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FACULTY OF GRADUATE STUDIES

EPIDIMIOLOGY OF AEROBIC BACTERIAL
INFECTIONS AMONG IUD (INTRAUTERINE DEVICE)
USERS IN THE NORTHERN WEST BANK

By

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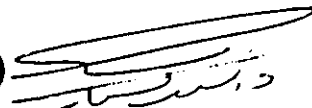
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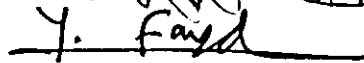
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**TO
MY PARENTS
BROTHERS, SISTERS, AND
FRIENDS
WITH LOVE AND RESPECT**

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Abstract

Intra Uterine Device (IUD) has been the most popular method of contraception among Palestinian women. It is one of the very effective contraceptive methods, with failure rate ranging from 0.5% to 3% (Hatcher et al, 1989) depending on the type of IUD. One of the main problems that face women using IUD is infection. Our study is a comparative study of IUD users and non-users. The study sample was from the FP clinics of MOH in the 4 main districts of northern West Bank. The purpose was to highlight the epidemiological pattern of IUD related infections in Northern West Bank as a representative of Palestinian women. 200 women (134 case, 66 control) were interviewed, and cervical swabs were collected and cultured for aerobic bacteria. All data were analyzed by SPSS.

In general the study findings were consistent with the literature.

The following statements worth reporting:

- The prevalence rate of isolated bacteria was higher among the IUD users than non-users ($p < .05$), and there was no relation to the type of IUD or duration of use in these rates. ($p = .027$)

- Regardless of the IUD use the study findings showed alteration in the vaginal discharge among women. However this alteration was significantly higher in IUD users (58%) compared to non-users (22%). (P=. 003)
 - The study also showed that the presence of RTI related symptoms among IUD users (61%) compared to non-users (26%) was statistically significant (p=. 000).
 - There was no relationship between the alteration of vaginal discharge with the type of bacteria isolated in both groups (IUD users and non-users). Among the IUD users (case group), isolation of different kinds of bacteria have no significant relation with the alteration of vaginal discharge, (p=. 105), (among the non-users p=0.667).

ملخص

يعتبر اللولب من أكثر وسائل منع الحمل شيوعاً في فلسطين ، حيث يعتبر من أكثر الوسائل فعالية، وتتراوح نسبة الفشل في استخدامه ما بين 0.2-3% وذلك حسب نوع اللولب. من أهم المشاكل التي تواجه السيدات اللواتي يستخدمن اللولب هي التهابات الجهاز التناسلي. في هذه الدراسة التحليلية تم إجراء دراسة مقارنة بين سيدات يستخدمن اللولب كمانع للحمل وسيدات لا يستخدمن اللولب. وقد تم اختيار العينة الدراسية من عيادات تنظيم الأسرة التابعة لوزارة الصحة الفلسطينية في محافظات شمال الضفة الغربية.

هدف الدراسة هو توضيح الحالات المرضية (التهابات) التي لها علاقة باللولب في محافظات شمال الضفة الغربية كعينة ممثلة للسيدات الفلسطينيات. تم اختيار مائتا سيدة (134 سيدة يستخدمن اللولب، 66 سيدة لا يستخدمن) وقد تم إجراء مقابلة شخصية مع كل سيدة كذلك تم اخذ عينة من عنق الرحم للزراعة والكشف عن البكتيريا الهوائية. تم استخدام برنامج الإحصائي SPSS في التحليل

بشكل عام نتائج الدراسة كانت متوافقة مع ما سبقها من دراسات وفيما يلي أهم النتائج التي تم التوصل إليها من خلال الدراسة:

- معدل انتشار البكتيريا الهوائية كانت أعلى بين السيدات اللواتي يستخدمن اللولب حيث كانت الدالة الإحصائية أقل من 5% ، مع انه لم يكن هنالك أية دالة إحصائية نتيجة اختلاف نوع اللولب أو المدة الزمنية لاستخدامه.
- بغض النظر عن استخدام اللولب أو عدم استخدامه دلت الدراسة على وجود تغيرات في الإفرازات المهبلية لدى السيدات ، ومع ذلك معدل هذه التغيرات كانت أعلى مع وجود دلالة إحصائية بين السيدات اللواتي يستخدمن اللولب (58%) مقارنة بأولئك اللواتي لا يستخدمن (22%). (قيمة الدالة الإحصائية 0.003).
- بينت الدراسة أن معدل مجود العلامات (الأعراض) التي لها علاقة بالتهابات الجهاز التناسلي كانت أعلى بين اللواتي يستخدمن اللولب (61%) مقارنة باللواتي لا يستخدمن (26%) مع وجود دلالة إحصائية عالية (0.000).
- بنت الدراسة بأنه لا توجد أية علاقة بين التغيرات في الإفرازات المهبلية ونوع البكتيريا التي تم عزلها من كلا المجموعتين. حيث لم يكن هناك أية علاقة بين التغير في هذه الإفرازات وبين نوع البكتيريا حيث الدالة الإحصائية كانت 0.105

Glossary

Bacterial Vaginitis: inflammation of the vagina caused by bacterial infection (Hatcher et al, 1997)

Bacterial vaginosis: a common vaginal condition caused by overgrowth of bacteria normally found in the vagina. Not generally sexually transmitted. Can come from douching, pregnancy, or antibiotics. Causes fishy- smelling discharges (Hatcher et al, 1997).

Cervicitis: inflammation of the cervix (Hatcher et al, 1997)

Cervix: the lower portion of the uterus that extends into the upper vagina (Hatcher et al, 1997)

Dysmenorrhea: painful menstrual period (Hatcher et al, 1997)

Endogenous Infection: infections, which are caused by overgrowth of organisms that, can present in the genital tract of healthy women. (Germain, et al, 1992)

Family Planning: FP

Gonorrhea: a sexually transmitted disease caused by the bacterium *Neisseria gonorrhoea* .it is transmitted by a person carrying the bacterium when one mucous membrane comes into contact with another's. Gonorrhea causes inflammation of the genital mucous membrane in both sexes. May also affect other parts of the body such as the anus and cervix (Hatcher et al, 1997)

GBS: *Group B Streptococcus*

Menses: monthly flow of bloody fluid from the uterus through the vagina in adult women between puberty and menopause. (Hatcher et al, 1997)

Menstrual cycle: a repeating series of changes in the ovaries and endometrium that includes ovulation and about two weeks later the beginning of menstrual bleeding. In most women cycle average about 28 days but may be shorter or longer. ((Hatcher et al, 1997)

Ministry of health: MOH

Non- users: women who were not using the IUD during the starting of the study and attend the FP clinics to initiate the IUD use or other contraceptive method. (by researcher)

Pelvic inflammatory disease: (PID) : infection in the uterine lining, uterine wall, fallopian tubes, ovary, uterine membrane, broad ligaments of the uterus, or membranes lining the pelvic wall. May be caused by a variety of infectious organisms including gonorrhea and Chlamydia (Hatcher et al, 1997)

Post partum: the first 6 weeks after childbirth. (Hatcher et al, 1997)

Potentially Pathogenic Bacteria: the following type of bacteria: *Escherichia. coli* , *Staphylococcus .aureus*, *Klebsiella*, *Enterobacter* (Ohm 1975).

Predominant Bacteria: *Streptococcus group B*, *Beta-Hemolytic bacteria*, *Coagulase -negative Staphylococcus*.(Ohm 1975).

Reproductive Tract Infection: RTI: have been broadly defined to include sexually transmitted infections, and infections that are not sexually transmitted, including endogenous infections and iatrogenic infections caused by improperly performed procedures as unsafe abortion, poor delivery practices, pelvic examination and IUD insertions. (Germain, et al, 1992)

Score of symptoms: in this study the scoring system was adopted to classify the client according to the number of symptoms they have. it was classified as following (by researcher)

- **Mild:** means the client reported to have from 1-3 symptoms

- **Moderate:** the client has 4-6 symptoms
- **Severe:** the women have 7-9 symptoms (by researcher)

Syndrome: a group of signs and symptoms that collectively indicate a particular or abnormal condition. (Hatcher et al, 1997)

Users: who are using the IUD during conducting this study (by researcher)

Vagina: the passage leading from the external genital opening to the uterus in females. The vagina serves as passage for the discharge of menses, and delivery of the fetus. (Hatcher et al, 1997)

Vaginitis: microorganisms such as gonococci, staphylococci, streptococci, and chemical irritation may cause inflammation of the vagina from use of too strong chemicals in douching. Fungus infection caused by *Candida albicans*. Protozoan infection; irritation from foreign bodies; vitamin deficiency as in pellagra; condition involving the vulva and the surrounding area such as uncleanness or intestinal worms. vulva the external female genitals. (Hatcher et al, 1997)

Vaginal score: the 4 symptoms that related to vaginal discharge in term of color, odor and consistency was computed to evaluate the condition in term of the number of abnormal points she have 0: no any abnormal discharge, 0.5: client have 2 points that are out of her usual discharge. 0.75; client has 3 points that is out of her usual discharge 1: client has 4 points that is out of her usual discharge (by researcher).

CHAPTER ONE

LITERAETURE REVIEW

1.1 Definition of Reproductive health

WHO defines Health as a state of complete physical, mental, and social well-being, and not merely the absence of disease or infirmity, reproductive health addresses the reproductive process, function, and system at all stages of life. **Reproductive health** therefor implies that people are able to have responsible, satisfying, and safe sex life and that they have the capability to reproduce and the freedom to decide if, when, and how often to do so. Implicit in this last condition are the right of men and women to be informed of and to have access to safe, effective, affordable and acceptable methods of fertility regulation of their choice, and the right of access to appropriate health care services that will enable women to go safely through pregnancy and childbirth and provide couple with the best chance of having a healthy infant. (Khanna, 1994)

1.2 Scope of reproductive health

From this definition one could conclude that this definition has emphasized on the special health needs for both women and men and their impact on the health of next generation too. At the same time it's clear that the main focus of the reproductive health programs are available and accessible family planning services, effective maternal care, safe mother-hood, responsible reproductive sexual behavior, effective control of reproductive tract infection, prevention and management of infertility and elimination of unsafe abortion (Khanna, 1994).

1.3 Reproductive Tract Infections

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Reproductive tract infections (RTI) are common among women all over the world. They include three types of infections, which involve the "sexually transmitted disease" type, as *Chlamydial infections*, *Gonorrhea*, *Trichomoniasis* and *Syphilis*. The second type of RTI is the endogenous infection that is caused by over-growth of organisms present in the genital tract of women as Bacterial Vaginosis and Vulvo-Vaginal Candidiasis. The third type of these infections is associated with medical procedures that manipulate the genital tract as unsafe abortion, Pelvic examination, and IUD insertion. (Germain, 1992)

1.4 Effect of Reproductive Infection on Women:

RTI are disorders that affect women's health in general they cause physical discomfort, marital conflict and personal embarrassment. RTI also compromise women's ability to achieve and sustain pregnancy or to give birth to a healthy child. RTI have great impact on women's health status, especially on her physical comfort (karkai).

1.5 Family planning is responsible to prevent both pregnancy and RTI:

In spite of the low socioeconomic status of women as they are the most vulnerable to disease, the poorest in the community, they are usually given a special attention in most of programs and conferences.

In the Alma-Ata conference 1978 Primary Health Care (PHC) was discussed and the emphasis was on the maternal child health, FP and prevention of early infection, but this conference did not mention the reproductive health problems of the women.

Even when women are mentioned in such programs the concern is still for reducing the birth rate or infant and child mortality, illness and disease during pregnancy and childbirth. Just recently women received attention in matters related to their own health, and there was a better understanding of women's health and problems that are unrelated to pregnancy and child birth but have great effect on the reproductive life (Karkai).

In 1994 in Cairo the International Conference on Population and Development (ICPD), emphasis was given on discussion of the definition, the scope and requirement for improving reproductive health.

1.6 Contraceptives; Uses and Epidemiology

In the past few decades the contraceptives were limited to very few natural methods as coitally related methods (Fathalla, 1994)

IUD is one of the most popular contraceptive methods used worlds wide, it ranked the second among other methods after sterilization. Nearly 86 million women around the world use IUD. The use of IUD varies from 32% of women at reproductive age in China to less than 2% in, Nigeria, and Brazil. (see table below)

The most common type is copper IUD, mainly the Copper-T 380 A, in Egypt, Turkey, Indonesia and Pakistan. In China the stringless, single-coil stainless steel ring, is widely used and so it is considered the most popular IUD over the world as 70% of the IUD in the world are used in China. (Hatcher, 1989).

Table 1: Global view on % of married women of childbearing age using IUD

Country	%Married women 15-44 years of age using IUD	Year	Most common IUD
China	32%	1985	Malua ring
Indonesia	13%	1987	Copper-T
Mexico	11%	1987	Copper-T
Turkey	9%	1983	Copper-T
Egypt	8%	1984	Copper-T
United kingdom	7%	1983	Multiload
United states	5%	1982	Copper-T
Japan	4%	1986	Ota ring
India	4%	1986	Copper—T 200
Pakistan	1%	1985	Copper-T380
Brazil	1%	1986	Copper—T 200
Bangladesh	1%	1985	Copper-T380
(Hatcher, 1989)			

1.7 Historical perspective of contraception:

Dyer, K.1990 summarized the history of contraception, he mentioned the main methods that were used in each ancient era.

