,500, while just the console alone for the laparoscope costs U.S. $3,000.

Several problems with the Laprocator that have become apparent during actual field experience were described in detail. It was noted that the instrument is based entirely on the use of silastic rings for tubal occlusion—what would happen if the rings are no longer used? Several design modifications were suggested. It was suggested that the instrument could be a little longer, and that the optics should be moved 1–1½ inches farther from the end so that one's face would not interfere with the hand movement. Another participant said that the fiberoptic connector should be moved to the top side of the Laprocator, and commented that the instrument was too large for small hands to handle. Additions to the design might include manipulating forceps and another channel for application of local anesthesia directly onto the tube. One way to accomplish the latter without instrument modification is to connect the local anesthesia syringe to the trocar stopcock and allow the local anesthesia to run down the Laprocator and onto the tube. Three additional comments were that the Laprocator's lenses are recessed too deeply making them harder to clear when fogged; the rigid trocar knife is hard to extract, requiring a very rapid introduction of the Laprocator to avoid escaping gas; and that the tongs should be lengthened to ease lifting and isolating the tube.

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Workshop: Equipment Problems and Needs

Rohit Bhatt, M.D.
Ronald T. Burkman, M.D.
Co-Moderators
Recorder: Kasturi Rajadhyaksha, M.D., M.P.H

The workshop on laparoscopic sterilization equipment and equipment problems focused on topics that cover instrument design and operative problems.

Falope-Rings. Proper handling and care of the Falope-Rings and loading cones will lengthen their effective life span and avoid problems. One must inspect the loading cones carefully before using. Any burrs or nicks on the cone could damage the rings and lead to ring failure. Handling the cone with metal handlers such as tongs can cause these defects and should be avoided. One must also inspect the rings themselves after they are loaded and before application. Any rings that appear damaged or asymmetrical should be discarded.

When applying the ring to the tube, one should be sure the tube blanches white. If blanching does not occur, a second ring should be applied in the same area but not in a sequential fashion. Sequential application risks catching the mesosalpinx because of hydrosalpinx formation.

It was generally concluded that Falope-Rings have failure rates comparable to other occlusion methods, and that postabortal and postpartum application of the rings is as effective as interval sterilization. Falope-Rings should not be applied to thickened tubes or tubes with adhesions. Electrocoagulation is not advisable as a back-up unless the surgeon has considerable experience with

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this method. Rather, minilaparotomy is suggested for these instances, and minilap kits should be provided along with the Falope-Rings.

As for sterilizing the rings, soaking in standard solutions and autoclaving are perfectly acceptable. Gamma radiation should not be used because of the barium in the ring itself, and because gamma radiation reduces the ring's tensile strength. In Colombia, ultraviolet light exposure for fifteen minutes has been used to sterilize rings and other equipment quite successfully.

Laprocator Design. In consideration of equipment design, one must remember that to create the ideal instrument that will meet the needs of every individual surgeon is impossible. A frequent suggestion was to lengthen the Laprocator to help its use in obese patients. Lengthening the instrument would increase its expense because multiple lenses would have to be added to the optical system. Some surgeons have been able to use the current Laprocator successfully in patients weighting over 200 or even 300 pounds by altering their technique. Pushing down on the abdomen in order to bring the Laprocator closer to the tube was one suggestion. With the adaptation, there should be almost no cases that cannot be done by the Laprocator.

Some discussants stressed the advantages of the trumpet valve trocar over the simple trocar because no spare parts are needed, and spare parts are not always easy to obtain. The trumpet valve must be cleaned often in order to keep it functional. Those who preferred the simple trocar did complain that the current self-sealing valve leaked too often.

The mini-light source was deemed adequate for use by well-trained laparoscopists, but it was agreed that a brighter light source was needed for training purposes.

The current Laprocator equipment is adequate for most diagnostic applications, and such use increases its cost-effectiveness. Simple tasks such as hydrotubation for infertility, inspection for ectopic pregnancy or endometriosis, and so on are easily accomplished with the Laprocator, but more complicated tasks such as ovarian biopsy or lysis of adhesions can only be carried out with a laparoscope equiped with electrocautery.

