

## **CASE 8**

### **BARTHOLIN'S ABSCESS: MARSUPIALIZATION**

**Name :** C.A.                      **Parity :** 1+0  
**Unit No:** 0611137              **Admission :** 20/09/99  
**Age :** 23 years                  **Discharge :** 24/09/99

#### **History of presenting illness**

The patient was admitted to the acute gynaecological ward with a 3-day history of painful genital swelling. The swelling had increased in size progressively. She had a whitish per vaginal discharge. There was no history of genital trauma.

#### **Obstetric and gynaecological history**

The patient attained menarche at 14 years of age. Her menses were regular every 28 days lasting 4 days. The first date of her last menstrual period was 15.09.99. There was no history of contraceptive use. She was para 1+0, and had a spontaneous vertex delivery at term in 1997.

#### **Past medical history**

There was no history of other major illness in the past.

#### **Family and social history**

The patient was a single, form 4-school leaver. She was a catholic by religion. She was a tailor and she lived with the sister in Nairobi.

#### **Physical examination.**

She was a young lady in fair general condition. She was not febrile, not pale and was not jaundiced. Her pulse rate was 80 per minute, regular with good volume. The blood pressure was 110/70mmHg. The chest was clear. The cardiovascular and central nervous systems were normal.

### **Abdominal examination.**

The abdomen was soft and not distended. There was no tenderness and there were no palpable masses.

### **Pelvic examination**

There was a fluctuant, erythematous, tender, warm swelling on the medial aspect of the posterior half of the right labium minus. The left side of the vulva was normal. There was a vaginal discharge, whitish in colour. Further examination was not possible due to the vulval tenderness.

### **Diagnosis**

A diagnosis of a right Bartholin's Abscess was made.

### **Management**

Baseline investigations were done:

|           |           |                           |
|-----------|-----------|---------------------------|
| Haemogram | Hb        | 13.6g/dl                  |
|           | WBC       | 12.8 x 10 <sup>9</sup> /l |
|           | Platelets | 261 x 10 <sup>9</sup> /l  |

#### **Serum urea and electrolytes**

|     |            |
|-----|------------|
| Na+ | 139mmol/l  |
| K+  | 5.5 mmol/l |
| BUN | 2.7 mmol/l |

The patient was prepared for drainage of the abscess and marsupialization. Informed consent for the operation was obtained from the patient. She was premedicated with intramuscular atropine sulphate 0.6mg and pethidine 50mg 30 minutes before surgery.



## **Operation**

The patient was wheeled to theatre on 21/09/99. On the operation table, the patient was put under GA. She was put to lithotomy position and vulvo-perineal toilet done. The bladder was catheterized aseptically and clear urine was drained.

Examination under anaesthesia was done. The swelling on the medial aspect of the posterior half of the right labium minus was confirmed. It measured about 8x3x2cm. The rest of the external genitalia was normal. The cervix was firm and closed. The uterus was normal in size and mobility. Both adnexa and pouch of Douglas were normal. The vagina was packed with a sterile pack. A longitudinal incision about 3cm was made along the muco-cutaneous junction on the abscess. The abscess cavity was opened into and all abscess loculi were broken into by blunt dissection. About 50mls of thick pus mixed with some blood was drained. The abscess cavity was then cleaned with warm saline water. Marsupialization was done using catgut 2/0 by stitching the abscess floor to the edge of the incision to effect eversion of the abscess cavity.

The vaginal pack was removed. A loose perineal pad was applied. Anaesthesia was reversed successfully. Her postoperative vital signs remained normal. She was wheeled back to the ward. A specimen of pus obtained in theatre was submitted for microscopy, culture and sensitivity.

## **Past operative management**

In the recovery ward, ½ hourly observations were made of blood pressure, pulse, temperature and respiration till the patient was fully awake. She received intramuscular pethidine 100mg 8 hourly for analgesia followed the next day by paracetamol 1000mg orally for 5 days. Intramuscular Crystapen 2mU 6 hourly and Gentamicin 80mg 6 hourly for 48 hours then, cap Amoxycillin 500mg 8 hourly and tabs metronidazole 400mg 8 hourly were given for antibiotic therapy and continued for a week. She was advised on thrice daily, warm saline sitz baths.

Postoperatively she recovered well. A repeat Hb on 3<sup>rd</sup> postoperative day was 13.4g/dl. The pus swab grew E. coli sensitive to gentamicin among other antibiotics.

She was discharged home on treatment on 24.09.99. She was reviewed in the GOPC after 2 weeks and was found to be well.

## DISCUSSION

This was a young lady with a Bartholin's duct abscess for which marsupialization was done. Bartholin's duct abscess is a common problem in women of reproductive age. It was found to account for 1.7% of total gynaecological admissions to Kenyatta National Hospital <sup>(1)</sup>. The patients were often young with a mean age of 16.2 years and of low parity.<sup>(1)</sup>

Bartholin's glands are situated bilaterally within the posterior third of the vulva. Each opens by a single duct into the vaginal orifice. Obstruction of the main duct of Bartholin's gland results in retention of secretions and cystic dilatation. Infections an important cause of obstruction, however inspissated mucus and congenital narrowing of the duct may also be causes.<sup>(2,3)</sup> During a mediolateral episiotomy or a posterior colporrhaphy, sutures can easily injure or even ligate the duct. Our patient's obstruction was as a result of infection since *Escherichia coli* was isolated on culture.

The commonest organism usually isolated is *Neisseria gonorrhoeae*, others include *Staphylococcus aureus*, *Streptococci* or a mixture of organisms including *E. coli*.<sup>(3)</sup> During acute infection, which may precede the actual cysts formation, an abscess often develops.

Though a simple gynaecological malady, Bartholin's abscess causes untold marital, psychological and social distress to the patient. Acute symptoms are ordinarily the result of infection which results in pain, tenderness, swelling for three days. Mumia found a mean duration of symptoms at presentation of 5.2 days <sup>(1)</sup>. The patients may have difficulty in sitting or walking due to the pain and discomfort caused by the lesion. The surrounding tissues become oedematous and inflamed and a fluctuant tender mass is usually palpable.

The risk profile of patients with Bartholin's duct abscess is similar to that of most sexually transmitted diseases <sup>(4)</sup>. The advisability of presumptive antibiotic treatment of these patients and examination and treatment of their sexual partners should therefore be considered. Our patient was single and was privy to her coital lifestyle, so contact tracing was not possible.