The ancient of Near East: during 1850 BC Egyptian Papyri report 3 methods of contraception, these were the gummy substances for the cervix and vagina, the honey and sodium carbonate, and the crocodile dung pessary. Hebron women at that time used mohk (sponge) and coitus interruptus. As they believed that twisting and violent movement following intercourse is a method for preventing pregnancy.

Ancient Greece: (between the 460 and 377 BC Hippocrates was the first to record a method like IUD “ a hollow lead tube filled with fat, was inserted into the uterus to prevent conception”

Ancient Rome: during this period sterilization and abortion were practiced. Other methods like “oil, honey and balsam tree juice, fresh acidic pomegranate pulp and woolen tampons”.

Ancient Far East: methods that were known at that time in Japan and China were the “misugani” oiled bamboo tissue paper disc, and “ Kabutoga a hard tortoise shell condom”, other methods were known in India as coitus reservatus, coitus obstructus and rock salt.

The European middle ages: At that time and due to Catholic Church, contraceptive knowledge was suppressed and no new methods were known for the next 700 years.

The Renaissance and after: Knowledge declined during the 17th century, the most common method during that period was the barrier method; condom and the sponge. By the 18th century contraceptives improved in term of material that was made off.

19th Century: this century saw improvement in Condom and Pessaries. Other methods also were known as vaginal douches, vaginal cap, condom, spermicide and withdrawal method.

The 20th century: During this period pills were known, clinics also were founded to provide services to public. IUD was introduced during World War II. Dalkon Shield became the most popular type in the 1970's and during this period also improvement in IUD continued.

1.8 IUD History and Evolution:

Principles of IUD is not new as it was first known by Hypocrite during the 460 and 377 BC as “ a hollow lead tube filled with fat, was inserted into the uterus to prevent conception” (Dyer, 1990).

Burner, 1984 highlighted that; modern pioneer was a German physician (Ernst Graefenlberg) 1928, who used silk worn guts, and later silver or gold wire coils were used and inserted in to the uterine cavity.

Use of IUD started by 1960s and it's use increased over the following decade. The reputation of Dalkon Shield due to infection and its link with the maternal deaths at that period had affected its use especially in America. This reputation leads to improving the types and developing new types of IUD. (Canavan, 1998).

Different studies have been conducted, which have shed new lights on the IUD. Some studies highlighted the economic value, safety and effectiveness of IUD, others review the development and evolution of IUD (Schmidt et al, 1986, Tatum et al, 1986).

The modern IUD started by 1909 when Richard Richter in Germany used a ring from silk worn gut. (Augustin, Hatcher, 1989)

By 1920s Ernst Graefenlberg conducted an experiment on a variety of IUD design including, a plain gut ring, a gut ring wound with silver wire, and a tightly wound spiral ring made of silver wire (Westhoff, 1996). In Japan in 1934 Tenery Ota developed an elastic metallic ring known as Ota ring. During the Second World War this IUD was imposed in the occupied territories in Asia (Augustin)

By 1950s and as a result of studies by Oppenheimer, and Ishihama revived attention to IUD as an effective simple, efficient method of contraception and so a new design of IUD began (Westhoff, 1996).

In order to develop new design of IUD, an international conference by 1962 was held in New-York city under the auspices of the population council and the WHO, to evaluate the IUD that were used at that time, as a result of infection cases that occurred after insertion. As a result of this conference the Dalkon Shield was developed and it was introduced in the market by 1970s.

The Dalkon Shield was multi-filament tail, so as to be easier while removing. By 1979 this type was no more marketed due to high rate of reported cases of infection and septic abortions.

By 1980s the use of IUD and developing of PID and tubal infertility was highlighted by a series of published papers, which led to decrease in the use of IUD in USA. New types were developed and before they were in the market, these types were tested on animals in vitro, these tests showed that the plastic with additional copper was effective IUD, currently the only type of IUD in USA (the copper-T 380A).

Another type of IUD that releases hormone progesterone was designed as T-shape with progesterone and it is widely used nowadays in Europe.

Roca Augustine divided the modern history of IUD into two distinct periods:

1. The inert IUD's: during 1960 s the IUDs were large with spiral Lippes loop, which was formed of polyethylene with barium sulphate added for the visibility on X-ray. After Lippes loop a flexible stainless steel ring with single or double coil was discovered.

2. The second period, the active medicated IUD period, this period is represented by the use of IUD types with Copper and with hormonal release.

By 1972 the copper -T appears with numbers, 200, 220, 380, etc, these numbers show the surface area of the copper in square mm.

In 1974, Multiload 250 was developed, which is arched shape with copper on the stem.

In 1976, the progestasert-a, T-shape IUD that has in the vertical stem, reservoir of 38-mg progesterone, releasing 65 micro -gram per day.

In 1979, Nova T IUD appeared. Other types as T Cu -220 with copper sleeves -2 on the arms and 5 on the stem.

1.9 Types of IUD:

Different types of IUD are known and used all over the world. As reviewed by Hatcher, 1989, the most common types of IUD used are:

1. The stringless, single -coil stainless steel ring. This is mostly used in china, the coil size ranges from 18-20 mm in diameter, and the size of the ring depends on the depth of uterus.

2. Lippes loop: this type has different sizes ranged from A-D, comes in sterile units or in packages with loops that must be sterilized with Iodine.

3. The Copper T 380: is provided through procurement channels that supply family planning programs in developing countries. About 8 million of these types have been distributed over 69 countries. This type of IUD has the lowest failure rate of the widely distributed types. It comes in pre-sterilized packages.

4. Copper -T 200: used in China and Mexico, It comes in pre-sterilized packages.

5. Copper-7 comes in pre-sterilized packages with an inserter. The use of this type has decreased due to the widely use of the copper-T 380.

6. Multi-load 375& 250 device comes in pre-sterilized packages with an insertor tube. These types have different numbers due to the copper surface that cover the vertical limb of the IUD it has 3 size, S, M, and L.

7. Progestasert-T This type comes in pre-sterilized packages the lower limb of the device releases progesterone

8. The levonorgestrel IUD T shape device (Mirena) the lower limb of the device releases 20 microgram of levonorgestrel daily. It has failure rate similar copper T380 but it is not widely used.

1.10 Side Effects and Complications:

Different studies were conducted to explore the IUD related disease, particularly that associated with infection. Some studies linked the infection-related disease to the insertion method and technique (Jacques et al, 1986, Pasquale, 1996, Kessel, 1989, Senanagake et al, 1980).

Jacques et al, 1986 proved that mode of insertion is the major factor in transforming the microbial colonization of IUD and that the presence of tail does not seem to play a significant role. Pasquale 1993 pointed to the epidemiological studies that proved the role of instrumentation during insertion of IUD as a source of PID within the first 20 days. Chow et al, 1986 stressed the risk of PID to “passive introduction of bacteria into the uterus during the insertion process”.

Others linked it with the type of IUD. Marrie et al, 1983 studied the adherent bacterial to the IUD according to the type of the device. Begum, 1980 proved that infection is related to the time of insertion and type of IUD. He found that the infection rate was higher among Copper-T device users than the Lippes Loop users. At the same time the rate of infection was higher when insertion was following the menstrual regulation procedure than that following post-partum or at intervals.

Other studies find a relationship of infection with the duration of use (Pasquale, 1996). Other studies relate it to the tail and string of the IUD by its effect on transmission of the pathogenic microorganisms and so the role of ascending infection (Senanayake, et al 1980). He highlighted also the role of tail in introducing the bacteria into the uterus, as he stressed that uterus of non-tailed device contains no bacteria in contrast to the uterus with tailed device, which contains bacteria similar to vaginal bacteria particularly after a month of insertion.

Dickinson et al, 1989 related the infection to mechanism of action, he believed that IUD produces an inflammatory reaction that is thought to interfere with fertilization. At the same time he considered it as any other device or catheter and so has its role in developing infections associated with foreign body.

The pattern of IUD-associated infections include acute Endometritis, Pelvic inflammatory disease, and unilateral Ovarian abscess. Aerobic and Anaerobic flora of female genital tract account for most IUD infections (Dickinson et al, 1989).

1.11 Pelvic Inflammatory Disease PID:

Different studies had revealed the association between the IUD and PID. Hatcher, 1989 stressed that PID is the most serious complication that is related to IUD, he reported that “ women using IUD other than Dalkon Shield have about 1.5 times greater risk of Pelvic Inflammatory Disease than women using no contraceptives”.

Hatcher et al, (1997) defined PID as an infection in the uterine lining, uterine wall, fallopian tube, ovary, uterine membrane, and broad ligaments of the uterus or membrane lining pelvic wall. It may be caused by a variety of infectious organisms including gonorrhea and Chlamydia.

Gorrie et al, 1994 defined PID as infection of the upper genital tract. He reported that it is one of the main health problems in USA, as about 1 million women seek medical attention for acute pelvic pain and others seek treatment due to complication of PID as ectopic pregnancy and infertility.

1.12 Etiology of PID:

PID has poly-microbial etiology (Stacey et al, 1992), may be initiated by the most pathogenic organisms as *Neisseria gonorrhoea*, (Kochar et al 1980, Stacey et al, 1992), or by organisms as *E.coli* or other anaerobic bacteria, (Kochar et al, 1980).

Different microorganisms cause PID, the primary organisms are *Chlamydia trachomatis*, *N.gonorrhoea*, and other organisms are *E.coli* and gram positive cocci. (Gorrie et al, 1994), *Streptococci* have been isolated from patient with salpingitis and post-partum sepsis, (Sweet, 1980, Perine, 1980).

PID can be chronic or acute. Two types of infections according to the method of spread are described: the first is the gonococcal infection that affects urethra, cervix or rectum. The second is caused by secondary causative organisms as *Staphylococcus*, *Streptococcus* or *E.coli*. This type of infection spreads through out the uterine canal into the uterine cavity, (Burner & Southern, 1984).

The pathogenic organisms that cause PID is usually introduced through cervical canal from out-side into the pelvic cavities. These organisms enter the cervical canal and break down the mucus plug that protects the internal organs from bacteria in the vagina and cause infectious cervicitis, or it ascends to the upper organs and infects them causing endometritis, salpingitis or oophoritis. It may cause tubal scarring and tubal adhesions that may cause infertility (Gorrie et al, 1994).

One of the severe types of these infections is endometritis that is due to complications of pregnancy or due to IUD, (Burner & Southern, 1984), or due to gynecological and obstetrical events as induced abortion, IUD insertion, and delivery, Begum, 1980.

1.13 Signs and Symptoms of PID

Abdominal pain, nausea, vomiting, fever, malaise, malodorous purulent vaginal discharge, and leukocytosis are important symptoms of PID.

PID leads to chronic pelvic discharge, ectopic pregnancy, sterility or infertility due to adhesions causing tubal obstruction (Gorrie et al, 1994).

1.14 Role of Tail-string IUD in Infection:

Ebi et al. 1996, showed the importance of the Tail-string IUD, he stressed the importance of the material that is made of because it may increase or have relation with increasing rate of PID. The tail-string has direct effect on the contraceptive efficacy either in positive or negative sides. On positive side it makes it easy to remove IUD, and it helps to confirm that IUD is in its place. On the other hand it enhances and influences the entrance of bacteria and so contamination to the uterus but it does not increase the PID among IUD users, and it may perforate the uterus during insertion. At the same time material of the tail-string was changed through out the time, the first was made from silk-worm-gut, then synthetic polymers were used, including nylon, high density polyethylene and polypropylene.

As reported by same author different studies were conducted to explore the role of Tail-string as a mean for ascending infection of bacteria into the uterus and so increase the risk of PID. The first study that found out this relationship was that about Dalkon Shield, another study was about the association with the polypropylene tail of the copper7 IUD.

In order to address the role of tail-string in invading the bacteria to uterus and so increase the rate of PID, Ebi et al 1996 reviewed all the studies and articles that studied the rate of PID for tailed versus tailless IUD. Also he reviewed the studies of copper T with tail-string manufactured from polyethylene versus polypropylene.

He evaluated 9 clinical studies about different types of IUD and he concluded that they showed difference in tail-string IUD and tail-less IUD. But when all studies were evaluated and other factors were controlled, he found that “while bacterial pathway have existed for the Dalkon -Shield, because of its controversy such pathway wasn’t established for other tail-string material. “Presence of IUD tail-string on an IUD doesn’t increase the rate of PID compared with the absence of tail-string”, at the same time he concluded, “ presence of a polypropylene versus a polyethylene tail-string doesn’t affect the rate of PID.

In his study Jacques et al, 1986, studied the microbial colonization of IUD on rabbits, tail and tailless devices were inserted into the uterus of rabbits vaginally and surgically. He concluded that the mode of insertion had the major factor influencing the microbial colonization of IUD and the presence of tail does not seem to play significant role.

Marrie et al, 1983, in order to determine the presence and adherence of bacteria on the surface of IUD, she studied 10 different types of IUD 4 C-T, 4C-7 and 2 T-coil. The study was conducted using 3 different methods; culture technology using blood, Machonkee and chocolate agar. The second method is scanning electron microscopy and the third is electron microprobe analysis. The study revealed that “considerable amount of surface material on the IUD”, most of material had various morphologic types of bacteria adherent or embedded on it. The importance of that study was to understand the adherent bacteria and the “surface material of IUD so as to develop IUD with surface material that resists bacterial colonization”.