Microsurgery. Microsurgical training is important, but it was stressed that surgeons learning these techniques

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must not only understand the use of magnification, but must also learn a whole host of changes in technique, use of special instruments and sutures, special tissue handling procedures and so on. The several available simple, inexpensive magnification systems such as hoods or loops are quite effective and should be considered over the more expensive equipment such as operating microscopes.

Prevention of Luteal Phase Pregnancies. Since the occurrence of luteal phase pregnancies discovered subsequent to laparoscopic sterilization can appear to be a procedural failure, any technique used to avoid them should be encouraged. There was mixed opinion about performing D & C's routinely during the luteal phase. Some discussants suggested avoiding this phase altogether and performing sterilizations only during menstruation or the first half of the menstrual cycle.

Workshop: Equipment Maintenance

Gamal I. Serour, M.D.
Dale J. Clapper
Co-Moderators
Recorder: Theodore M. King, M.D., Ph.D.

Both major and minor damage has been rendered to laparoscopic equipment from the moment it is uncrated because physicians and nurses have not been properly trained in equipment care and maintenance. The workshop on this issue reached several conclusions to help correct these problems. It also discussed and approved a guide prepared by Mr. Dale Clapper, Equipment Manager of JHPIEGO, for the establishment of in-country preventive maintenance centers. The guide follows this summary of the discussion.

Solving the problems of equipment maintenance requires two simultaneous steps—training users in regular care, and establishing technicians in maintenance centers that will specialize in laparoscopic equipment service. All physicians and nurses should be instructed in equipment care including handling, assembly, disassembly, cleaning, sterilizing and mending minor defects. This training should begin very early in their didactic training and continue through the supervisory field visits. A check sheet should be posted in the operating theater listing all regular maintenance steps so these can be carried out without fail after each procedure and each day. The workshop advised that technicians may be unsuccessful in teaching physicians directly in equipment care because of physician self-image sensitivities.

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Ideally the technicians who will staff the maintenance centers should be trained in their own country so they will be familiar with the unique problems they will actually face in practice. The initial demands on such a center will be great because beginning laparoscopic programs often face a very high case load. The equipment will be heavily used and will require frequent maintenance. The demand for repair may drop off as much as 50% as a laparoscopic program matures and initial patient demand is satisfied. Estimates regarding minimal number of laproscopes needed in-country before establishing a maintenance center ranged from 10 to 90. The group also agreed that national governments should help support these centers when at all possible. Finally, both the manufacturer (KLI) and the educational program (JHPIEGO) were asked to prepare manuals on equipment care and maintenance. These manuals should be clearly written in detail with photographs and illustrations wherever necessary. Every part should be fully described and illustrated. These manuals should be prepared as much as possible in the languages of the recipient country.

Establishment of In-Country Maintenance Centers

Concept. An in-country maintenance center is a facility which will provide, minimally, a rehabilitative service for instrumentation within a prescribed geographical area.

Purpose. The center will establish a sound Preventive and Corrective Maintenance Program involving the training of technicians and the controlled maintenance of laparoscopic equipment parts, in order to keep equipment continually functioning.

Objectives. The three *long-range* objectives of a maintenance center are:

- To provide the necessary maintenance and repair of all types of laparoscopic equipment.
- To train, on an ongoing basis, the technicians who will provide maintenance service for the equipment.
- To establish a Preventive and Corrective Maintenance Program which will have administrative control over the services and parts supplied.

There are several short-range objectives of the center, including: resolving the problem of equipment that is out-of-service; establishing a continual flow of necessary parts, and an equipment maintenance/repair shop; instituting routine maintenance service of equipment before major breakdowns occur; and preparing for increases in the number of laparoscopes in the program, and for refinements in existing equipment or to new equipment designs.

Procedures. Where it has been determined that sufficient and capable technicians and locations for their work exist, the maintenance center should implement the following procedures. First, all employees must have a job description in writing. The center must then plan how to "advertise"—to let laparoscopy users know the center exists. After establishing a complete inventory and record-keeping system, the center should develop a formula and procedure for providing maintenance and emergency repair visits to its clients. A list of the types of repairs that can be handled by the center in-country, and those that cannot, should be prepared. Procedures need to be established for the loan of laparoscopes and spare parts, and the shipping and handling of parts both in-country and out-of-country. In this regard, the center must seek duty-free customs clearance for equipment shipment.