Though injection of an antibiotic into the abscess has been tried for treatment of the acute infection, the method has proven to be no more effective than systemic antibiotic therapy<sup>(3)</sup>. Simple incision and drainage bring almost immediate relief to the patient and may be accomplished under local anaesthesia. However this is a temporary relief since the opening tends to become obstructed and recurrent cystic dilatation and infection may result <sup>(2,3,5)</sup>. Marsupialization is the preferred method particularly for chronic or recurrent abscesses <sup>(2,3,5)</sup>. Marsupialization followed with antibiotics and analgesics was used for treatment in 95.6% of the patients with Bartholin's abscess at KNH <sup>(1)</sup>. The latter was the mode of treatment given to our patient.

Marsupialization has had limited use since the Word catheter was introduced <sup>(2,3,5)</sup>. The Word catheter accomplishes the same result as surgery with minimal or no trauma, and can be performed in the office. The use of Silver Nitrate (Ag No3) stick inserted into the Bartholin's abscess for 48 hours has been shown to be as effective as excision and has fewer complications <sup>(6)</sup>. It is a simple, inexpensive procedure requiring the least anaesthetic, which can easily be carried out in the outpatient setting.

Postoperative care should include daily sitz baths as was done in our patient. Labial hematomas may form due to bleeding from the vestibular bulb following surgery. This should be treated with bed rest, ice pack and pressure dressing if it arises. Our patients had an uneventful postoperative period.

Bartholin's duct abscesses are associated with frequent recurrence. At KNH a recurrence rates of 3% per year was reported<sup>(1)</sup>. Recurrence arises due to recurrent infection resulting in cystic dilatation of the duct. Recurrence is avoided by leaving a



permanent opening for drainage as was done in our patient. She did not suffer any complications after the operation.

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## **CASE NO. 9**

### **SECONDARY INFERTILITY WITH TUBAL BLOCKAGE – TUBOPLASTY DONE**

**Name:** E. N. M.

**DOA :** 8/11/99

**Age :** 32 Years

**DOD :** 17/11/99

**IP No. :** 0648429

**Parity :** 0 + 1

#### **Presenting Complaints**

The patient was booked at our gynaecology outpatient clinic with complaints of painful menstrual periods, lower abdominal pains and inability to conceive for 6 years.

#### **History of presenting complaints**

She had been married for 6 years and they had engaged in normal unprotected and regular sexual intercourse but had not achieved another pregnancy. The periods had been regular, heavy and in clots. She gave no history of previous sexually transmitted diseases or post-abortal sepsis.

#### **Obstetric and Gynaecological History**

She was para 0 + 1. She had an elective termination of pregnancy in 1994 at 4/12 for unwanted pregnancy. Her menarche was at 15 years and her periods were regular, occuring every 24 days and lasting 3 days. They were heavy and in clots and associated with pain. She had never used any form of contraceptive. Her last menstrual period was on 14/10/99.

#### **Family and Social History**

She had been married to a 35-year-old man, who was a businessman, but they had separated one month before presentation due to the inability to conceive. She lived at Machakos, where she was a small-scale business lady. She took alcohol occasionally but did not smoke cigarettes. As far as she knew, the husband had not fathered children



elsewhere. She confessed to having had 3 boyfriends and had sexual relationships with them prior to her marriage. There was no family history of any chronic illnesses.

### **Past Medical History**

She did not suffer from any chronic illness. She had never been admitted to hospital or had any surgery. She had never been treated for any sexually transmitted disease.

### **Physical Examination**

She was a young lady in good general condition. She was not pale or febrile, and had no oedema. She was not obese and had a normal female habitus and secondary sexual characteristics. She had no goitre. She had no abnormal hair growth or distribution. Her temperature was  $36.4^{\circ}\text{C}$ , blood pressure 120/80mmHg. Pulse rate was 78 per minute and regular. Respiratory rate was 20 per minute. Her breasts were well developed and not active.

### **Abdominal Examination**

The abdomen was soft and had no traditional therapeutic marks. She had a small infra-umbilical scar. There were no masses or areas of tenderness.

### **Pelvic Examination**

She had normal female pubic hair distribution. Her external genitalia were normal. The vaginal mucosa and fornices were normal. The cervix was firm, long and the os was closed. The uterus was normal sized, anteverted and mobile.

Her cardiovascular, respiratory and central nervous systems were examined and found normal. Her husband had been examined earlier during the clinic visits, general examination, external genitalia and the testes were all normal.

### **Investigations**

1. Husband semen analysis: Volume 2.5mls, pH 7.5, Colour Grey-White, Motility 90% actively progressive, 5% dead. Over 65% were of normal morphology. No leucocytes were seen. The sperm count was 60 million per ml.

2. Pap smear - Pap Class I (CIN-O)
3. HIV test by ELISA - Negative for HIV I and II antibodies.
4. Pelvic U/S - Normal
5. HSG - Normal uterine cavity, dye outlined both tubes but there was bilateral terminal loculation of dye and no spill.
6. Diagnostic laparoscopy (18/7/99) - Uterus was of normal size and shape. There were flimsy adhesions in the pouch of Douglas. Also flimsy adhesions involved both tubes with fimbrial end agglutination. Both ovaries were found normal. On instillation of dye there was no free spill bilaterally, the tubes were distally distended with dye.
7. Endometrial curettings (18/7/99) - Indicated secretory phase corresponding to 24 – 25<sup>th</sup> day of a 28 – day cycle (LMP – 23/6/99). There were no alcohol and acid fast bacilli (AAFB) seen.
8. Haemogram - Haemoglobin - 11.4g/dl  
WBC count -  $5.6 \times 10^9/L$   
Platelets -  $162 \times 10^9/L$
9. Urea and electrolytes - Sodium 144mmol/L, Potassium 4.3mmol/L, BUN 3.5mmol/L

## Management

The patient was admitted to the ward and informed consent for tuboplasty under general anaesthesia was obtained. The patient was fasted from midnight of the operation day. On the morning of surgery she was shaved at the pubic and lower abdominal regions. Premedication with intramuscular atropine 0.6mg and Pethidine 50mg were given half-hour before surgery. She was then wheeled to theatre. In the operating theatre, the patient was anaesthetised and then placed in lithotomy position. The vulva and vagina were cleaned using antiseptic lotion. Aseptic catheterisation was done and 200mls of clear urine obtained. Examination under anaesthesia confirmed earlier findings. The vagina was packed with a moist gauze roll to elevate the uterus. The patient was repositioned supine and the abdomen cleaned and draped. The abdomen was opened through a pfannenstiel incision. The uterus was found to be normal sized and anteverted.

There were thin and thick adhesions around the left tube. Irrigation was started with Darrow's solution and adhesions released by cautery. The tube was freed and mobilized but the fimbrial end was not visualized. Terminal salpingostomy was done to open the distal part of the tube.