Grimes et al, 1999, pointed to the role of insertion as the source of IUD related upper genital tract infection. He stressed that not the string or the device that related to developing of infection but the insertion process that carries bacteria into the endometrial cavity which leads to infection, particularly in early weeks of IUD insertion.

1.15 Normal and pathogenic flora of the genital tract

Different factors affect the flora of the female genital tract, pH, estrogen, concentration of the mucous, which depends on the female age. During reproductive age women withhold large number of facultative bacteria, as *Streptococcus*, *Staphylococcus* and *Group B beta-Hemolytic Streptococcus*, which may be transmitted to the neonate during child birth causing meningitis and other diseases (Baron, et al 1994).

Flora of the female reproductive tract has been evaluated in different studies to find out its role in the pathogenic cases. These studies revealed that different microorganisms were found and these vary in relation to menstrual cycle phase, age, and pregnancy. Ohm 1975 isolated the following types from women pre-

hysterectomy, *Streptococcus*, *Staphylococcus* and *E.coli*. He emphasized on the importance of knowing the types of these microorganisms to understand the etiology of pelvic infection.

1.16 Gram –Negative Bacterial Infection:

A group of gram negative bacteria such as *E.coli*, *Klebsiella*, *Enterobacter*, and *Pseudomonas aeruginosa* are responsible of nosocomial infection that is acquired during hospitalization, either due to low resistance or immunosuppressive drugs (Burner & Suthern, 1984). These organisms are responsible for infections related to or developed due to invasive procedures such as indwelling catheter, at the same time *E.coli*, *Klebsiella* and *Enterobacter* are responsible for any infection in the genitourinary tract. Other invasive procedure related to reproductive system such as abortion, instrumentation (IUD insertion), also can be associated with *E.coli* and *Bacteroids*. (Burner & Suthern, 1984).

1.17 Leukorrhea & simple Vaginitis:

Leukorrhea is the presence of whitish vaginal discharge, which is normal at the time of ovulation or onset of menstruation (Burner & Suthern, 1984, Tindall, 1987). The amount may be scant to moderate, in the normal physiologic case, the color is clear to white. The vagina is protected from infection by its acid secretion (pH. 3.5-4.5), and by the presence of *Doderlein bacilli*. If *E.coli*, *Staphylococci*, or *Streptococci* invade the vagina more profuse discharge or inflammation of the lining of vaginal wall develops that is called vaginitis. It is characterized by white or creamy discharge when fresh, when dried leaves abnormal yellow stain on clothing, it never causes pruritis or never offensive (Tindall, 1987).

Often vaginitis is accompanied by urethritis because of the proximity of the urethra to vagina. Discharge may cause some itching, redness, and burning (Burner & Suthern, 1984). The most common types of vaginitis are Candidiasis, Trichomoniasis, and Bacterial vaginosis.

1.18 Inflammatory Discharge:

Inflammatory discharge is the discharge caused by infection; it is mucopurulent or frankly purulent. Its color varies from creamy to yellow or green, and it is offensive. The commonest lesions causing discharge are vulvovaginitis, cervicitis, or endometritis (Tindall, 1987).

The organisms commonly causing infection of the genital tract are the *Gonococcus*, *Streptococcus*, *Staphylococcus*, *Pneumococcus*, *E.coli*, *Chlamydia* and *Bacteroids*.

In case of vaginitis the discharge amount ranges from moderate to profuse, the color may be white, green or yellow.

1.19 Vaginal Infection:

Vaginal infection includes different types, such as bacterial Vaginosis, Trichomoniasis, Vulva-vaginal Candidiases, other types of these are Sexually Transmitted Disease.

Vaginitis is inflammation of the vagina that is characterized by discharge, irritation and or itching, (Sieber et al, 1998, Schwebke, 1999). Vaginal infection is very common, it is one of 25 common causes for consulting physician, Just 40% of women with vaginal symptoms will have type of vaginitis. Bacterial Vaginosis is one of the most common causes of vaginitis in women of childbearing age. In symptomatic women the percent reaches up to 24-37% and it has been found in 16-29% of pregnant women. Evaluation of the epidemiological factors revealed that IUD use and douches are common among women with bacterial Vaginosis.

Determination of the vaginitis can't be based just only on the symptom or physical examination, it also requires laboratory test such as microscopic evaluation of the vaginal fluid (Schwebke, 1999)

1.20 Bacterial Vaginosis:

BV is the most common cause of vaginitis, it is also known as non-specific vaginitis. It is due to change in the vaginal fluid and normal flora of *Lactobacillus* bacteria, which enhances increasing number of organisms such as *Gardenella vaginitis* (Public health, 1992).

There are different types of microorganisms that present in high concentration in the vagina of women with bacterial vaginosis (Hill, 1993). The most popular organisms are from the group of *Gardenella*. Other types that have been isolated besides *Gardenela* are *Coagulase -negative Staphylococci*, *Streptococci*, in moderate colonization, also *Gram-negative bacilli* certainly *E.coli*, have been found in about 25% of women with bacterial vaginosis (Hill, 1993).

IUD is another cause that may increase the risk of acquiring bacterial vaginosis (public health, 1992, Amsel, 1983, Mead, 1993).

Egan, 2000. Reported that 40-50 percent of US women complains of vaginitis and about 50 percent of these cases were at childbearing age. The popular cause of vaginitis is a bacterial organism as *Gardenella*, *Mycoplasma* and *Streptococcus*, he reported that IUD, and vaginal douches and pregnancy are considered as risk factors of bacterial vaginosis.

Definition of BV is still not clear, and so it is difficult to diagnose and to treat this type of infection (Seiber, 1998). At the same time different studies were conducted to find out the microorganism associated with this infection. In pregnant women different microorganisms were found in association with this infection, these were *Gardenella*, in about 50%, *group B Streptococcus*, *C. albicans*, *E.coli*, and *Trichomniosis*. (Seiber et al, 1998). The microorganisms found among IUD users were *coagulase -negative Staphylococcus*, *Streptococcus*, and *E.coli*.

The importance of studying the aerobic bacterial microorganism as *E.coli* lies on fact that these organisms are opportunistic pathogens in the female genital tract and are associated in the pathogenesis of UTI, also *S. aureus* has its role in developing toxic shock syndrome (Chow et al, 1986).

1.21 Aim of the Study

- The purpose of this study was to investigate the relationship between aerobic bacteria, the use of IUD and the possible subjective symptoms reported by women.
- To estimate the prevalence rate of aerobic bacteria among IUD users compared to non users
- To find the most common causative microorganism that may lead to genital infection in association with IUD use among Palestinian women.
- To explore the profile of the women who are using IUD
- To explore pattern of discomfort versus side effects (infection) among IUD users in Palestine and methods of minimizing these discomfort and side effects.
- To determine pattern of microorganisms those are associated with or common among IUD users

1.22 Research hypothesis:

- Use of IUD, as a contraceptive method is associated with high rate of aerobic bacterial infection.
- The occurrence of RTI among IUD is higher than non-users.
- The length of using IUD has an association with the presence of the aerobic bacteria.
- There is no association between the presence of symptoms reported by women and the result of culture.

CHAPTER TWO

METHODOLOGY

2. Methodology

This chapter describes the population and the subject of the study, data collection, the measuring instrument, tool, and the analysis methods.

2.1 Population of study / sample

The study population was chosen from women visiting FP clinics in the governmental sector in the northern West Bank districts (Nablus, Qalqelia, Jenin, Tulkarm.) either requesting IUD insertion, or already using IUD and visiting the clinic for check up.

It was proposed to conduct this study on the nine district of West Bank but due to recent political situation (Al-Aqsa Intefada) and difficulties in reaching the southern and middle district, the study was limited to northern districts. The study clinics were the four central clinics in the northern West Bank related to MOH, they were selected because of the high utilization rate per month (> 50 women).

UNRWA clinics were contacted to enroll their patients in the study, however we were told that they are unable to participate because of internal regulations.

The sample was randomly collected according to the utilization rate of each clinic. Women who were excluded from the study are those having one or more of the following selection criteria 1.heavy blood during menstrual period at the time of sample collection 2. If they report that they are on antibiotic during the previous 15 days. 3. Anyone who is known to be diabetic.

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The sample study consists of total 200 women divided in the following rate according to the total utilization rate of the clinic in each district, Jenin (98), Nablus (58), Tulkarm (24), and (20) from Qalqulia. The percent of the sample was 49, 29, 12 and 10 from Jenin, Nablus, Tulkarm and Qulqeelia respectively. The total number of clients in the four districts were (2429) for 1999, ranking as, 1199(49%), 700 (29%) 300(12%), 240(10%), for Jenin, Nablus, Tulkarm, and Qalqulia respectively.

FP services were started in the government sector by 1996, funded by EU, all physicians, midwives and nurses were well trained regarding methods of family planning either theoretical or the practical part.

2.2. Data collection

Data were collected during the period of Sep, 2000- Jan, 2001 using structured interview and specimen collection.

The Questionnaire used in the interview has been evaluated, reviewed carefully, and then pre-tested on 10 women.

These questions (annex. I) Focused on three main parts. The first part was about the social status in terms of women's age, education, occupation and years of schooling. The second part was about obstetric history in terms of the previous pregnancy, parity and abortion, menstrual period and related problems, and the use of contraceptives either the previous one or the current method. The third part was about previous history of genitourinary tract infection, the current signs and symptoms, and the hygienic practice.

The second part of data collection consisted of Laboratory test, an Endo-cervical specimen for culture was obtained while women were undergoing vaginal exam for IUD check up or IUD insertion.

2.3 Procedure:

An agreement ethical letter (annex. II) was obtained from the MOH to perform the study in the government family planning clinic to facilitate the researcher's work including data collecting from the annual utilization report of FP clinics, clients interviewing, and sample collection. An initial visit was conducted to each district. The annual utilization report for family planning clinic was also obtained to calculate the sample distribution and percentage of specimen to be collected from each district.

Data were collected during Sep, 2000- Jan, 2001. The rate of researcher's visits to each target clinic was about 2-6 visits depending on the number of sample

Data were collected during Sep, 2000- Jan, 2001. The rate of researcher's visits to each target clinic was about 2-6 visits depending on the number of sample needed from each clinic, and the number of the clients attending the clinics at that day.

The purpose of the study was explained for each woman and informed consent (annex.III) was also signed. Serial number was used, and each woman was given the same serial number on the filled questionnaire and the swab culture container.

First the researcher interviewed each woman, to fill the questionnaire, then when the same women underwent vaginal exam including insertion of speculum; the researcher also obtained endo-cervical swab using a sterile cotton swab. The swab was inserted in the cervix and pulled around for 60 seconds and then put in wet media for transport (Stewart Emi media). In the lab the specimen was cultured on a blood and Macchonky agar for 24 h at 37 °c. The isolated bacteria were identified by Colonial morphology, gram stain, catalase test, oxidase test and other biochemical test (sugar utilization, urea, H2S motility, Indole production, identified the isolated bacteria. (Reference 80)

2.4. Data Analysis

All the data and results of the tests were computed using SPSS program and applying Chi-Square test.

2.4.1 Analysis of clinical picture

In this study Scoring system approach was adopted to evaluate the clinical picture of the women in terms of the presence or absence of the RTI related symptoms. (Similar approach is also used in obstetrics to evaluate the high-risk pregnancy). WHO has a protocol (syndromic approach), in treating the STD's. This syndromic approach depends on presence of at least one symptom to initiate treatment of the RTI. Such symptoms are presence of odorous vaginal discharge or abdominal pain. In our study the following scoring system was used in evaluation of the vaginal discharge and its characteristics, in terms of color, odor and consistency, each one was given 1 point (answers to ques. 38-41 in the attached questionnaire).

Score	Number of symptoms
0	No symptoms related
0.5	1-2 symptom
0.75	2-3 symptoms
1	4 symptoms

Other symptoms that evaluate women's condition and severity of infection such as abdominal pain, pain during intercourse, fever, itching and burning were also given 1 point (answers of ques. 38-45 with attached questionnaire). These scores were averaged and summarized in the following tables:

Score	Number of symptoms	Degree
0	No symptoms	Asymptomatic
1	1-3 symptoms	Mild
2	4-6	Moderate
3	7-9	Severe

2.4.2 The Microbiological Culture:

Vaginal micro-flora is opportunistic bacteria, These bacteria as *Streptococci*, *Staphylococcus*, *E.coli*, are vaginal inhabitant. Ohm 1975 in his study classified them into two groups, the first is the predominant bacteria like *S. epidermids*, other group is the potentially pathogenic, (*S. aureus*, *E.coli*, *Streptococcus group A*).

In our study similar classification was also used. Taking in consideration other factors that might have effect on the pathogenicity of these microorganisms on women. For example *E. coli* & *Klebsiella* have their direct effect on the development of UTI. *S. aureus* also has its relation with Toxic Shock Syndrome, and Bacterial Vaginosis. *Streptococci* (*S. agalactiae*) have their pathogenic role during delivery mainly on the neonate causing neonatal sepsis & meningitis.