The center's corollary task to these steps is the preparation of record-keeping forms for the supply and repair procedures. The following forms are recommended:

- Work order for corrective maintenance.
- Work order for routine preventive maintenance.
- Equipment history card.
- Inventory control for hospitals.
- Inventory control of the spare parts with max./min./total.
- Requisition forms to withdraw spare parts from central stores.
- Requisition for materials and repair orders from central maintenance to the U.S.
- Acknowledgement of order form.
- Proof of delivery.
- Report from the store room as to their inventory.

Training. Providing for the in-country training of equipment technicians is an extremely important function of

the center. If possible, every attempt should be made t train more than one technician, depending on the amount of equipment within a country. For example, three technicians would work together in the following manner. The master repair technician would hold primary responsibility for service, and would train others in the event more are needed at a later date, or if there is turnover in the original staff. The second repair technician would carry out continuing repair/maintenance services to all institutions having equipment. The third individual would act as the controller of inventory, supervise record-keeping, and handle procedures for disbursing and receiving, and so on.

There are many advantages to training repair technicians in-country. The cost of training four repair technicians in-country is approximately the same cost of training one technician in the United States. Overall per diem and expenses are less per student trained, the length of training in the classroom can be shortened by as much as one-half, and the students feel much more accustomed to their own cultural environment. If needed, qualified translators are readily available in-country, and the technicians can train in the actual local hospital environment. All the various levels of personnel using the equipment—nurses, doctors, technicians—can be trained together, and the training can be tailored to the particular needs of the country organization. In-country training also means that the technicians can install the actual equipment to be used under direct supervision.

Conclusion. After the in-country training of regional technicians is completed and the repair shops are established, the maintenance center has helped accomplish many steps necessary to a successful laparoscopy program. Communications between all parties concerned have been strengthened, the doctors and nurses responsible for the equipment know that maintenance is available, the maximum operating potential is assured from each machine, repair technicians have been trained and have the proper equipment to work with, and funding sources and other donor agencies know that the equipment is being properly maintained.

Workshop: Analgesia/Anesthesia

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A wide variety of analgesia/anesthesia agents and methods are used among JHPIEGO-sponsored hospitals and clinics around the world. Since we are dealing with such diverse situations created by differences in availability of trained anesthetists, equipment and drugs from one center to the other, it is impossible to formulate universal standards for analgesia/anesthesia. Furthermore, no single agent or method is entirely safe, suitable and satisfactory for all patients in every situation.

Analgesia/anesthesia plays a very important role in the successful outcome of laparoscopic procedures for fertility control. Analgesia/anesthesia contributes a fair share of the intraoperative and postoperative complications and mortality associates with laparoscopy.

The following are the recommendations formulated by this workshop for the safe conduct of analgesia/anesthesia for laparoscopy.

Preoperative Preparation

History and physical examination including the respiratory, cardiovascular and routine gynecologic examination should be done on all patients. Minimum laboratory tests

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required for laparoscopy include hemoglobin or hematocrit and urinalysis. Additional tests may be needed in patients with certain systemic diseases. Informed consent should be obtained. In some countries or institutions this may involve consent from the husband as well.

The patient should be instructed in advance to take nothing by mouth for at least six to eight hours prior to the surgery. Other procedures and steps necessary for patient safety should also be explained. Preparing the patient psychologically is also very important. Detailed information and descriptions of laparoscopy should be presented including the effects of pneumoperitoneum, the analgesia/anesthesia methods, and the postoperative discomfort to be expected. Especially when local anesthesia with systemic sedation is employed, we should inform the patient that they cannot expect to have 100% pain relief. Sensitive preoperative counseling will relieve patient anxiety and lessen postoperative discomfort.

Selection of Analgesia/Anesthesia

Selection of the analgesia/anesthesia method depends on the desires and the needs of the patient. It also depends upon the availability of trained anesthetists and equipment in the center or the camp setting. Other factors involved are the experience and skill of the operator, the cost to the patient, and the presence of any contraindications in the patient to any particular method.