The right tube was also buried in thin and thick adhesions. These were released by cautery and the tube was freed. The fimbrial ends appeared healthy. Both ovaries were freed from adhesions and appeared healthy. A cervical clamp was placed and methylene blue hydrotubation was done, bilateral spill was noted. The pelvic cavity was cleaned with Darrow's solution after haemostasis was achieved. Swabs and instruments were counted and found correct and the abdomen was repaired in layers. The patient was then reversed from anaesthesia and taken to the recovery area.

### **Post Operative Care**

She was observed hourly until she was fully awake and then four hourly. She got intravenous crystalline penicillin 2mu, 6 hourly and gentamycin 80mg, 8 hourly for 48 hours for prophylaxis. She also got intramuscular pethidine 100mg 6 hourly for 24 hours. She was later commenced on oral amoxycillin 500mg, 8 hourly, flagyl 400mg, 8 hourly and paracetamol 1gm, 8 hourly. Intravenous fluids 500ml, 5% dextrose alternating with normal saline were given 6 hourly until the second post operative day when she was started on oral sips. On the fourth post-operative day, she had no major complaints and was discharged home. She was to be reviewed in the gynaecology clinic in one month.

### **Follow-up**

She was seen at the gynaecology clinic on 27<sup>th</sup> December 1999. She had no complaints. The wound had healed well. She had not yet received her periods. She was to be seen in 2 months but she was lost to follow up.

### **DISCUSSION**

This was a 32 year old patient, who presented with secondary infertility due to tubal blockage and peritubal adhesions bilaterally. She was managed by tubal surgery. Child



bearing to the woman is the ultimate expression of womanhood and to the man fathering children is seen as affirmation of masculinity. A woman's social status in societies of many developing countries is often pegged to her fertility. Failure to have children is seen as a social disgrace that causes stigmatization, marital upsets and psychological anguish (1, 2).

Infertility is defined as failure to achieve a pregnancy within a stipulated period of time, usually one year of regular, unprotected intercourse (1,2,3,4). In primary infertility neither of the couple have ever achieved a pregnancy while in secondary infertility, a pregnancy has been achieved at some time in the past (1-4). The patient presented here had secondary infertility.

About 25% of women will become pregnant during the first month of unprotected intercourse, 63% in 6 months, 75% in 9 months and 80 – 90% in 1 year. An additional 10% will achieve pregnancy in the second year (1-3). The patient presented here had regular unprotected sex for 5 years without achieving a pregnancy. She delayed in seeking medical advice.

Estimates of the prevalence of infertility are not very accurate and they vary from region to region. In general about 8% of couples experience some form of infertility during their reproductive lives (4). Other works have estimated the prevalence of infertility at 10 – 30%. Sub-Saharan Africa has average prevalence of infertility of 10.1% (1). The exact statistics for Kenya are not known, but Mati found that 60% of all patients attending the gynaecology clinic at Kenyatta National Hospital complained of infertility (5).

The female patient is often blamed for infertility but the woman contributes to 40 – 50% of cases. In 20 – 30% there are both male and female factors and the male contributes to 30% of cases. No cause was identified in 10 – 20% of patients (1, 2). In the patient presented here, the husband was investigated and found to be normal while the patient was found to have bilateral tubal blockage.



Infection constitutes the most important and most preventable cause of infertility. Sexually transmitted diseases (STDs), post partum and post abortal infections play an important role in certain parts of the world particularly in Africa. 85% of infertile women in Africa had infection-related infertility according to a WHO study in 1987. The high prevalence of STDs and the lack of their early and efficient management in Africa may have led to high levels of infertility and serious social consequences of this (1, 6). The patient presented here did not give a positive history of having suffered from STD but she had had an elective termination of pregnancy at an earlier date. Pelvic inflammatory disease complicates about 10% of elective abortion. *Chlamydia trachomatis* has been implicated (4).

In Africa, tubal blockage accounts for 85% of cases and in 49%, it is bilateral. 70 – 75% of tubal blockages are due to pelvic inflammatory disease (6). In the patient presented here, the tubal blockage was found to be bilateral.

Ovulation disturbances contribute to 20 – 25% of female infertility. These may arise from obesity or weight loss, psychological disturbances, Sheehan's syndrome, prolactinoma, hypo or hyperthyroidism, adrenal hyperplasia, polycystic ovary disease or premature ovarian failure (2).

Male causes of infertility include defects in the production of sperms or to a block in sperm transport from the testis, abnormalities in sperm count, morphology, motility and ejaculatory problems. Infection plays a lesser role in male infertility than in the female (1, 7).

At Kenyatta National Hospital (KNH), a male partner with satisfactory semen analysis or with children by another woman, the last-born being younger than the duration of infertility is considered normal (8). The husband of the patient presented had normal semen analysis, though it was not known if he had fathered children with another woman. Environmental pollutants like high levels of pesticides reduce sperm counts.

Occupational exposure to extreme heat may also lead to male infertility. Alcohol, drug abuse and excessive smoking have also been implicated in male infertility (1).

None of these factors were noted in the husband of the patient presented here. Coital problems account for 3 – 5% of infertility while unexplained infertility is found in 10% of infertile couples. There is also age related decline in fertility after 35 – 40 years in women (2).

The goals of the infertility evaluation are to determine the probable cause of infertility, provide accurate information regarding prognosis, provide counselling, support and education throughout the process of evaluation and to provide guidance regarding options of treatment (2).

Both partners need evaluation as infertility could arise from any of them. Investigation of the infertile couple begins with a careful history and physical examination, the age of the couple, duration of the marriage, previous reproductive histories for both and results of any previous investigations. Any past or present history of STDs, drug use or abuse, sexual interactions are reviewed. Menstrual history is also reviewed (1-3).

The male partner is then evaluated since investigations for the woman are more invasive, time consuming and expensive. Semen analysis is done for the male partner to assay the sperm count, motility, morphology and vitality (2, 4).

For the female, investigations are aimed at giving information about tubal patency and ovulation. Recording the basal body temperature is the simplest and least invasive method of detecting ovulation. Hormonal assays and endometrial curettage for dating may confirm this (1, 4).

Hysterosalpingography done around day 6 – 10 of the cycle outlines the uterine cavity and lumen of the tubes. Congenital malformations of the uterus, submucous fibroids, uterine synechia and polyps may be demonstrated (1, 2, 4).

It has been observed that 30% of women have enhanced fertility following HSG and a 3 – 4 month delay is advisable before further intervention procedures (2, 4). In the case presented here, HSG demonstrated a normal uterine cavity and distal bilateral tubal blockage.