CHAPTER THREE

RESULTS

3 Results

3.1 Profile of the population study;

3.1.1 Social profile

Age group of the study population ranges between 19-45 years old, 57% of the population study was in the 20-30 age group, 22% of which were from the control group, and 35% were from the case group. 36.5% were in 31-40 age group. Just 3% of the population size were at the age of 19 and below, and most of them (2.5%) were from the control group. The lowest percent of IUD users were from those of age group of <20, the same percent for those who were more than 40.

It was found that 39.5% of the sample have had their secondary education, and 12.5% have academic education. Most of women in the study were housewives (85.5%). According to husbands of women in the study, 37.5% have their secondary education, and 21.5% have academic education. For their occupation 69% were laborers, and 23.5% were employees.

Table2 Social profile of the population study in relation to IUD use

	CATEGORY	IUD USERS		NON IUD-USERS		TOTAL	
		N.	%	N	%	N	%
Age (year)	<20	1	0.5	5	2.5	6	3
	20-30	70	35.5	44	22	114	57
	31-40	56	28	17	8.5	73	36.5
	>40	7	3.5			7	3.5
Women Education	Elementary	31	15.5	4	2	35	17.5
	Preparatory	39	19.5	22	11	61	30.5
	Secondary	49	24.5	30	15	79	39.5
	Academic	15	7.5	10	5	25	12.5
Husbands Education	Elementary	29	14.5	6	3	35	17.5
	Preparatory	29	14.5	18	9	47	23.5
	Secondary	46	23	29	14.5	75	37.5
	Academic	30	15	13	6.5	43	21.5
Women Occupation	Household	112	56	59	29.5	171	85.5
	Working	22	11	7	3.5	29	14.5
Husband Occupation	Laborer	92	46	46	23	138	69
	Employee	33	16.5	14	7	47	23.5
	Employer	3	1.5	4	2	7	3.5
	Unemployed	6	3	2	1	8	4

3.1.2 Obstetric profile

About half (44%) of women in the study have 4-6 children, 41.5% had 3 children or less. Most of women in the sample have never had abortion (62.5%), and 37.5% had at least one abortion, just 12% of which have dilatation and curettage after abortion. The last delivery in most of women at the study was normal (93%).

Table (3) obstetric profile of the population study in relation to IUD use

Item	Category	IUD users		Non users		Total	
		N	%	N	%	N	%
N of children	<3	47	23.5	36	18	83	41
	4_6	65	32.5	23	23	88	44
	>7	22	11	7	3.5	29	14.5
Hx of Abortion	Yes	52	26	23	11.5	75	37.5
	No	82	41	43	21.5	125	62.5
Type of Abortion	Spontaneous	34	17%	17	8.5%	51	25.5%
	With D&C	18	9%	6	3%	24	12%

3.1.3 Menstrual and contraceptive profile

Table 4 menstrual & contraceptive profile of population study in relation to IUD use

Hx of Menstrual Problem	Category	IUD users		Non users		Total	
		N	%	N	%	N	%
Problem	Yes	67	33.5	12	6	79	39.5
	No	67	33.5	54	27	121	60.5
Kind of Problem	Pain	6	3	4	2	10	5
	Heavy	36	18	3	1.5	39	19.5
	Irregular	13	6.5	5	2.5	18	9
Hx of using Contraceptives	Yes	84	24	40	20	124	62
	No	50	25	26	13	76	38
Method of Contraceptives	IUD	26	13	48	24	74	37
	Pills	13	6.5	33	16.5	46	23
	Others	1	0.5	3	1.5	4	2
Causing of Choosing IUD	easy to use	40	20	29	14.5	69	34.5
	Less complicated	28	14	14	7	42	21
	Both	51	25.5	20	10	71	35.5
	Rx by Dr	15	7.5	3	1.5	18	9

More than half (60.5%) of women had no problems associated with their period. 39.5% had different problems, 19.5% complained of heavy menses, 18% were from the case group, and those who have irregular menstrual period rated 9%.

According to the previous history of contraceptive use, 62% of the women included in the study have used a kind of contraceptive method, 38% have never used any type of contraceptives before the current method. Thirty seven percent of the former group have used IUD, 23% have used pills. Just 27% of contraceptive users had used that previous method for about 1-12 months before stopping it. Several causes of discontinuing a contraceptive method among women studied were found. Desire to conceive ranked number one (27%), the other cause was infection (9%).

3.1.4 History of previous genitourinary infection

More than half (53%) of the study population had history of urinary tract infection of which 37% already using the IUD.

According to the previous history of genital infection, 84% of population study had history of reproductive infection, 56% of them are using IUD. Almost all of them were treated (80%).

From those who were treated, 49% had a topical treatment and just 9.5% had systemic treatment, 21% had both types of treatment, 40.5% of those who had infection, had recurrence of infection

According to the husbands of the women included in the study, 16.5% had a history of genital infection.

Table 5 History of previous genitourinary infection

Character	category	IUD users		Non users		Total	
		N	%	N	%	N	%
Urinary tract Infection	yes	74	37%	32	16%	106	53%
	No	60	30%	34	17%	94	47%
Genital Infection	Yes	112	56%	56	28%	168	84%
	No	22	11%	10	5%	32	16%
If treated	Yes	105	52.5%	55	27.5%	160	80%
	No	7	3.5%	1	0.5%	8	4%
	No infection	22	11%	10	5%	32	16%
Type of Tx	Topical	66	33%	32	16%	98	49%
	Systemic	12	6%	7	3.5%	19	9.5%
	Both	27	13.5%	16	8%	43	21%
If returned Back	Yes	63	31.5%	18	9%	81	40.5%
	No	49	24.5%	38	19%	87	43.5%
Husband Infection	Yes	24	12%	9	4.5%	33	16.5
	No	92	46%	52	26%	144	72%
	DK	18	9%	5	2.5%	23	11.5%
If he treated	Yes	14	7%	8	4%	22	11%
	No	10	5%	1	0.5%	11	5.5%

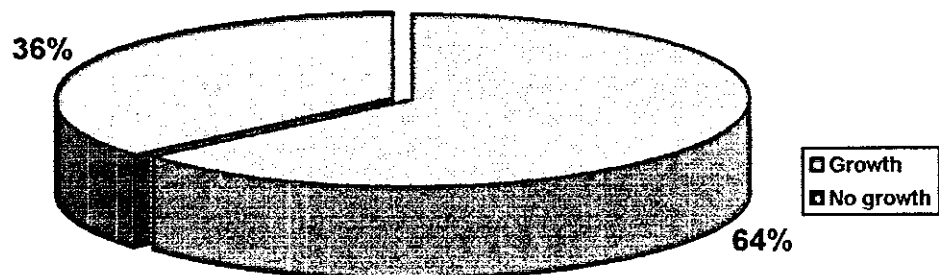
3.2. Results of Laboratory Culture Test

3.2.1 Culture result

Two hundred endo-cervical swab specimens were cultured for aerobic bacteria (128) 64% of all cultured swabs were positive, and 36% had no growth.

Table 6 results of laboratory culture test

Results of test	Frequency	Percent
Growth	128	64.0%
No growth	72	36.0%
Total	200	100.0%



Results of Laboratory Culture Test

Figure .1

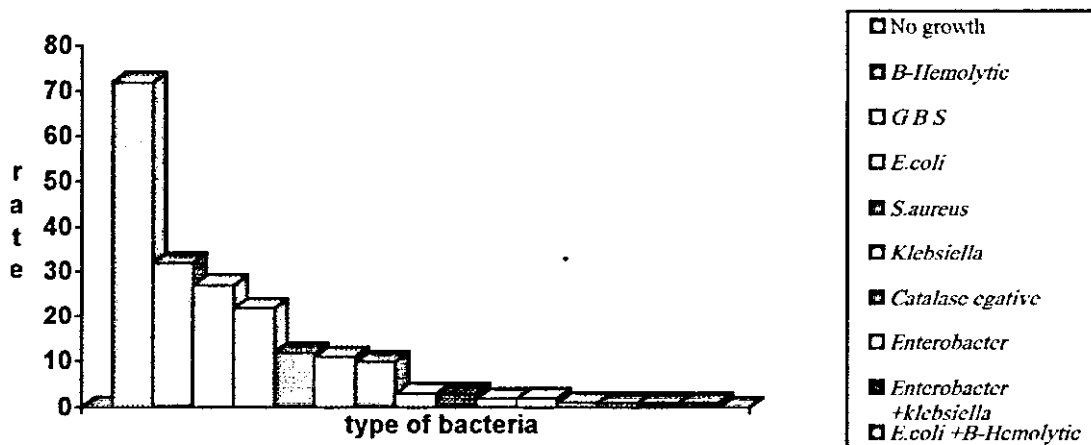
3.2.2 Types of the positive culture results

4.2.2a. Microorganism that were isolated from the endo- cervical canal

More than half (64%) of the isolated culture were positive, 16%out of these were *Beta -Hemolytic Streptococcus*, and *Group B Streptococcus* consisted up to 13.5% of the culture. *E.coli* reached up to 11%. Other types were *S. aureus* (6%), *klebsiella* (5.5%) and Coagulase negative *Staphylococcus* (5%).

Table7 Frequency & Percent of isolated bacteria

Type of bacteria	Count	Percent
No growth	72	36.0%
<i>B-Hemolytic Streptococcus</i>	32	16.0%
<i>G B S</i>	27	13.5%
<i>E.coli</i>	22	11.0%
<i>S.aureus</i>	12	6.0%
<i>Klebsiella</i>	11	5.5%
<i>Coagulase -negative Staphylococcus</i>	10	5.0%
<i>Enterobacter</i>	3	1.5%
<i>Enterobacter +Klebsiella</i>	3	1.5%
<i>E.coli +B-Hemolytic Streptococcus</i>	2	1.0%
<i>E.coli +Enterobacter</i>	2	1.0%
<i>E.coli +Klebsiella</i>	1	.5%
<i>Klebsiella +B- Hemolytic Streptococcus</i>	1	.5%
<i>S- aureus + pseudomonous</i>	1	.5%
<i>S aureus +E.coli</i>	1	.5%
Total	200	100.0%



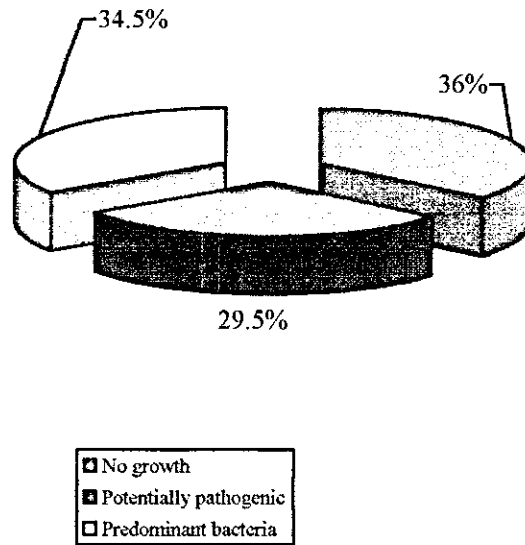
Frequency & Percent of isolated bacteria
Figure 2

3.2.2b Groups of Bacteria

The types of isolated bacteria were classified into two groups. The first one was the habitat or predominant bacteria in the genital tract, this group comprises 34.5%, the other one was the potentially pathogenic bacteria, Which consisted of 29.5% of all culture.

Table 8 Classification of culture results

	No growth	Potentially pathogenic	Predominant bacteria	Total
Count	72	59	69	200
% of Total	36%	29.5%	34.5%	100.0%



Classification of culture results

Figure 3

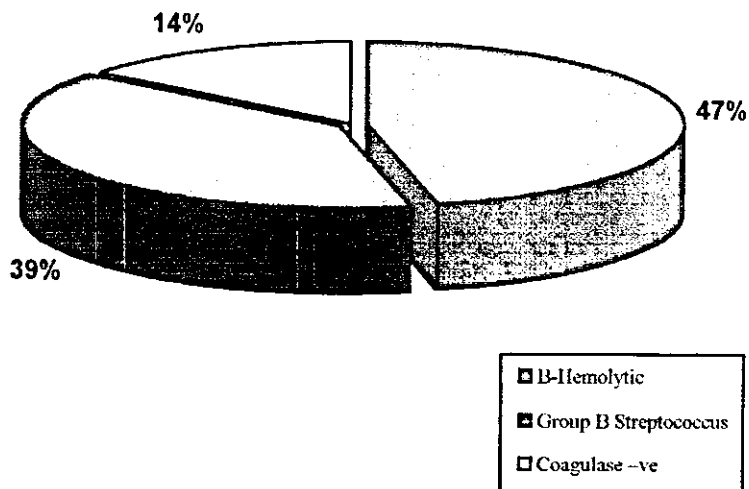
3.2.3. Types of bacteria according to their main group:

3.2.3a. Types of predominant group

Table 9 shows the types of predominant, B-Hemolytic streptococcus consisted of the major of predominant bacteria (46.4%). GBS ranked the second in this group (39.1%). The rest were Coagulase negative Staphylococcus (14.5%).