Local Anesthesia

The maximum amount of local anesthestic (lidocaine seems to be the most popular anesthetic agent) should not exceed 400 mg at any given time. This dose is equivalent to 40 cc of 1% lidocaine. That total includes local infiltration, infiltration on the fallopian tube, and any paracervical blocks.

One should never start with a large dose of an analgesic. Systemic analgesics should be given in small increments, and one should allow enough time for the peak effect. For instance, if one starts the operative procedure within five minutes of an injection of an analgesic agent such as

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meperidine, the patient may not have the full effect from the analgesic agent and may complain about pain. If one waits a little longer, despite being pressed for time, the analgesia will have a more complete effect.

It is important to maintain consciousness of the patient at all times when using local anesthesia supplemented with analgesic agents, and to establish and maintain an intravenous line until the patient is fully recovered from the effect of the analgesic. In some countries, IV solutions are not available or difficult to obtain. In that case, one should at least have some means to administer emergency medications intravenously.

It is important to continuously monitor the vital signs—blood pressure, pulse rate, respiratory rate, and electrocardiogram, if available. In order to be as safe as possible, this monitoring should be done by fully trained personnel who do nothing but monitoring. Monitoring should continue postoperatively in the recovery room or holding area by a trained person who is equipped to handle emergency situations, including emergency resuscitative methods.

General Anesthesia

Since general anesthesia will only be given by a well-trained anesthesiologist or anesthetist, detailed recommendations are not necessary, but a brief outline follows. Preinduction oxygenation should last for 2–3 minutes. Pre-curarization should be used to prevent succinylcholine-induced fasciculation which causes postoperative muscle pain. There should be no positive pressure ventilation prior to intubation with a cuffed endotracheal tube. Decompression of the stomach (when distended) should be accomplished with a nasogastric tube prior to insertion of the pneumoperitoneum needle or trocar. The patient should be mildly hyperventilated to avoid hypercapnea. Preoperative antacid administration, preferably using sodium bicarbonate, can be used to prevent acid aspiration pneumonitis. Antacids such as magnesium trisilicate can cause severe problems if aspirated and should not be used.

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Neuroleptic and Dissociative Anesthesia

Induced by innovars and ketamines, these analgesics or anesthetic agents produce complete dissociation from realit y. The patients may look conscious because their eyes are open and sometimes they respond to painful stimulus, but if the dosage is too high, the patient will go into a complete anesthetic state. It is recommended that when these agents are given, one should start with a very small dosage and titrate upwards. Even though ketamine is a relatively short-acting drug, it should give at least half an hour of analgesia. One can always add but once too much is given, it cannot be reversed. Again, continuous monitoring of vital signs by personnel trained in techniques of resuscitation is essential.

Regional Anesthesia

Regional anesthestics—spinals and epidurals—should never be given by unqualified personnel. It may seem easy to put a needle in the spine and inject local anesthetic, but the effect produced by local anesthetic in these spaces is sometimes devastating. One must have full knowledge of the pathophysiology of spinals and epidurals and the management of their complications before attempting to use them with the high degree of block necessary for laparoscopy.

Resuscitation Equipment and Training

For resuscitation, one needs at a minimum an ambu bag, laryngoscope, endotracheal tubes in different sizes, stylet, and oxygen supply, various connecting tubes and a hard board for cardiac compression. The required minimum cardiac drugs include epinephrine, sodium bicarbonate, calcium, aminophylline, isuprel, digitalis and vasopressors.

It is also important, in view of reports of a couple of deaths from apparent overdosage of narcotic agents, to

have on hand a narcotic antagonist such as Narcan (naloxone).

There should be an ongoing training program in resuscitation for all personnel involved in patient care. The basic knowledge and skills required include mouth-to-mouth resuscitation; how to maintain the airway, including the head tilt; external cardiac massage; and "ambu bagging" (giving positive pressure ventilation).

Other Procedures

Two additional anesthetic techniques useful to laparoscopy are paracervical blocks and tubal application of local anesthetic. It is desirable to have on hand the trained personnel and required equipment necessary for these procedures.