Laparoscopy allows visual demonstration of intra-peritoneal pathology, like peritubal adhesions, fimbrial agglutination, endometriosis and other tubal or uterine pathology. At laparoscopy, the operability of the case and the prognosis is assessed. Surgical intervention where feasible can be carried out (1, 2, 4).

Dye instillation at laparoscopy demonstrates patency of the tubes. Laparoscopy in the patient presented here demonstrated peritubal adhesions and no dye spill bilaterally. The endometrial curettings at the same sitting showed late phase secretory endometrium and no acid-alcohol fast bacilli. The post-coital test (PCT) assesses the status of the sperms in cervical mucus after ejaculation (1, 4).

Ultrasound and hormonal assays including prolactin levels are also useful diagnostic procedures and can also be used to monitor therapy (1). Other tests are Salpingoscopy or Falloposcopy which are not available in our set up (9).

Treatment of infertility is often frustrating, unsuccessful, long and expensive and an emphasis on prevention is more appropriate (1). Infection related infertility, which accounts for a large proportion of cases in developing countries can be prevented by control of STDS through health education, promotion of condom use, early diagnosis and effective treatment, contact tracing and screening of high risk populations. Improvements in obstetric care and hygiene, avoidance of unduly prolonged and traumatic labour will prevent puerperal infections and its serious sequelae including infertility. Reduction of unsafe abortions and provision of family planning services may act as a preventive measure against infertility. Early effective treatment of complications of illegal abortion also reduces the risk of permanent damage (1).



Pregnancy will occur without treatment in 15 – 20% of couples diagnosed as infertile (2). Treatment is directed at the identified cause of infertility in other cases. Tubal occlusion requires micro-surgical management either at laparoscopy or laparotomy. Available options include pelvic adhesiolysis, salpingolysis, fimbriolysis and salpingostomy. Tube resection and re-implantation to the uterus or end-to-end anastomosis may be done (1-3,7,10). 6 – 15% of pregnancies that occur after successful surgery for blocked tubes are ectopic (1).

The success rate of tubal surgery depends on patient selection, type of surgery and the experience of the surgeon. Good prognosis patients have peritubal adhesions, minimal tubal pathology and obstruction on the fimbrial ends (2, 3, 10). Generally the success rate of surgical treatment is 25 – 30%, but in our set up the success rates is even lower (2, 10). Micro surgical technique gives better outcome and would improve success rates even in our set up (10). The patient presented here had pelvic adhesiolysis, salpingolysis bilaterally and cuff salpingostomy on the left tube. The results of surgery were unknown since she was lost to follow up.

In couples with infertility and whose therapy has been unsuccessful and all options of treatment have been exhausted, adoption may be advised. In-vitro fertilization where practised offers an alternative mode of management with pregnancy rates of 15 – 20% per transfer at best (3). This is not available in our set up and patients may require to travel out of the country for these services.

Treatment of infertile couples should also encompass management of the psychological effects of infertility on both parties (1).

Public health measures for control of STDs, prevention of puerperal and post abortal sepsis as well as changes in personal behaviour are important tools in fighting infertility in the developing countries including ours where results of surgical treatment are poor and the process long and expensive.

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## **CASE 10: MULTIPARITY- BILATERAL TUBAL LIGATION**

|                |          |                       |          |
|----------------|----------|-----------------------|----------|
| <b>Name:</b>   | B.A.     | <b>Last delivery:</b> | 16/08/99 |
| <b>Unit:</b>   | 0485385  | <b>Operation:</b>     | 06/10/99 |
| <b>Age:</b>    | 37 years | <b>Discharge:</b>     | 06/10/99 |
| <b>Parity:</b> | 5+0      |                       |          |

### **Presenting complaint**

The patient presented to clinic 66 on 30/09/99 and requested for sterilization because she had achieved her desired family size. She had no illness.

### **Obstetric and gynaecological history**

She had menarche at 14 years of age. Her menses had been regular every 28 days lasting 4 days. She had not received her menses since her last delivery on 16/08/99. She had used an intrauterine contraceptive device between 1989 to 1991, and Depo provera between 1991 to 1998. She was para 5+0 and all deliveries were spontaneous vertex at term in hospital.

### **Past medical history**

There was no history of major illness. She had no known drug allergies.

### **Family and social history**

The patient was a married tailoress. Her husband worked as an Accountant at the Ministry of Works. Both lived in Kibera, Nairobi. There was no known chronic illness in the family. She did not smoke and did not take alcohol.

### **Physical examination**

She was in good general condition. She was not febrile, not pale and not jaundiced. Her pulse rate was 76 per minute, blood pressure was 110/60mmHg.

The chest was clear, the cardiovascular and central nervous systems were normal.

### **Abdominal examination**

The abdomen was not distended. It was soft, non-tender and had no masses.

### **Pelvic examination**

She had normal external genitalia. The cervix was about 2cm long, firm and the os was closed. The uterus was anteverted, normal size and freely mobile. The adnexa and pouch of Douglas were clear.

### **Diagnosis**

A diagnosis of Multiparity with Desired Family Size was made.

### **Management**

The patient was planned for mini-laparotomy for bilateral tubal ligation. The procedure was explained to her and she gave an informed consent together with her husband. She was advised to fast after dinner of 5.10.99 and to shave her pubic and abdominal hair in the morning of 6.10.99. She was to report to clinic 66 at 7.30 a.m. on 6.10.99 with an escort and completed sterilization form.

On presentation on the morning of operation, the patient was re-examined and found to be healthy and she had correctly followed the given instructions. She was told to empty her bladder. The patient was dressed in a

theatre gown and was premedicated with intramuscular Atropine sulphate 0.6mg 30 minutes before being taken into theatre.

## **Operation**

In theatre the patient was put in semilithotomy position on the operating table. Vulvo-vaginal toilet was done. The patient was draped. Repeat of pelvic examination confirmed earlier findings. A Cusco's speculum was inserted into the vagina and positioned to expose the cervix. A uterine elevator was introduced through the cervical os into the uterine cavity.

The abdomen was scrubbed and draped with the patient in supine position. At the center of pubic crease 15mls of 1% Lignocaine hydrochloride was infiltrated. A transverse mini-laparotomy incision about 2cm long was made. The abdomen was opened in layers.

The patient was put in the Trendelenberg position to help deflect the gut. By manipulating the uterine elevator fundus was brought into view. From the fundus the right fallopian tube was tracked and hooked, then grasped using a Babcock forceps. Employing the Pomeroy's technique the tube was ligated. The procedure was repeated for the left fallopian tube. Haemostasis was ensured. The abdomen was closed in 3 layers and the wound was dressed. The operation lasted 15 minutes and the patient experienced no discomfort throughout the procedure. The uterine elevator was removed. The patient was wheeled to the recovery room.