Table 9 Type of bacteria according to group/ predominant bacteria

Type of microorganism	Count	% of this group	%of +ve culture
B-Hemolytic strept.	32	16.0%	46.4%
Group B Streptococcus	27	13.5%	39.1%
Coagulase -ve	10	5.0%	14.5%
Total	69	34%	100%



Type of bacteria according to group/ predominant bacteria

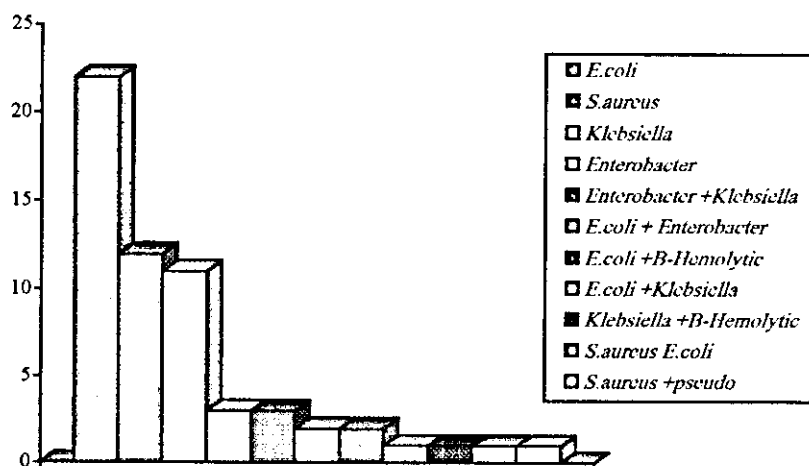
Figure 4

3.2.3b. Types of potentially pathogenic bacteria

The potentially pathogenic bacteria that were found in the positive culture consisted of 29.5% of all culture results. *E.coli* ranked the first among this group, it reached up to 37.3%, and the second was *S.aureus* which consisted 20% then *Klebsiella* and *Enterobacter* which reached 18%, and 5% respectively.

Table 10 Type of bacteria according to group/potentially pathogenic bacteria

Type of microorganism	Count	%
<i>E.coli</i>	22	37.3%
<i>S.aureus</i>	12	20%
<i>Klebsiella</i>	11	18.6%
<i>Enterobacter</i>	3	5%
<i>Enterobacter + Klebsiella</i>	3	5%
<i>E.coli + Enterobacter</i>	2	3.4%
<i>E.coli + B-Hemolytic</i>	2	3.4%
<i>E.coli + Klebsiella</i>	1	1.7%
<i>Klebsiella + B-Hemolytic</i>	1	1.7%
<i>S.aureus + E.coli</i>	1	1.7%
<i>S.aureus + pseudomonous</i>	1	1.7%
Total	59	100%



Type of bacteria according to group/ potentially pathogenic bacteria

Figure 5

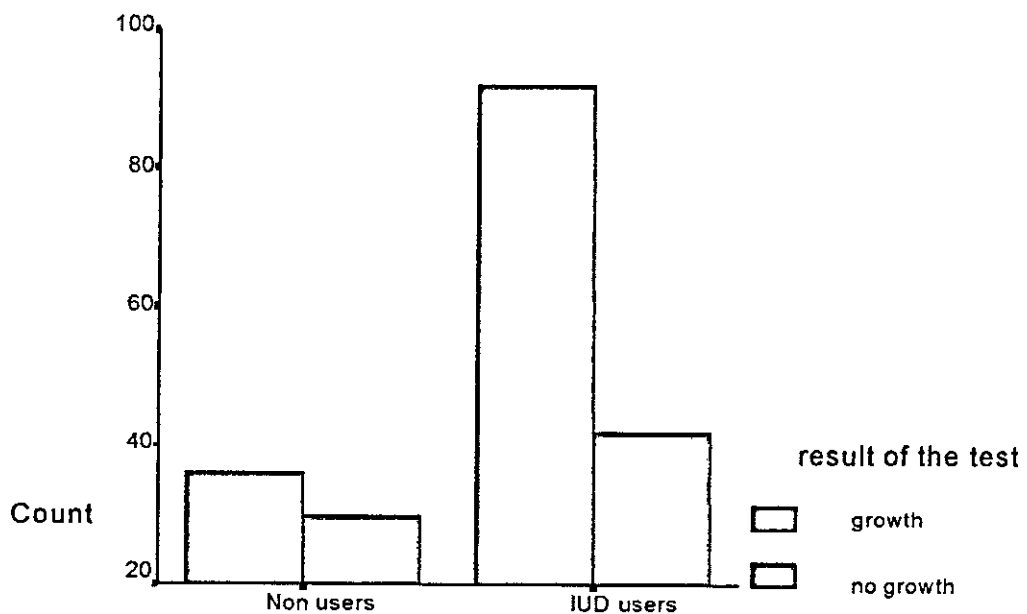
3.2.4 Culture results and bacteria group in relation to the IUD use

34.2.3a. Culture results in relation to the use of IUD

The results showed that the number of positive cultures was 128(64%), 46% of all cultures was among the IUD users and 18% among the non-users, While the negative cultures reached up to 15% among the non-users.

Table1 culture result in relation to use of IUD

Result of the test	Count/%	Non Users	IUD Users	Total
Growth	Count	36	92	128
	% of Total	18%	46%	64%
No growth	Count	30	42	72
	% of Total	15%	21%	36%
Total	Count	66	134	200
	% of total	33%	67%	100%



Culture result in relation to use of IUD

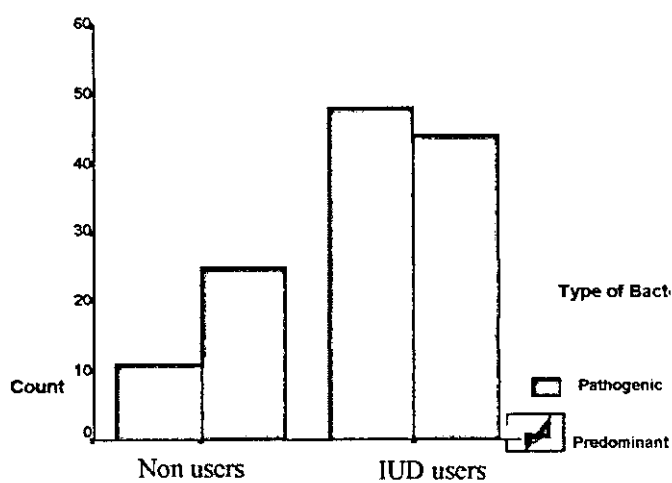
Figure 6

3.2.3b. Bacterial groups in relation to use of IUD

The positive cultures among the IUD users were 92(71.9%), 37.5% were potentially pathogenic bacteria, and 34.4% were predominant bacteria. The potentially pathogenic bacteria reached up to 8.6%among non-users while the predominant bacteria were 19.5%.

Table 12 bacteria groups in relation to IUD use

Bacteria group	Count/%	USE of IUD		Total
		Non users	IUD users	
Pathogenic	Count	11	48	59
	% of Total	8.6%	37.5%	46.1%
Predominant	Count	25	44	69
	% of Total	19.5%	34.4%	53.9%
Total	Count	36	92	128
	% of Total	28.1%	71.9%	100.0%



Bacteria groups in relation to IUD use

Figure 7

3.2.3c. Culture results among the IUD users according to the type of IUD

The negative cultures (no growth) among IUD users were 31.3%, 24.6% were among the Copper -T IUD users, while 5.7% were Multi-Load users. The positive cultures among the copper-T users reached up to 55.2% and only 13.4% among Multi-Load users.

Table13 culture results in relation to type of IUD

Culture results		Type of IUD		Total
		Multi-load	Copper-T	
No growth	Count	9	33	42
	% of Total	6.7%	24.6%	31.3%
Pathogenic	Count	11	37	48
	% of Total	8.2%	27.6%	35.8%
Predominant	Count	7	37	44
	% of Total	5.2%	27.6%	32.8%
Total	Count	27	107	134
	% of Total	20.1%	79.9%	100.0%

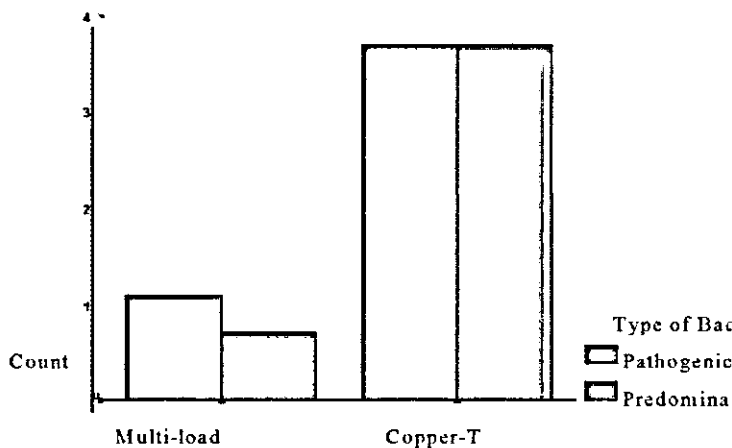
3.2.3d. Group of bacteria among IUD users according to the type of the IUD

It was found that 80.4% of positive cultures were among those who use Copper -T IUD. These were equally divided between the predominant bacteria and the potentially pathogenic group.

The predominant bacteria among the Multi-Load users were 7.6% from the total positive cultures of the IUD users, and pathogenic bacteria 12%.

Table 14. Bacteria group in relation to type of IUD

Bacteria group		Type of IUD		Total
		Multi-load	Copper-T	
Pathogenic	Count	11	37	48
	% of Total	12.0%	40.2%	52.2%
Predominant	Count	7	37	44
	% of Total	7.6%	40.2%	47.8%
Total	Count	18	74	92
	% of Total	19.6%	80.4%	100.0%



Bacteria group in relation to type of IUD

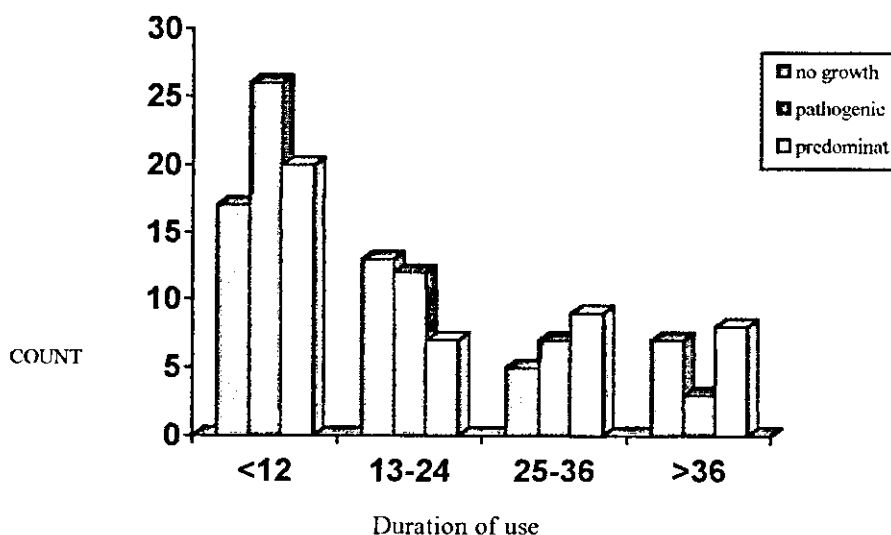
Figure 8

3.3.2e Culture results in relation to duration of use / months

The negative culture (no growth results) reached up to 31.3% among the IUD users, two third (18.6%) of them were among those who have been using it for more than a year, and about one third (12%) were among those who were using it within the first year (first 12-months)

Table 15. Culture results in relation to duration of IUD use

Culture results		Duration of use				Total
		<12	13-24	25-36	>36	
No growth	Count	17	13	5	7	42
	% of Total	12.7%	9.7%	3.7%	5.2%	31.3%
Pathogenic	Count	26	12	7	3	48
	% of Total	19.4%	9.0%	5.2%	2.2%	35.8%
Predominant	Count	20	7	9	8	44
	% of Total	14.9%	5.2%	6.7%	6.0%	32.8%
Total	Count	63	32	21	18	134
	% of Total	47.0%	23.9%	15.7%	13.4%	100.0%



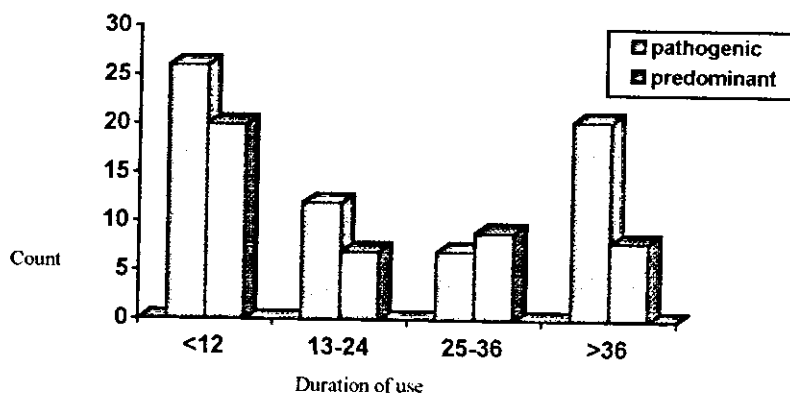
Culture results in relation to duration of IUD use
Figure 9

3.3.2d. Group of bacteria in relation to duration of use / month

The results showed that potentially pathogenic bacteria group reached up to 52.2%, the major portion were among those who have been using the IUD for less than 12 months (28.3%), only 3.3% were IUD users for more than 36 months. The predominant bacteria group also was higher among the same group (<12month of use); it reached up to 21.7%.