Clinical Experience

The collective experience reported in the workshop with respect to mortality from anesthesia includes about 220,000 cases of laparoscopy and 240,000 cases of minilaparotomy. There have been three cases of mortality attributed to anesthesia associated with minilaparotomy procedures. There have been two deaths related to anesthesia reported in association with laparoscopy procedures, both under general anesthesia with sodium pentothal. Since the vast majority of the procedures reported here have been performed under diazepam-meperidine analgesia with local anesthesia, it is interesting to note that only one death was reported with this method (a minilaparotomy procedure), and this patient apparently received an overdose sufficient enough to produce respiratory arrest. No deaths were reported for laparoscopic procedures under local anesthesia.

The general consensus and experience of the workshop was that laparoscopic sterilization procedures carried out under diazepam-meperidine analgesia and local anesthesia carry a minimal risk of mortality.

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Workshop: Training: Techniques and New Advances

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The workshop considered the implications of new surgical equipment and techniques for the training of personnel in general, and for the JHPIEGO program in particular. The discussion focused on the following six topics: status of the Laprocator, maintenance problems, surgical techniques, supervision of trainees, educational materials, and reversal of sterilization.

What is the Current Status of the Laprocator?

Should JHPIEGO continue to provide trainees with the instrument, and thereby recommend its usefulness and reliability? Are there limitations on the usefulness of this instrument? Is it proving to be a satisfactory instrument for diagnostic laparoscopy and for therapeutic uses such as occlusion of the fallopian tubes by the silastic ring? Can it be used satisfactorily for demonstrations of the technique of laparoscopy to a trainee with no previous experience using a laparoscope? Can it be satisfactorily and safely used by a trainee when doing his or her first few cases? Are there problems in its use, particularly the length of the instrument? Are the problems of maintenance increased or decreased by the use of a Laprocator rather than a laparoscope?

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The workshop agreed that the Laprocator is a satisfactory instrument for use by the experienced laparoscopist, both for diagnostic and therapeutic use. The length of the instrument is rarely a problem. When obesity is the problem, resorting to a minilaparotomy for sterilization is often a wiser course. When a full length laparoscope is not available for exploration of an obese abdomen, an exploratory laparotomy may be indicated. It was emphasized that laparoscopy should not be attempted or learned by a physician who is not already a competent and experienced abdominal surgeon.

When possible, beginning laparoscopists should learn with both a standard laparoscope and a Laprocator. To improve visualization and to allow use of a teaching attachment, the latter instrument can be connected to the fiberoptic light source of the standard laparoscope.

Therefore, each major clinical practice and teaching center with a heavy caseload ideally should be provided with laparoscopic capability equivalent to at least a system A or B, a teaching attachment and a Laprocator with both CO_2 and room air capability. It was considered important to have each major instructional center so equipped so that the trainee could learn to use the conventional laparoscope and then be instructed in the use of the Laprocator.

What are the Current Probems in Regard to the Maintenance and Repair of Laparoscopic Equipment?

What criteria should JHPIEGO observe in deciding where and when facilities and personnel should be encouraged, organized and at times supported by JHPIEGO in order to assure satisfactory maintenance and repair capability in-country? There was prompt agreement that training physicians, nurses and hospital-based technicians in preventative maintenance is just as important to the life and usefulness of the laparoscope as making available the services of a specialized laparoscope technician. An effort should be made to develop repair capability on a regional basis, probably with the cooperation of the manufacturer, so the laparoscopic "down time" would not be such a problem in so many places. The reputation of

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the laparoscope as a reliable instrument is continually being jeopardized by the frequent need for repair or the unavailability of spare parts.

What Surgical Techniques for Female Sterilization by Laparoscopic and/or Minilaparotomy Procedures Should be Approved by JHPIEGO?

Should the team approach to training be recommended and should simultaneous educational programs for physician-trainees and their theater nurses and hospital technicians be encouraged? Among those training centers represented in the workshop, all provide instruction in the techniques of tubal occulsion by minilaparotomy as well as by laparoscopic techniques. The workshop recommended to the conference that the basic instruction as well as the clinical practice provided all trainees should assure their capability of using both techniques, with appreciation of when one or the other seems preferable for the individual to be sterilized.