## **Post operative management**

Half hourly observations were made of temperature, pulse, blood pressure and respiratory rate and these remained normal. The patient was started on oral Amoxycillin 500mg 8 hourly for 5 days and paracetamol 1g 8 hourly for 3 days. She was advised to keep the wound dressed for one week, when she will come back for removal of the skin stitch. She was discharged



home 6 hours after the operation. She was seen in the clinic after 1 week, the patient had no complaints. The wound was healed. The skin stitches were removed and the patient was allowed home.

## DISCUSSION

Voluntary surgical contraception (VSC) has over the last 3 decades become one of the most widely used family planning methods. In African nations, use of tubal sterilization remains low <sup>(3)</sup>. In Kenya 6% of married women have been sterilized. <sup>(2)</sup>

Tubal ligation was first performed in 1823 to prevent pregnancy in women who would need repeated caesarean section <sup>(4)</sup>. Sterilization is a permanent method of contraception. Female sterilization is ideal for those persons who are certain they need no further children and who need a reliable contraceptive method, and those women whom subsequent pregnancy may have an adverse effect on the woman's health. Our patient had obtained a completed family size form and she volunteered herself for sterilization.

Female sterilization is used more commonly by older women with a median age being 32 years, whereas other methods, pills, injections and Norplant are used by younger women in the peak child-bearing age <sup>(2,5)</sup>. Our patient was 37 years and had 5 living children.

In general the countries with the highest rates of fertility also have the highest rates of maternal, infant and child mortality <sup>(1)</sup>. African people have long valued fertility and as a result many couples have large families. Cultural conditions influence the use of VSC e.g. the husband's approval to female sterilization. <sup>(3)</sup>

In Kenya reports of the 1989 census indicated that the intercensal population growth rate for Kenya was 3.4 percent per annum, although the current growth rate is probably around 3.0 percent or slightly less <sup>(2)</sup>.

The national population policy for sustainable development has a set of goals, objectives and targets to guide its implementation up to the year 2010, amongst them, reduction of the total fertility rate (average no. of births per woman) from 5.0 in 1995 to 4.0 by the years 2000 to 3.5 by 2005 and 2.5 by 2010, and increase in the contraception prevalence rate from 33% in 1993 to 43% by year 2000 to 53% by 2005 and to 62% by 2010 <sup>(2)</sup>. The current contraceptive prevalence rate for Kenya is about 39% <sup>(2)</sup>.

Knowledge of family planning methods is nearly universal with 96% of all women 15-49 years and 98% of all men 15-59 years knowing at least one modern method of family planning <sup>(2)</sup>. However, the contraceptive use lags behind this high knowledge level.

The decision of when or even whether to have children is a basic human right <sup>(1)</sup>. Family planning decisions should be made on a completely voluntary basis, but also on the basis of thoroughly informed choice on the part of the individuals or couples <sup>(1,2,3,4)</sup>. Our client was extensively counseled on the other available methods of contraception, the irreversibility of the procedure, the nature of operation and the anaesthesia to be used. She then signed a consent form along with her husband.

Preoperative enquiries should include previous history of pelvic disease, previous abdominal surgery, lung disease, bleeding problems, allergies and recent infection. A pelvic examination is done to check uterine mobility and to rule out presence of pelvic infection or masses. It should also be ensured that the woman is not pregnant before sterilization. These were sought in our patient and were negative.

The timing of female sterilization, whether pregnancy related or not is very important in choosing the surgical approach and method of occlusion, Postpartum VSC offers greater convenience to the client and provides lower costs, greater ease of surgery and more efficient use of health resources<sup>(4)</sup>. However clients who are sterilized in the immediate postpartum period are more likely to have regret after the procedure. They should therefore have decided for the permanent method well before delivery or pregnancy related outcome. Our patient had an interval sterilization.

Minilaparotomy is a popular procedure. For postpartum sterilization a subumbilical minilaparotomy incision is made and for interval sterilization a suprapubic minilaparotomy is done, as in our client. This is done under light sedation with local anaesthesia. General anaesthesia is usually for most female VSC procedures and its risks outweigh its benefits. Minilaparotomy is difficult if the client is obese, the uterus is immobile or if the tubes have adhesions from infection or previous surgery. Laparotomy with incisions longer than 5cm may be performed under general anaesthesia when minilaparotomy is not feasible. Laparoscopy is also used, and is less painful, has lower complications, shorter operation and recovery time and leaves a small scar, but is not recommended for the immediate postpartum period<sup>(3,4)</sup>. Culdoscopy/culdotomy has been used to access the tubes but it is difficult and is associated with high infection rates<sup>(4)</sup>. The transcervical route has also been used for hysteroscopic injection of sclerosants but it is expensive, difficult and has lower success rates and it is still on experimentation.<sup>(3)</sup>

Sterilization in women involves mechanically blocking the fallopian tubes to prevent the sperm from reaching the eggs. This is accomplished by various methods. Our patient had ligation by Pomeroy's method. Pomeroy's method is the most widely used in Africa<sup>(3)</sup>. Besides the many methods of



ligation available, tubal occlusion is used, but is not very popular due to high failure rates from fistulae formation<sup>(3)</sup>.

Sterilization is associated with low rate of complications which include wound infection, haematoma formation, perforation of the uterus with the elevating instrument, bladder injury and sterilization failure. Following sterilization, pregnancy rates of <1% have been reported<sup>(3)</sup>. This may occur as a result of, the woman being pregnant at the time of sterilization, surgical error and equipment failure, fistula formation or spontaneous recanalization. Ectopic pregnancy should be ruled out any time a woman shows signs of pregnancy following tubal occlusion.

When standard techniques are used, sterilization is effective within the first day of use. It has a lower risk of pregnancy than do most temporary contraceptive methods. A number of circumstances usually hard to predict, may lead users to regret that sterilization procedure was performed, losing their children, getting divorced or remarried or wishing for additional children. Only 1% of women who undergo tubal sterilization request reversal<sup>(3,4)</sup>. The success of reversal is dependent on the length of normal tube preserved. Pomeroy's method has reversal rates approaching 50% and it is higher after use of clips and bands<sup>(4)</sup>. Reversal is also associated with high ectopic pregnancy rates<sup>(4)</sup>.

It is important to inform the client that sterilization does not protect against sexually transmitted diseases including HIV/AIDS. Family planning can help couples reduce factors that place the health of women and children at risk. Reproduction health care programs should therefore provide the widest range of service.