Table 16 bacteria group in relation to duration of use

Bacteria group		Duration of use / month				Total
		<12	13-24	25-36	>36	
Pathogenic	Count	26	12	7	3	48
	% of Total	28.3%	13.0%	7.6%	3.3%	52.2%
Predominant	Count	20	7	9	8	44
	% of Total	21.7%	7.6%	9.8%	8.7%	47.8%
Total	Count	46	19	16	11	92
	% of Total	50.0%	20.7%	17.4%	12.0%	100.0%



Bacteria group in relation to duration of IUD use

Figure 10

3.3 Results of the Clinical Picture

3.3.1 Symptoms as reported by women

Table 17 shows the symptoms reported by women and compares between the two groups, IUD users and non- users. Women who reported to have vaginal discharge were 79.5%, 58% were from the IUD users, and the rest (21.5%) were non-user. Odorous vaginal discharge was reported among 42.5% of the women, 31 % were IUD users and 11.5% were non-users. Women who had lower abdominal pain were 45.5%, 37.5% were those who use IUD, and the rest (8%) were from the non-users. Less than one third (29.5%) of women had lower abdominal pain during intercourse. The percent among the IUD users reached up to 25%, while it was 4.5% among the non-users. Itching was reported by 30.5% of the women. 23% were from those who use the IUD and 7.5% were among the non-users. Twenty three percent of all women had burning sensation, 17% were from the IUD users and 6% were from the non-users.

Table 17 percent of reported symptoms according to IUD use

Sign	IUD users		Non users		Total	
	No.	%	No.	%	No.	%
Vaginal discharge	116	58%	43	21.5%	159	79.5%
Odor	62	31%	23	11.5%	85	42.5%
Lower abdominal pain	75	37.5%	16	8%	91	45.5%
Problem during Inter course	50	25%	9	4.5%	59	29.5%
Any fever	10	5%	5	2.5%	15	7.5%
Itching	46	23%	15	7.5%	61	30.5%
Burning	34	17%	12	6%	46	23%

3.3.2. Vaginal discharge and use of IUD

Table 18 showed the relationship between the vaginal discharge and its characteristics and the use of IUD. A Good proportion of the population studied (30%) reported to have 4 suspicious characteristics of the vaginal discharge (score 1) most of them were from the IUD users (23.5%) and the rest 6.5% were from the non users. Those who have 3-points (0.75) ranked the second, since the percent reached up to 28.5%. The users were (19.5%, and non-users 9%). Just 20.5% of all population studied have no abnormal vaginal discharge, 11.5% were from those non-users, and the 9% were among the IUD users.

Those who have at least 2 suspicious characteristics of vaginal discharge were 21%, most of them (15%) were from the IUD users, and 6% were from the non-users. The difference between the IUD users and non-users was statistically significant ($p = .003$).

Table18 Alteration of vaginal discharge according to IUD use

Item		Score of vaginal discharge *				Total
		0*	0.5*	0.75*	1*	
Non users	Count	23	12	18	13	66
	% of Total	11.5%	6%	9%	6.5%	33%
IUD users	Count	18	30	39	47	134
	% of Total	9%	15%	19.5%	23.5%	67%
Total	Count	41	42	57	60	200
	% of Total	20.5%	21%	28.5%	30%	100%

*Score of vaginal discharge given according to presence of 1-4 symptoms (Ques. 38,39,40,41)

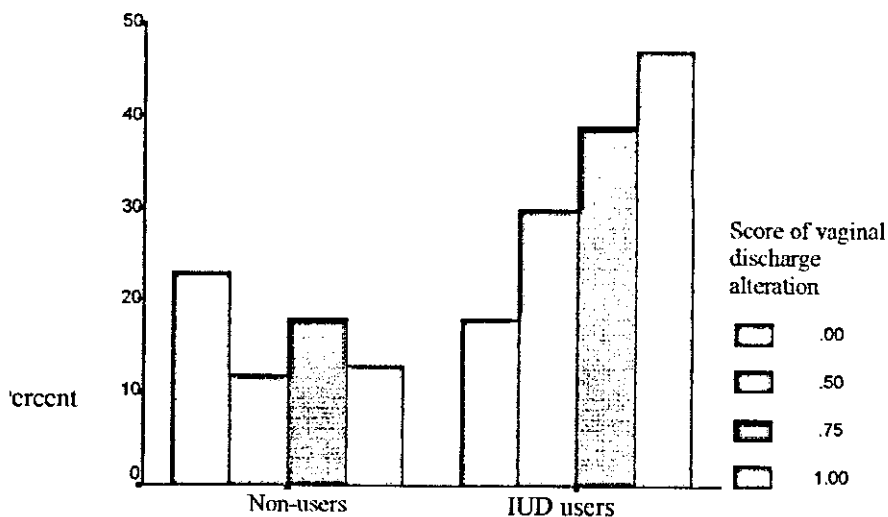


Figure.11 Table18 Alteration of vaginal discharge according to IUD use

3.3.3. Presence of symptoms of reproductive tract infection and use of IUD

Table 19 showed that 13% have had no symptoms of vaginal infection, with no difference between the IUD users or non-users (6%, 7% respectively). Thirty one percent of the population studied were diagnosed as having mild* infection (complained or had 3 of the symptoms of infection), around 14.5% were from non-users, and 16.5% were from IUD users. For moderate infection 34% were from IUD users and 9.5% from non users, 10.5% from IUD users had severe infection as they had at least 6 symptoms of vaginal infection.

The results showed much higher percentage of moderate* and severe* infection in IUD users compared to non-users, (34% moderate, 10.5% severe) the difference was statistically significant with $p < .05$. (Chi test $\chi = 18.6$, $p = .000$).

Table 19: Severity of symptoms in relation to Use of IUD

Score of Symptom*		Use of IUD		Total
		Non users	Users	
No symptoms	Count	14	12	26
	% of Total	7%	6%	13%
Mild‡	Count	29	33	62
	% of Total	14.5%	16.5%	31%
Moderate†	Count	19	68	87
	% of Total	9.5%	34%	43.5%
Severe‡	Count	4	21	25
	% of Total	2%	10.5%	12.5%
Total	Count	66	134	200
	% of Total	33%	67%	100%

The chi test ($\chi = 18.6$) $p = .000$

* The score was given according to the number of symptoms that women complain of
 ‡ 1-3 symptoms † 4-6 symptoms ‡ 7-9 symptoms

3.3.4. Severity of RTI by clinical picture and duration of use:

Table 20 showed that 36.6% of the population study have symptoms related to suspected moderate infection, the highest (17.9%) are those who have been using the IUD during 12 months. (Chi test $\chi^2=7.147$ with $p=. 0.622$).

Table 20 Severity of symptoms according to duration of IUD use.

Duration of use/ month		Severity of Symptoms				Total
		Not present	Mild	Moderate	Severe	
<12	Count	7	21	24	11	63
	% of Total	5.2%	15.7%	17.9%	8.2%	47.0%
13-24	Count	1	15	12	4	32
	% of Total	.7%	11.2%	9.0%	3.0%	23.9%
25-36	Count	3	6	9	3	21
	% of Total	2.2%	4.5%	6.7%	2.2%	15.7%
>36	Count	1	8	4	5	18
	% of Total	.7%	6.0%	3.0%	3.7%	13.4%
Total	Count	12	50	49	23	134
	% of Total	9.0%	37.3%	36.6%	17.2%	100.0%

3.3.5 Severity of symptoms and type of IUD

The results in table 21 showed that 9% of the IUD users have reported to have no symptoms of infection, 3% out of those were from Multi-load IUD group and 6% from Copper-T IUD group. Those who classified to have mild infection reached up to 37.3%, (29.9%) were from the Copper –T users. Those who have moderate degree of infection were also from Copper –T users (29%), and 14.9% from the Copper-T users have severe infection. The difference of having these infection-related symptoms between the two types of IUD was not statistically significant. (P=0.568).

Table 21 severity symptoms according to IUD type

Type of IUD		Severity of Symptoms				Total
		Not present	Mild	Moderate	Severe	
Multi-load	Count	4	10	10	3	27
	% of Total	3.0%	7.5%	7.5%	2.2%	20.1%
Copper-T	Count	8	40	39	20	107
	% of Total	6.0%	29.9%	29.1%	14.9%	79.9%
Total	Count	12	50	49	23	134
	% of Total	9.0%	37.3%	36.6%	17.2%	100.0%

Chi=2.021

p=0. 568

3.4 Association of the culture results and the reported symptoms of the RTI

3.4.1 Association of the culture results and the symptoms related to vaginal discharge.

Table 22. Relation of the vaginal discharge to the results of culture

Result of culture		Score of vaginal discharge				Total
		.00	.50	.75	1.00	
No growth	Count	20	15	13	24	72
	% of Total	10.0%	7.5%	6.5%	12.0%	36.0%
Pathogenic	Count	7	16	18	18	59
	% of Total	3.5%	8.0%	9.0%	9.0%	29.5%
Predominant	Count	14	11	26	18	69
	% of Total	7.0%	5.5%	13.0%	9.0%	34.5%
Total	Count	41	42	57	60	200
	% of Total	20.5%	21.0%	28.5%	30.0%	100.0%

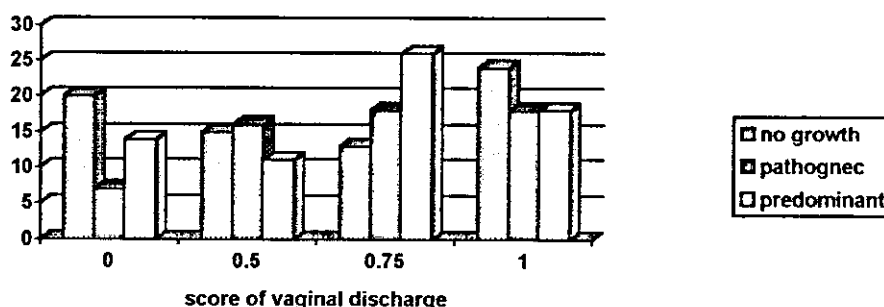


Figure 12 Relation of the vaginal discharge and the results of culture

Those who have the highest score of abnormal vaginal discharge (point 1) reached up to 30%, about half of them (12%) have no growth as culture result. And the rest was divided equally of having either predominant bacteria or potentially pathogenic group, 9% for each group. The rate of those who have the score of 0.75 reached up to 28.5%. The highest rate were found to have predominant bacteria (13%), and those who have potentially pathogenic bacteria reached to 9%, and just 6.5% have no bacteria. Those who have one symptom of abnormal vaginal discharge, reached 21%, they respectively had predominant bacteria, potentially pathogenic and no bacteria, (5.5%), (8%), (7.5%).

The group who have no symptoms, were found to have, predominant bacteria in rate of (7%), and the rate of those who have pathogenic bacteria reached to 3.5%, however 10% have no bacteria.

3.4.2 Association of the culture results and the over all reported symptoms

Table 23 severity of symptoms in relation to bacteria group

Result of Culture	Count/%	Score of symptoms				Total
		not Present	Mild	moderate	Severe	
No growth	Count	12	22	31	7	72
	% of Total	6.0%	11.0%	15.5%	3.5%	36.0%
Pathogenic	Count	6	13	30	10	59
	% of Total	3.0%	6.5%	15.0%	5.0%	29.5%
Predominant	Count	8	27	26	8	69
	% of Total	4.0%	13.5%	13.0%	4.0%	34.5%
Total	Count	26	62	87	25	200
	% of Total	13.0%	31.0%	43.5%	12.5%	100.0%

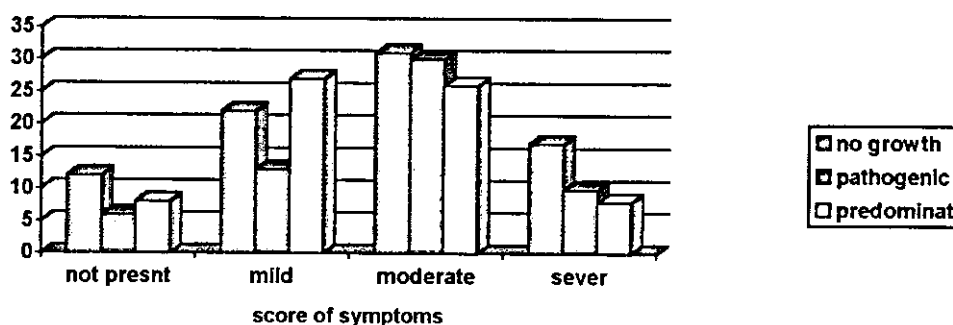


Figure13 severity of symptoms in relation to bacteria group

The results showed that 29.5% of population study had pathogenic group of bacteria, 15% had moderate score of symptoms (4-6 symptoms), and 5% had severe degree of symptoms related infection.

About one third (34.5%) were found to have predominant bacteria, from those 13% had mild and 13.5% had moderate degree of symptoms. Just 4% of them have severe degree and also 4% have no symptoms.

The group who had no bacteria, were as follows, 12% no symptoms, 22% mild, 31% moderate, and 7% severe degree.