Individual centers can provide instruction in either the gas pneumoperitcnium or open "room air" laparoscopy techniques. While laparoscopic techniques should be taught to only those physicians with experience in abdominal surgery, if surgical sterilization is to make any significant impact on the population problem, the less skillful and less experienced surgeons must also be providing sterilization services. In that context, the "open" technique of laparoscopy or the miniiaparotomy techniques of tubal occlusion are safer in the hands of the less-experienced operator. A laparoscopic Clinical Practice Center ideally should be provided with a Hasson cannula if that center prefers that instrument when teaching the "open" and "room air" techniques for laparoscopy. While atmospheric air is acceptable for pneumoperitoneum, the need for a means of deliverying a source of air rapidly into the abdominal cavity was emphasized. The conference should recognize the importance of investigations designed to perfect a readily available source of rapidly induced room air at a controlled rate and pressure.

Though JHPIEGO's courses for nurses will be training future trainers of nurses and other health personnel for

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laparoscopy, the more immediate need in some countries is for courses designed to improve the knowledge and techniques of those who are assisting physicians in their efforts to improve maternal and newborn care as well.

What is the Minimal Number of Laparoscopic Procedures A Physician-Trainee Should Perform Before an Experienced Laparoscopist Should be Expected to Conclude and Report on the Trainee's Competence?

Clinical practice experience should include not less than 15 procedures (laparoscopic plus minilaparotomies) by the trainee, followed by another 15 procedures under the supervision and observation of a JHPIEGO consultant in the trainee's home institution, using the equipment that would remain available to him in the institution.

What should be done when the trainer concludes that the trainee should not be approved to do laparoscopy? It was agreed that the trainer (or a JHPIEGO consultant making a site or field visit and observing a trainee's performance) should report to JHPIEGO that he does not approve of the trainee's performance of laparoscopy but would have no objection to re-evaluation by a second consultant. It should be understood, however, that depending on other sources of evaluation of the trainee's technical competence, JHPIEGO itself might not provide for re-evaluation by a second consultant.

What Educational Materials Should be Provided Each Institution that Serves JHPIEGO as a Training Center?

What materials should be kept by the center and what should be given to each trainee? The usefulness of the educational packages which JHPIEGO has been sending designated Clinical Practice Centers and other teaching institutions was not questioned. Nevertheless, the workshop strongly recommended the development of training manuals. JHPIEGO should either develop these themselves or approve of the use of existing teaching or training manuals for both physicians and non-physician personnel. JHPIEGO should not only provide such manuals, but even more importantly should support their in-

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country translation into the native language. Such manuals should teach minilaparotomy as well as laparoscopy. Furthermore, the information presented in the maintenance film should be made available as a slide set for each individual service unit (see Appendix). As for educational materials on maternal care and family health, it was assumed that JHPIEGO would provide appropriate educational materials to the extent that budgetary restrictions will permit.

What is the Place of Infertility Management and Sterilization Reversal in JHPIEGO Training Programs?

There was considerable discussion on the importance of instruction in the management of infertility, as well as in microsurgery for the restoration of tubal patency. In countries where tubal occlusion is being made available, there is an obligation to support the development of perhaps a single national center for the restoration of fertility when such restoration is desired. Training in management of infertility or the restoration of tubal function should be quite separate from and not combined with the development of contraceptive services. Infertility management and tubal patency requires narrower professional interest and the development of technical skills not essential to the provision of adequate contraceptive services. JHPIEGO should be highly selective therefore in the consideration and acceptance of physicians for training in these techniques.

Since women being sterilized today may later desire restoration of tubal function, attention should be paid to the actual site of surgical interruption of tubal patency and more emphasis placed on the avoidance of extensive coagulation of the severed segments of the tube when electrosurgery is employed. The application of a silastic ring, a suitable clip or a suture tie occluding the isthmus portion of the tube usually results in a degree and site of occlusion which is both effective and amenable to surgical restoration of tubal patency.

The workshop also concluded that though JHPIEGO would probably consider any involvement in infertility management or sterilization reversal as part of the training of ob/gyn trainers, the objectives of such a curriculum

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should be the dissemination of information and technical skills to all physicians interested and willing to help the community achieve reproductive health.