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## CASE NO. 11

## PELVIC ABSCESS - LAPAROTOMY AND DRAINAGE

|                       |                       |
|-----------------------|-----------------------|
| <b>Name</b> :P. A.    | <b>Parity</b> :1 + 0  |
| <b>Age</b> :22 Years  | <b>DOA</b> :9/7/2001  |
| <b>IPNO.</b> :0722633 | <b>DOD</b> :24/7/2001 |

## Presenting History

The patient was admitted through GOPC where she had presented with complaints of lower abdominal pains, abnormal vaginal discharge and lower abdominal swelling for 6 months.

## History of Presenting complaint

She had been well until September 2000 when she underwent an emergency caesarean section at Kisumu Hospital due to fetal distress. Thereafter she noted foul swelling vaginal discharge associated with lower abdominal pains. She also noted that she had frequency of micturition, and dysuria. The incision wound healed well but the above complaints persisted. She was started on antibiotics in various health facilities with no improvement. She later noted a lower abdominal swelling, which was increasing in size. She was therefore referred to our out patient clinic for follow up and further management.

### Obstetric and Gynaecological History

She was para 1 + 0, having undergone a casearean section in September 2000 at term and the baby succumbed after a week. She had her menarche at 14 years. Her L.M.P. was on 15/6/2001. Her periods lasted 3 days in a 30 days cycle. She had never used any contraceptive method.

### Past Medical History

This was not significant.



### **Family and Social History**

She was a single lady, staying with her aunt at Kayole. She was unemployed. She never drank alcohol or smoked cigarettes. There was no history of chronic illness in the family.

### **Physical Examination**

The patient was in fair general condition. She was not pale, not jaundiced and was afebrile. The body temperature was  $36.5^{\circ}\text{C}$ , and a blood pressure of 110/70mmHg. Her pulse rate was 98/minute regular and of good volume. The respiratory rate was 22/minute. The cardiovascular system, respiratory and central nervous systems were essentially normal.

### **Abdominal Examination**

There was a subumbilical midline incision scar. The lower abdomen was obviously distended. There was marked supra pubic tenderness and a firm mass arising from the pelvis equivalent to a 14 week gravid uterus. The mass was attached to the structures below but not the skin over it. The mass was not mobile.

### **Vaginal Examination**

The external genitalia were normal. The vaginal walls were moist and healthy. The cervix was long and os closed. There was a mass involving both adnexa and the uterus was involved in the mass. The mass was fixed to the surrounding structures. The pouch of Douglas was full. Cervical excitation was negative.

### **Diagnosis**

A diagnosis of an adnexal mass was made to rule out a pelvic abscess.

### **Investigations**

1. PAP Smear - Sample satisfactory with few polymorphs and no evidence of malignancy.
2. U/E -  
Na<sup>+</sup> - 140 mmol/l  
K<sup>+</sup> - 4.2 mmol/l  
Urea - 4.5 mmol/l  
Creatinine - 48 micromol/l
3. Full haemogram -  
WBC -  $6.4 \times 10^9/l$   
RBC -  $3.64 \times 10^9/l$   
HB - 10.2 gm/dl
4. Blood group - O Rhesus (D) Positive
5. U/S - The uterus appears normal in size and echogenicity. There is a complex mixed echo mass with a thick wall measuring 77 x 68mm in size in the left adnexal region and anterior to the cervical region. There is a small amount of fluid in the Pouch of Douglas.  
  
The bladder wall shows significant thickening.  
  
Both kidneys show dilatation of the pelvicalyceal system and ureter.
6. I.V.U. - Showed features of bilateral pyelonephritis more severe on

the right. There was proximal bilateral ureter dilatation. A

soft pelvic mass was noted on the left.

7. ELISA for HIV - Negative

### **Management**

She was planned for exploratory laparotomy. An informed consent was obtained and 2 units of blood were grouped and crossmatched ready for theatre. She was not allowed to eat anything from midnight of the day before surgery. On the morning of the day of surgery the patient was premedicated with atropine 0.6mg and pethidine 50mg both given intramuscularly 1/2 hour before theatre.

### **Laparotomy and Drainage**

In theatre, the patient was put under general anaesthesia. She was positioned in dorsal lithotomy position and vulva-vaginal toilet was done. She was catheterised and 200mls of clear urine obtained. Examination under anaesthesia confirmed earlier findings. Patient was then re-positioned in the supine position. The abdomen was cleaned and draped with sterile towels. The abdomen was opened in layers through the old sub umbilical incision scar. The omentum was found adherent to the uterus and abdominal wall. A lot of pelvic adhesions were found. The uterus and bladder were joined together into a huge pelvic mass and both the ovaries and tubes were adherent to the uterus.

The omentum was dissected from the anterior abdominal wall. The pelvic adhesions were also bluntly dissented and gently released. The bladder was dissected away from the uterus and a lot of greenish -white pus was found in the uterovesical pouch. This was drained out. The bladder was opened to confirm the origin of the pus since it looked like there was some pus in the

bladder wall. Inspection of the bladder showed a normal cavity, with a thickened bladder wall. The bladder was closed in 2 layers. All pockets of pus were opened and the abdominal cavity cleaned with Rifocin. A pus swab was taken and sent for microscopy, culture and sensitivity. Two corrugated drains were left in situ, one in the pouch of Douglas and brought through the right iliac fossa. Haemostasis was achieved. Swab and instrument were counted and found to be correct. The abdomen was closed by mass closure using number 1 nylon suture. The estimated blood loss was 1.2 litres and therefore she was transfused one unit of blood. She was successfully reversed from general anaesthesia.

### **Post Operative Care**

The patient was observed in the recovery room until she was fully awake and then transferred back to the ward. An indwelling bladder catheter was left in situ for 10 days. She was put on intravenous injection of flagyl 500mg, 8 hourly, crystalline penicillin 2 mega units 6 hourly and gentamycin 80mg still for 5 days. Pethidine was given intramuscularly 100mg, 6 hourly for 24 hours to relieve pain. On the 1st post operative day bowel sounds were still absent and hence I.V fluids continued.

On the second post operative day bowel sounds were present and hence the patient was allowed to have oral sips. The temperature was not elevated. Drains remained active, draining up to the 6th post operative day when they were removed. Check haemoglobin was done on the third post operative day and was 9.6gm/dl. The results for the pus swab revealed no growth of any organism. Urinalysis was also done on the third day and was normal. Stitches were removed on the 10<sup>th</sup> post operative day, and had healed well. The catheter was also removed and patient could control bladder function well. She was discharged home to attend GOPC in 6 weeks.