This showed that there was no significant relation between the presence of the bacteria and the degree or severity of symptoms.

3.5 Association of the culture results, vaginal discharge and the use of IUD

Table 24 alteration in vaginal discharge in relation to bacteria group and the IUD use

Use of IUD	Culture result	Count/%	Score of the vaginal discharge				Total
			.00	.50	.75	1.00	
Non users	No growth	Count	12	5	7	6	30
		% of Total	18.2%	7.6%	10.6%	9.1%	45.5%
	Pathogenic	Count	3	2	2	4	11
		% of Total	4.5%	3.0%	3.0%	6.1%	16.7%
	Predominant	Count	8	5	9	3	25
		% of Total	12.1%	7.6%	13.6%	4.5%	37.9%
Total	Count	23	12	18	13	66	
	% of Total	34.8%	18.2%	27.3%	19.7%	100.0%	
IUD users	No growth	Count	8	10	6	18	42
		% of Total	6.0%	7.5%	4.5%	13.4%	31.3%
	Pathogenic	Count	4	14	16	14	48
		% of Total	3.0%	10.4%	11.9%	10.4%	35.8%
	Predominant	Count	6	6	17	15	44
		% of Total	4.5%	4.5%	12.7%	11.2%	32.8%
Total	Count	18	30	39	47	134	
	% of Total	13.4%	22.4%	29.1%	35.1%	100.0%	

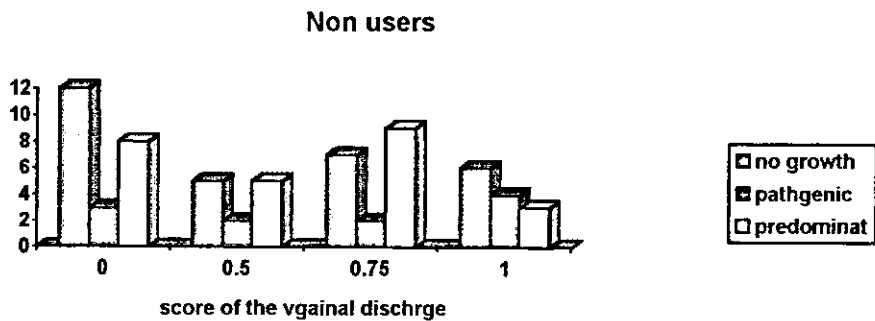


Figure14

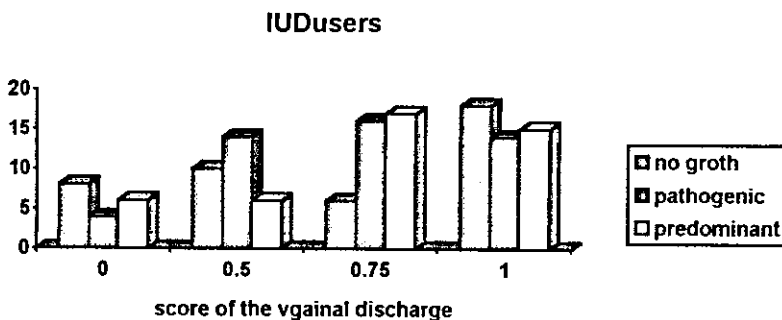


Figure15

Referring to table 24 it was noticed that among IUD users, 31.5% had no growth, only 13.45 of them had severe degree of symptoms related infection, 4.5% had moderate symptoms. At the same time among the non-users 45.9% had no growth, only 9.1% had severe degree of symptoms related infection, and 10.6% had moderate degree of symptoms related infection.

This concludes that although there is some relationship between the positive bacterial culture and the presence of symptoms, it is not statistically significant in either groups (IUD users, $p=0.105$, non-users, $p=0.669$)

3.6 Other findings for risk factors of infection among IUD users

3.6.1 Associations of age of women, vaginal discharge and group of bacteria

Referring to table 25, it was found that high rate of women, (30.5%) had high score of point related to alteration in the vaginal discharge (1), 20.5% of them were from age group of 20-30. The second high rate group was the score of (0.75) group which reached 28.5%, about half (13.5%) of them were from age group of 20-30, and the second half (12.5%) were from the group of 31-40. there is significant relationship between the vaginal discharge and age, ($p=0.46$).

Table 25 association between women age and the alteration of vaginal discharge

Women's age		Score of vaginal discharge				Total
		.00	.50	.75	1.00	
<20	Count	4		2		6
	% of Total	2.0%		1.0%		3.0%
20-30	Count	22	24	27	41	114
	% of Total	11.0%	12.0%	13.5%	20.5%	57.0%
31-40	Count	14	18	25	16	73
	% of Total	7.0%	9.0%	12.5%	8.0%	36.5%
>40	Count	1		3	3	7
	% of Total	.5%		1.5%	1.5%	3.5%
Total	Count	41	42	57	60	200
	% of Total	20.5%	21.0%	28.5%	30.0%	100.0%

Chi=17.164 $p=.046$

3.6.2. Association between the level of women's education, vaginal discharge and presence of bacteria

Our study found that there was no significant association between the education of women and having vaginal discharge ($p=0.433$), or reporting symptoms related to infection and education ($p=0.931$). At the same time there was no significant association between the presence of bacteria and the level of women's education, ($p=0.509$).

3.6.3. Association between husband's occupation, vaginal discharge and Presence of bacteria.

This study found that there was no significant relation between husband's occupation and the presence of abnormal vaginal discharge among women ($p=.391$), or having infection related symptoms ($p=.906$) or presence of bacteria, ($p=.593$).

CHAPTER FOUR

DISCUSSION

4. Discussion

4.1 Social Profile

4.1.1 Age

According to the Palestinian statistical bureau survey 2000, it was found that IUD is the most popular method among other contraceptive methods, the use rate was (24.6%). At the same time most of users start to use IUD after having the 3rd child.

In our study more than half of the study population (57%) were in the age group of 20-30 years, just 3% were below 20 years old. This reflects the national policy of the FP program in the MOH, which does not prefer to apply the IUD to young age, or to nulli-para women. And also goes along with the Palestinian statistical bureau 2000, which states that the percent of women who are currently using IUD at the age below than 20 is 3.7%.

4.1.2 Education and Occupation:

Most of the study population, either women or their husbands have their secondary education, (table.1). At the same time the highest percent of women were housewives, for their husbands they were laborers, which reflects the population's social and demographic status of the clients in the MOH, although the FP service provision in the MOH is free of charge.

Most of women who use IUD have 3-6 children (56%), 23.5% have at least 3 children. Eighteenth percent of them have not used any method before, and this is supported by statistical bureau 2000, which stated that 15.1% of women in the West Bank have used a contraceptive method for the first time after the third child.

It was found that 33.5% of women have menstrual problems related to the use of IUD. Out of those 18% had heavy period, 6.5% had irregular bleeding, and this is emphasized by Hatcher et al, 1997, who reported that common side effect of IUD is menstrual changes (longer, heavier menstrual period).

4.2 History of Contraceptive use.

Most of women (84%) in the study have previously used contraceptive method, 37% have been using IUD, which reflects that IUD is the most popular method among other contraceptives in Palestine, and this is supported by the survey of Palestinian statistical bureau 2000 (IUD usage rate 24.6%).

Desire to conceive was found to be the main reason for discontinuing the use of the IUD (27%), and removing the IUD due to infection was 9%. The cumulative gross termination rate of Copper IUD use because of infection during a period of 60 month is around 3per 100 in Finland, (Spark, 1981).

4.3 History of Genitourinary tract infection and treatment:

Half (53%) of women have had history of UTI, 84% also had previous history of genital infection, this reflects the association between UTI and the RTI due to the approximate anatomy of vagina and urethra. Also it may reflect the hygienic practice and contamination.

Eighty percent of the population who had previous history of genital infection had been treated, 40.5% have recurrent infection, and 49% used topical treatment. The high rate of recurrent infection might point to different causes (ineffective treatment, recurrent cause or other causes).

4.4 Microbiological findings:

Different approaches are followed all over the world to diagnose, treat and manage the symptoms related to RTI at the level of PHC either in the FP or MCH clinics, examples are culture swab, gram stain, Amsel criteria , or syndromic approach that have been developed by WHO. This depends on the level of the clinic, its equipments and the other related services provided through that clinic.

For these reasons the MOH and PHC at level of the FP clinics adopted the WHO syndromic approach in diagnosing, managing and treating the RTI and STD's.

Syndromic approach as seen by Hawkes et al, 1999 have proven to be so effective in poor countries with high prevalence rate of STD, and where limited services have been available for use in the diagnosis.

In our study, isolation of potentially pathogenic bacteria was higher among the IUD users than non-users, p value < 0.05 , ($p = 0.027$). Pathogenic bacteria group was higher among the IUD users (37.5%) compared to non-users (8.6%). The type of IUD has no relation, since the isolation rate of bacteria has no statistically significant difference ($p > 0.05$). (With notice that the rate use of Copper -T in this study was much higher than the Multi-Load)

The isolation of bacteria, both the pathogenic and predominant were higher among IUD users within the first 12 months, (28%, 21%), (see table 15), and it decreased during the following months, but this was not statistically significant difference.

In our study different types of aerobic bacteria were isolated by endo-cervical swab culture, these were *Beta-Hemolytic streptococcus*, *GBS*, *E.coli*, *S.aureus*, *Klebsiella*, *Coagulase -negative staphylococcus* and *Enterobacter*. This is supported by different studies, which have been conducted to evaluate the bacteria that adhere to IUD, and that colonize the vagina and cervix while using the IUD. Kochar 1980, found that *E.coli*, was the most common microorganism.

This is also compatible with the study by Sparks et al 1981, in which, *GBS*, *E.coli* and *Streptococcus* were isolated from the cervical canal and ectocervix of women with IUD. Our results also go with that by Marrie et al, 1983, as the main microorganisms cultured from Copper-T were *GBS*, *S.aureus*, *Enterococcus*, and *C. albicans*, these were cultured from the tailed IUD in contrast to the tailless IUD which remained sterile in uterus.

Also our results go with those of Hawkes et al 1999, who found that endogenous infection (candida, bacteria) diagnosed by culture were high with IUD users (53%) than non-users (32%).

The study by Haukkamaa, 1986 supported the types of bacteria isolated from cervix in women using oral contraceptives and IUD. This study found that both aerobic and anaerobic bacteria were higher among IUD users. He wondered whether the increased risk of PID in the IUD users is connected with the increased number of bacteria found in the cervix.

Sharief, 1998 found a strong association of *Klebsiella* with IUD use (14.5%) and much less association with isolation of *E.coli* and *S.aureus* in percent of 4.3% and 8.7%.

Jacques, 1986 in his study on rabbits found that IUD contamination during insertion via the vagina and cervix showed microorganisms colonization. In contrast the inserted IUD where contact with vagina and cervix was avoided, remained uncolonized. The most common organism was *S.epidermids*.

Marrie, 1983 found different types of microorganism recovered from 10 IUDs (copper7, copper-T and safe T-coil). All IUDs had adherent material, the organisms were *S. epidermides*, *GBS*, *S.aureus*, *Corynebacteria*, and *Enterobacter*.

Few studies explained the isolation of these types of bacteria among the IUD users, Chow, 1986, Smith, 1983, in their studies tried to identify the factors that affect the isolation of *E.coli* from the vagina of women. They found that isolation of *E.coli* were higher among IUD users than those who use no contraceptives, also higher during 1-7 days of menstrual cycle (20%) than in pre-menstrual, and higher among women with history of UTI (22%0).

The effect of menstrual cycle phase on the isolation of *E.coli* or *Streptococcus* bacteria explains the presence of these types of bacteria among the non-users in our study, taking in consideration that this group has attended the clinic while conducting the study to initiate use of IUD, (usually the time of insertion is at 5-7th day of the menstrual cycle).

Senanayake et al, 1980 reported that studies have shown that the insertion of IUD through the cervix introduces bacteria into the uterus, however a month later no bacteria were found on the endometrial culture. At the same time he believed that uterus containing IUD with a tail also contain bacteria similar to the vaginal flora, while the uterus without an IUD, or with a tail-less IUD contain no bacteria.

These results go with the study by Hill, 1993 and by Schwebke, 1999, who found that organisms that have been isolated from the IUD were *coagulase-negative Staphylococcus*, *Streptococcus* and in moderate concentration *E.coli*, in 25% of women with BV.

Zawaneh et al, 1981 found *GBS* to be in high concentration among pregnant and non-pregnant women. Adherence of *GBS* on vaginal epithelial cells was affected by different days of menstrual cycle, reaching the maximum on day 14. This explains the presence of the *GBS* among the non-users in our study, as those come to clinic for initiating use of IUD on the 5th –7th day of menstrual cycle. Other factors also influenced the isolation of *GBS*, these were IUD, history of sexual intercourse and the phase of menstrual cycle.

In our study the bacteria was abundant in the women cervix, with a higher percentage among the IUD users (71.9%) in comparison to non-users (28.1%). These findings can be explained by the presence of tail among the IUD users, as was found by Ebi, 1996. Since the comparative study of tail and tailless IUD revealed the role of the tail in ascending bacterial vaginal flora to the cervix and uterine cavity, but have no association in developing PID. Spark, 1981 also studied the role of tailed IUD and concluded the role of tail in allowing vaginal bacteria to pass into uterus.