Conclusions and Recommendations

The Laprocator has proven to be a satisfactory instrument and provides for the needs of both a diagnostic and a therapeutic instrument. The Laprocator is not a satisfactory instrument with which an inexperienced trainee should learn laparoscopy unless one utilizes the fiberoptic light source. The instructor should teach laparoscopy using a conventional laparoscope with a teaching attachment initially. Instruction should later include use of and clinical practice with the Laprocator, since the trainee may only have a Laprocator to use in his or her home institution. The Laprocator should be provided:

(1) if there is no other laparoscope available to the institution of the trainee when he or she returns home;
(2) if the institution is conducting training in the use of the Laparocator, even if that center has several conventional type laparoscopes in operating condition;
(3) if the volume of practice in an institution already supplied with one or more laparoscopes warrants an additional instrument; and/or
(4) if a laparoscope is to be replaced.

Both the conventional laparoscopic technique employing a CO_2 induced pneumoperitoneum and the "open" laparoscopic technique (including the use of atmospheric air to provide the degree of pneumoperitoneum desired) appear to be appropriate for use in JHPIEGO Clinical Practice Centers and during site or field visits by JHPIEGO consultants. The Hasson cannula should ideally be provided to training centers which elect to teach trainees the "open" technique of laparoscopy.

Investigative effort should be encouraged to develop a source of atmospheric air that can be rapidly introduced into the abdominal cavity for pneumoperitoneum with reliable control of both the rate and pressure involved.

JHPIEGO should encourage the development of a national center for fertility restoration in countries evidenc-

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ing interest and in which tubal occlusion services have been made available.

During clinical practice the trainee learning laparoscopy should perform diagnostic and/or therapeutic laparoscopic procedures in a satisfactory manner for at least 15 cases and an equal number should be performed later in the trainee's home institution under the supervision and observation of an experienced laparoscopist who has been designated a JHPIEGO consultant.

When elective tubal occlusion is to be performed it is recommended that the tubal continuity be interrupted in the isthmus portion by a technique which disrupts only a minimal amount of tubal length such as the Falope-Ring.

Physicians to be trained in laparoscopic techniques must have previously demonstrated capability and competence in abdominal surgery.

Nurses and assisting health personnel that are accepted into a JHPIEGO-conducted or supported course should be those working with physicians in the provision of maternal care and/or sterilization services or trainers of such personnel.

Educational materials to be provided by JHPIEGO should include:

(1) training or teaching manuals illustrating both laparoscopic and minilaparotomy techniques for physicians, nurses and other physician-assisting personnel, translated ideally into the native language of the country in which the manuals are made available;
(2) films illustrating laparoscopic technique and preventative maintenance of equipment (for the teaching centers); (see Appendix) and
(3) slide sets illustrating the same points in preventative maintenance (for each service unit using a laparoscope or Laprocator).

The ultimate objective of the JHPIEGO programs should be to help prepare the capability of every willing physician to actively participate in the improvement of reproductive health in their community.

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** Member, International Advisory Board, American Association of Gynecologic Laparoscopists

Appendix

Audio Visual Materials

Two films developed by JHPIEGO in collaboration with the George Washington University for use in JHPIEGO educational programs were previewed during the meeting.

1. *The Technique of Laparoscopy*—This film emphasizes current technique and practice relative to the use of the Laprocator for both diagnostic and therapeutic endoscopy. Proper technique, patient management, and informed consent are emphasized. The majority of the film footage was shot at the Chulalongkorn Hospital in Thailand, and emphasizes the performance of a surgical technique in an ambulatory setting in a developing country.
2. *Laparoscopic Equipment Care*—This film emphasizes proper preventative care and maintenance of laparoscopic equipment, and was designed for use in the training of nurses and technicians who assume the responsibility for maintenance of laparoscopic equipment programs overseas.

These films are available in English, French, and Spanish, and are distributed by JHPIEGO for in-country educational programs.

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The Johns Hopkins Program for International Education in Gynecology and Obstetrics is a program which has been in existence since 1974 and is funded primarily by the Agency for International Development. JHPIEGO is about reproductive health—improving the health and well-being of mothers and children—and meeting this international need through medical education. JHPIEGO's objective is to make well-demonstrated reproductive health technologies, as they evolve, available to medical schools and other institutions in the developing world. This objective is met through the offering of training programs in reproductive health for physicians and allied health personnel from developing countries.

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