### **Follow Up**



She was seen as per the appointment and she had no complaints. She was not pale. The wound had fully healed and abdomen was soft. She was counselled on the effect of the infection on her future obstetric carrier and therefore advised to seek medical attention if she notices any difficulty in conceiving, since pelvic infection can lead to tubal blockage and hence infertility.

## Discussion

Presented is a patient who developed a pelvic abscess following a caesarean section for which laparotomy and drainage was done. Pelvic abscess is a collection of pus in the pelvic region including the pouch of Douglas. It is a major cause of morbidity and mortality among reproductive age group. Fomulu found that 1/3 of all gynaecological admissions at Kenyatta National Hospital are due to pelvic abscess (1). It was also found that of those admitted at Kenyatta National Hospital due to pelvic abscess, 30% were of age group 26 - 28 years. The incidence was high in nulliparas, and 63% were unmarried (2). In menopausal women, a pelvic abscess is usually secondary to pathology in the intestinal tract. The patient presented was 22 years old and was para 1 + 0.

A pelvic abscess may result from late or inadequate treatment of upper genital infection e.g. acute pelvic inflammatory disease, post abortal sepsis or puerperal sepsis. The infection may also be due to instrumentation e.g. insertion of IUCD, dilation and curettage or hysterosalpingography (3). At Kenyatta National Hospital, 18.2% of abortions were followed by pelvic abscess (1). The patient presented had a pelvic abscess following puerperal sepsis after a caesarean delivery. She sought treatment, but she was not adequately treated.

The bacteriology of the pelvic infection is a mixed picture of anaerobic and aerobic organisms of the upper genital tract. These include *N. Gonorrhea*, *E. coli*, *Actinomyces israelii*, *M. hominis*, *C. trachomatis*, and *Ureaplasma* (1-3).

Fomulu (KNH) found aerobes and anaerobes with *E.coli* occurring in 5% of all cases (1). The laboratory results for culture and sensitivity for our patient showed no growth, hence the cause of the infection was not known.

Patients usually present with lower abdominal pains, fever and vaginal discharge. The severity of the symptoms is often directly proportional to the size of the abscess, but occasionally even a large abscess may be totally asymptomatic. Dysuria and frequency of micturition may occur (3,4). A fluctuant mass may fill the cul-de-sac and cervical motion tenderness may be present. The patient presented had a firm pelvic mass and cervical excitation was not positive but she had dysuria and frequency.

The combination of physical findings, laboratory results with leucocytosis and occasional anaemia, and ultrasound examination usually allows the diagnosis to be made with confidence (3). Our patient had an ultrasound, which showed a complex adnexal mass, which was highly suspected to be an abscess. She was not anaemic.

The patient with pelvic abscess should be admitted in Hospital for management. Supportive measures are vital especially for the very ill patient in form of analgesia, intravenous fluids, nasogastric suction, blood transfusion and parenteral antibiotics. Some abscesses will resolve adequately with antibiotic treatment. Such response is defined by absence of fever, a decrease in WBC count by at least 3000 per mm<sup>3</sup>, a decrease in the size of the adnexal mass as well as general clinical improvement in the patient's condition. Where such response is not forthcoming then surgery is advocated (3, 4, 5).

Colpotomy drainage of a pelvic abscess is possible if the abscess is midline and should be adherent to the cul-de-sac peritoneum and should dissect the rectovaginal septum to assure the surgeon that the drainage will be extraperitoneal and that pus will not be disseminated transperitoneally. Also,

the abscess should be cystic or fluctuant to ensure adequate drainage (3). This was not possible in our patient since the pelvic mass was firm and adherent to the pelvic structures.

Experience with percutaneous drainage of intra-abdominal and pelvic abscess under ultrasonographic or computed tomography guidance has been reported (6, 7).

In exploratory laparotomy, pelvic adhesions should be released and the bowel should be packed off before the pelvic dissection commences. When both adnexa must be removed, a hysterectomy should be performed. Jackson Pratt suction drains are often placed above the fascia and brought out through a separate incision (3). The patient presented underwent laparotomy and 2 corrugated drains were left in situ one in the pouch of Douglas and the other in the utero-vesical pouch. Due to the young age of our patient and given that the tubes looked relatively healthy hysterectomy was not done.

Complications of pelvic abscess include chronic ill health, pelvic pain, dysmenorrhoea, Dyspareunia, bowel obstruction, infertility and ectopic pregnancy. Fertility is impaired in up to 10% of patients following conservative medical management. Septicaemia, septic shock, renal failure and septic thromboembolism are early complications, which have a high incidence of morbidity and mortality (3, 4).

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**CASE 12:****CERVICAL INTRAEPITHELIAL NEOPLASIA (CIN): TOTAL ABDOMINAL HYSTERECTOMY**

**Name :** M.W.                      **Parity :** 7+0  
**Unit No:** 0474101              **Admission:** 17/08/99  
**Age :** 43 years                  **Discharge :** 24/08/99

**Presenting history**

The patient had been followed up at a private clinic where she had presented with lower abdominal pain, backache and menorrhagia since 1991. An ultrasound that was done revealed small uterine fibroids. A Pap smear done showed moderate dysplasia. Directed biopsy was done at colposcopy which on histology showed CIN II. She was then referred to KNH for further management.

**Obstetric and gynaecological history**

She was a para 7+0. Her last delivery had been in 1991. Her last menstrual period had been 7/11/97. The cycles were 28 days and lasting 4 days. They heavy and in clots. There was no history of contraceptive use. She could not remember her age at menarche.

**Social and family history**

She was a married farmer whose spouse was a teacher. There was no history of chronic medical diseases in the family. She neither smoked cigarettes nor ingested alcohol.

**Past medical history**

There was no history of previous admissions or drug allergy.,.

**Physical examination**

Her general condition was good, she was not pale or febrile. The respiratory, cardiovascular and central nervous systems were normal.

### **Abdominal examination**

The abdomen was soft and non tender. There was no organomegaly.

### **Vaginal examination**

The external genitalia were normal, the vagina was also normal. The cervix was firm and the uterus normal size and mobile. There was no adnexal mass. On speculum examination, there was no macroscopic lesion on the cervix.

### **Diagnosis and management**

A diagnosis of CIN II in a 43 year old para 7+0 was made. The patient was scheduled for total abdominal hysterectomy. Hysterectomy was considered as the treatment of choice because the patient was of high parity and had menorrhagia in addition to cervical intraepithelial neoplasia.

### **Investigations**

A haemoglobin level done was 10.0 g/dl.

Urea and electrolytes were normal.