The technique and insertion through the vagina might also play a roll in introducing the bacteria to the cervix and uterine cavity, as mentioned by (Burkman 1996, Jacques, 1986, Pasquale, 1996, chow, 1980). Senanayake, 1980 stressed the role of insertion process in the passive introduction of bacteria in the uterine cavity, and he proved the higher rate of bacteria during the first month after insertion.

Our study shows high percentage of *GBS* among IUD users during the first year after insertion.

4.5 Clinical Picture

Our study shows high prevalence rate of symptoms related to different types of RTI (vaginitis syndrome, PID, endogenous infection) among women attending FP clinics. This finding was particularly high among the IUD users, either that related to alteration of vaginal discharge (58%), or symptoms related to RTI (61%). These findings could be explained by several causes, either a reaction to foreign body or due to alteration of predominant bacteria, or presence of pathogenic bacteria.

In our study the rate of women reported to have alteration in vaginal discharge was 79.5%, those who reported to have odorous vaginal discharge were about 42.5%, itching rate was 31% (table 18). These symptoms were significantly different between IUD users and non-users. $P= .003$ (table 19). But among the IUD users there was no significant difference between the two types of IUD's, and there was no significant difference in the relation to the duration of use.

Our study found a high percent of women to have symptoms related to alteration in the vaginal discharge or symptoms related to reproductive infection (table 19 &20). Thirty percent have alteration in 4 indicated symptoms of vaginal discharge, and 28.5% have changes in the 3 symptoms. These changes were higher among the IUD users than non- users with statistically significant difference.

Our study found that the reported alteration in vaginal discharge was higher among the young group age (20-30) the percent was 57%, with a statistically significant difference ($p= .04$). However, other factors like education, occupation of husband were found to have no association either in the alteration of the vaginal symptoms or in the isolated bacteria. Sharief, 1996 who found that the highest infection rate (94.7%) was among women in the age 15-25 age group, which supports our findings. This might be explained by a fact that young group is the most sexually active one with more tendency to develop infection. Microbiological findings in PID

studies indicated that the ratio between isolation of STD organisms and endogenous vaginal flora decrease with increasing age (Farely, 1992).

Beerthuizen, 1996 referred to the presence of IUD as a foreign body, which causes reaction to the host and response of endometrial tissue to the device similar to foreign body reaction. This can partially explain our study findings.

Vaginal infection whether termed as by vaginitis, vaginal infection or inflammation of the vagina, is characterized by discharge, irritation, itching. (Dep. public health, 1992). Vaginal discharge and its characteristics might be related to different types of reproductive tract infection, Such as endogenous infection (bacterial vaginosis, vaginitis, and cervicitis)

Berg et al, 1984 reported that different nonspecific symptoms (GU) as dysuria, priritus, vaginal discharge are translated into clinical syndromes as cystitis, vaginitis, and cervicitis.

Hawkes, 1999 described Vaginal discharges as one of the most common clinical complaint among women of reproductive age in many parts of the world. Egan, 2000 reported that 40-50% percent of American women complains of Vaginitis, and the most common bacterial organism was *Gardenella*, *Mycoplasma*, and *Streptococcus*.

Different studies revealed the association between vaginitis, and use of IUD (Sieber, et al 1998). Amsel, 1983 found a strong association of nonspecific vaginitis with the use of IUD.

Bruner, 1984 highlighted the association of presence of *E.coli*, *Streptococcus*, and *Staphylococcus* when invading the vagina and the more profuse yellowish mucoid discharge as a simple vaginitis, or inflammation of the lining of the vaginal wall.

On the other hand several studies indicated that vaginal isolation rate of *E.coli* are not increased among women with vaginitis or abnormal vaginal discharge (8%-16%) compared to asymptomatic women. Chow, 1986). Hawkes, 1999 found in his

study that endogenous infection (candida, bacterial vaginosis) was diagnosed by laboratory in 32% of symptomatic women. Method of contraception was the only significant factor with endogenous infection ($p=0.035$), endogenous infection was 53% among IUD users. Women with IUD were more likely to have an endogenous infection than those using no contraception.

In our study the presence of alteration of vaginal discharge did not show relation to the microbiological results, for example 3.5% of asymptomatic women had pathogenic bacteria, and 12% of women with significant symptoms (score1) had negative culture. Also women who scored 0.5-1 for their vaginal discharge had different patterns of culture results, 26% had pathogenic bacteria, 27% had predominant bacteria, and 26% had no growth. However, the culture results can't explain the negative results in symptomatic women, or the positive results in asymptomatic ones. These results might indicate either presence of other microorganisms causing the symptoms not included in our study (*Trichomonous*, *Gardenerella*, or *Candida*), or non-infectious causes for symptoms such as foreign body reaction.

Hill, 1993 in his study found that *coagulase negative Staphylococci*, and *Streptococci* to be in low to moderate concentration in women with bacterial vaginosis, and gram negative bacilli (*E.coli*) have been noted in approximately 25% of women with BV.

Symptomatic infection of upper genital tract is initiated always by gonococcus, which paves the way for secondary infection, with microorganisms from the flora of the cervix and vagina (Perine, 1980, Sweet, 1980)

Disruption of bacteria (micro-flora of vagina) puts the host at risk for infection. Symptom based treatment with an anti-fungal agent in the absence of yeast colonization may be quite harmful to vaginal microflora, it might result in an anticipated deleterious effect on the patients as increased risk of re-infection with yeast or infection with other microorganisms (Ross et al, 1995). Potentially pathogenic microorganisms are associated with BV particularly by replacing the normal flora (*Lactobacillus*) in lower genital tract. These microorganisms also have

been isolated from the endometrial culture of women with PID, however evidence supporting a link between BV and PID is inconclusive, Korn et al, 1995.

4.6 Conclusion

This is the first study regarding IUD related infection among Palestinian women. The study showed that RTI is quite common among Palestinian women. The isolated aerobic bacteria related to RTI in the study were significantly high among IUD users in comparison to non-users. Our study highlighted the followings

- A noted difference between women using IUD and control group in terms of isolated aerobic bacteria. No significant relation between the isolated aerobic bacteria and the type of IUD or the duration of IUD use.
- Positive association between the alteration of vaginal discharge and the IUD use. This association was found regardless of the type of IUD or the duration of use.
- Positive association between the presence of RTI related symptoms and IUD use regardless of the type of IUD or the duration of use.
- No relation between the isolated aerobic bacteria and the presence of symptoms in both groups (IUD users vs. control). Note that this negative relation is true whether the symptoms are due to alteration of vaginal discharge or RTI related symptoms.

4.7 Recommendation

In a country like Palestine, the over all prevalence rate of STD's might be low and endogenous infection is high (29.5%) it is worth and needed for the abnormal vaginal discharge and other related symptoms to be explored and investigated. Our study points to a high incidence of endogenous infection among women, therefore it seems to be important to do more investigations about vaginal discharge and other related symptoms. In contrast to the STD's which seems to be of low incidence. The following are some suggestions for further evaluation

- Further study to evaluate other types of microorganisms and their association with IUD using other different diagnostic tests.
- Comparison study to evaluate syndromic approach and other methods of treatment in term of their effectiveness in treatment and economic aspect.
- More in depth studies are needed to explore relationship between symptoms and RTI.
- Action program at the family planning clinic level including: training the health care providers in the management of endogenous infection in women, with emphasis on better diagnostic techniques.
- Developing and strengthening of referral system for women who fail to respond to first line treatment.
- Primary prevention and information campaign, which aims to explore the issues of menstrual hygiene and physiological discharge, and to encourage women to visit health care provider if there were any changes out of normal.
- Provision of the PHC/FP & MCH clinics with simple laboratory facilities like microscopes, to enable health care providers to diagnose manage and treat the endogenous infections and do culture when necessary.
- Recommend considering antibiotic prophylactic use during insertion of IUD.
- Consider developing referring criteria for difficult cases to be seen by more trained physician (specialist) e.g. previous cesarean, low parity.
- Consider use of Levonorgest device as it causes less bleeding compared to other IUD types.

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Annex I

An Najah University
Faculty of Graduate study

Women Profile(IUD users and non-users)

#	رقم الاستمارة	التاريخ				
1	District	1. Nablus	2. Jenin	3. Ramallah	4. Tulkarm	
		5. Salfet	6. Hebron	7. Qalqeliah	8. Jerecho	
2	Name of clinic	9. Biethlehem				
3	File number					

Social and Demographic Status

4	Women age				
5	Women education				
6	Women occupation	1. Working	2. House-hold		
7	Husband education				
8	Husband occupation	1. Laborer	2. Employer	3. Employee	
		4. UN employed			
9	Number of pregnancies				
10	Number of children				
11	Type of last delivery	1. Normal	2. Caesarian	3. Instrumental	
12	Date of last delivery				
13	Did you have any abortion	1. Yes	2. No		
14	if yes when was it				
15	Type of abortion	1. Spontaneous	2. Induced	3. No abortion	
16	Problems associated with menstrual period			1. Yes	2. No
17	If yes what are they	1. Dysmenorrhea	2. irregular	3. Heavy	4. 2+3

history of previous method

18	Did you use any contraceptive before that			1. Yes	2. No
19	Type of contraceptives used	1. IUD	2. Pills	3. Condom	
		4. Others			
19a	Length of use /months				
20	Cause of discontinuing that method	1. Desier to conceive	2. Infection	3. Bleeding	
		4. Insertion problems	5. Hypertension	6. Pain	
				7. Pain&bleeding	8. Vericosevein
				9. Expulsion	10. Others

History of current method

20a	why did you visit FP clinic	1, ask for IUD	2, follow up visit		
21	Type of IUD	1. Multi-load	2. Copper T	3. DK	
		4. To be used			

22	Time of insertion	1. Post partum	2. Post menstrual	
23	Length of use /months	0, To be used		

24	Cause of choosing IUD .	1. Prescribed by Dr	2. Esy to use	3. cheepe
		4. less complicated	5. 3+4	
25	Have your husband ever used condom		1. Yes	2. No
26	If yes : frequency of use	1. Always	2. Sometimes	
27	Did you have urinary tract infection		1. yes	2. no

28	Did you have any previous history of genital infection		1. Yes	2. No
28a	period of having that infection/month			
29	Did you treat for this infection	1. Yes	2. No	3. No infection
30	Length of treatment/ month			
31	type of treatment	1. Topical	2. Systematic	3. No infection
32	Did this infection return back after treatment		1. Yes	2. No
33	Did your husband have any infection	1. Yes	2. No	
34	Did he get any treatment for it	1. Yes	2. No	
35	Hygienic practice :	1. Gintal washing	2. Vaginal douching	
36	Times of that per day	1. 1-5	2. +5	3. Non
37	product used for that	1. Water only	2. Soup	3. albocal
		4. detole	5. salt	6. herbs

Current history of infection

Do you have any of these symptoms

38	vaginal discharge	1. yes	2. no	
39	is there any odor	1. Yes	2. No	
40	what is the color of these discharge	1. Transparent	2. white	3. Creamy
		4. Grain	5. Brown	6. Yellow
41	consistency of discharge	1. watery	2. Thick mucus	3. Cheesy
42	length of this discharge			
43	lower abdominal pain	1. Yes	2. No	
44	problems during intercourse	1. Yes	2. No	
45	fever	1. Yes	2. No	
46	vaginal itching	1. Yes	2. No	
47	vaginal Burning sensation	1. Yes	2. No	
48	Did you receive any treatment for this proble	1. Yes	2. No	
49	Length of treatment/ month			
50	Type of treatment	1. Topical	2. systematic	3. No infection
51	result of the test	1. growth	2. no growth	

if growth

52

type microorganism

53

colony count

54

sensitivity

بِسْمِ اللَّهِ الرَّحْمَنِ الرَّحِيمِ

Palestinian National Authority
Ministry of Health
General Administration of Research,
Planing & Development



السلطة الوطنية الفلسطينية
وزارة الصحة
إدارة العامة للبحث والتخطيط والتنمية

No.:
Date: السيد زكيه لادان السيد
مختبر
يرجى العلم وانتم لست
مع
8/14

ع.ع. / 184 / 2000
2000/8/13

الدكتور ماهر المنتشة المحترم
نائب الرئيس للشؤون الأكاديمية
جامعة النجاح

الموضوع: إجراء مشروع بعنوان
" Reproductive Infection among IUD Users "

تحية طيبة وبعد،،،

إشارة الى كتابكم رقم ن ك ص / 19 تم / 2000 تاريخ 2000/7/31 والمتعلق
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Annex III

نموذج المرافقة على إجراء الفحص المتعلق بالبحث

جامعة النجاح الوطنية

كلية الدراسات العليا

برنامج الصحة العامة

أنا السيدة _____

بعد أن تم توضيح وشرح أهداف الدراسة التي تقوم بها الطالبة مريم الطلل / ضمن برنامج ماجستير الصحة العامة م جامعة النجاح ،

أوافق بمحض إرادتي على تقديم المساعدة والتعاون من خلال إجراء الفحص اللازم بشرط أن تكون هذه المعلومات سرية وتخدم أغراض

البحث لا غير كذلك إعلامي بنتيجة الفحص.

التوقيع