Preoperative preparation was done as described in the introduction.

### **Operation**

The abdomen was opened via a lower midline incision. The uterus, ovaries and fallopian tubes were grossly normal. There were no adhesions. Total abdominal hysterectomy was done as described in the introduction Swabs and instruments were counted and reported corrected and the abdomen closed in layers. The patient was transfused one unit of blood intraoperatively. Estimated blood loss was 600mls.

## **Postoperative management**

The patient was started on oral sips after 24 hours when she was also ambulated. A check haemoglobin done on the third postoperative day was 10.1 g/dl. The stitches were removed on the seventh postoperative day and the wound was clean. The patient was discharged home.

She was seen in the gynaecology outpatient clinic after six weeks. The wound was well healed but she still had some mild abdominal pain. Histology showed that there was CIN II. When reviewed at the clinic after six months, the patient was pain free. She was discharged to be seen only when necessary.

## **DISCUSSION**

The patient presented was a 43 year old para 7+0 who had been followed up for lower abdominal pain, backache, and menorrhagia for a period of six years. She was noted to have moderate dysplasia on Pap smear. Directed biopsy was done at colposcopy that on histology showed CIN II.

Cervical intraepithelial neoplasia is a neoplastic change confined to the surface epithelium without invasion of the stroma <sup>(1)</sup>. Dysplasia refers to disordered growth and development. On the cervix, this term is applied to abnormal zones where only part of the thickness of the squamous epithelium has been replaced by abnormal cells. Dysplasia is divided into mild, moderate and severe depending on the degree of involvement of the epithelium. In severe cases, the histological appearance resembles carcinoma in situ with the exception that a few cell layers near the surface are still capable of maturation. Carcinoma in situ exists when all of the cell layers from the basement membrane to the surface disclose an immature, disorganized pattern. If untreated, severe dysplasia will progress to carcinoma in situ and even invasive cancer in about one third of patients <sup>(2)</sup>.



The various degrees of dysplasia can be classified as cervical intraepithelial neoplasia (CIN), with mild dysplasia CIN I, moderate dysplasia CIN II and both severe dysplasia and carcinoma in situ as CIN-III<sup>(2)</sup>.

The epidemiological factors in CIN are similar to those of cancer of the cervix. It appears to be associated with various factors. These include low socioeconomic status, early age of marriage, early age of first coitus, uncircumcised sexual partners, high parity, multiple sexual partners, human papilloma virus and herpes simplex type II infection. The prevalence figures vary from 1.2 to 3.8% in non pregnant patients. Pregnancy may produce changes in the cervical epithelium that may mimic those of CIN. Some of these variations may be related to folic acid deficiency. The peak incidence is in the age group 25 to 35 years.

CIN is a condition in which the patient is asymptomatic and there is not even a grossly visible lesion on the cervix. Nevertheless, a thorough history regarding intermenstrual or contact bleeding should be taken and careful palpation of the cervix and speculum examination should be performed with every gynaecological examination. When there is a visible lesion present on the cervix, it should be biopsied and a smear obtained whether or not the lesion looks like cancer<sup>(3)</sup>. A Pap smear which examines samples of exfoliated or scraped cells from the surface of the cervix or vagina serve as microbiopsies by which the cytopathologist studies the multiple processes of health and disease. It is a relatively inexpensive, painless and accurate method of diagnosing cervical dysplasia and cancer. It is ideal for population screening to detect cervical neoplasia<sup>(4,5)</sup>.

In a patient with cervical abnormality, colposcopy can locate the suspect area, evaluate its size and severity and take directed biopsies to establish the histological diagnosis. If there is a lesion on the cervix, the



examiner must be able to see the entire extend of this abnormality, or the examination should be listed as inadequate <sup>(5)</sup>.

When the squamocolumnar junction can not be visualized with the colposcope, the lesion extends in to the canal and the upper limits can not be seen, or if the smear, colposcopic evaluation and the directed biopsy do not agree, then a diagnostic cone biopsy is indicated. If microinvasive carcinoma is suspected, cone biopsy must be done. If colposcopy is not available and there is no gross lesion on the cervix nor non staining areas on Schiller test, a diagnostic conization is indicated <sup>(3)</sup>.

The patient presented was a 43 year old para7+0 who was followed up for menorrhagia. A pap smear done revealed moderate dysplasia. Colposcopy and directed biopsy was done which on histology showed CIN II.. She also had menorrhagia and an ultrasound showed small uterine fibroids.

Treatment of CIN is not standardized and many different factors enter into the therapeutic decision. Prompt therapy for all women with a diagnosis of any degree of CIN is recommended based on the proven poor follow-up of this group of patients and the uncertainty of which lesions will progress and how rapidly this progression may occur in any given patient. 15% of patients with mild dysplasia will progress to carcinoma in situ over prolonged periods of follow-up <sup>(6)</sup>. The severity of abnormality and its location and extent together with the social situation of the patient may all influence the choice of treatment. Various approaches including cryotherapy and laser cone biopsy, hysterectomy and even radiation therapy on rare occasions may be employed. Interferon gel applied topically has also been reported to be effective therapy for CIN. Although all methods of treatment have an inherent failure rate because of lack of complete destruction or removal of the neoplastic epithelium, incorrect pretreatment evaluation resulting in a failure to diagnose

invasive cancer is an added problem with destructive methods of therapy. Hysterectomy remains the treatment with the lowest recurrence rate.

Treatment of CIN is not recommended during pregnancy. Once invasive cancer had been ruled out, the patient may be followed up to be sure a rapidly progressive lesion does not exist. A complete re-evaluation of the situation is done 8-12 weeks post partum and appropriate therapy utilized <sup>(3)</sup>.

In the patient presented, simple hysterectomy was employed as treatment and on histology of the hysterectomy specimen, the diagnosis was CIN II. Hysterectomy was chosen because in addition to cervical intraepithelial neoplasia, the patient had menorrhagia.

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## **CASE NO .13**

### **IMPERFORATE HYMEN - CRUCIATE INCISION**

**Name** :J. K.

**DOA** :31/6/2001

**IPNO** :0722657

**DOD** :9/7/2001

**Age** :18 Years

**Date of Operation** :6/7/2001

#### **Presenting Complaint**

The patient experienced cyclical monthly lower abdominal pain for 2 years.

#### **History of Presenting Illness**

The pain was cramp-like and would disappear after two to three days. There was no associated vaginal bleeding. She had noted a mass at the vaginal opening, which she described as egg-like in shape. She had been seen at Makindu Sub - District Hospital of Makueni District whence she was referred to us for further management.

#### **Past Medical History**

This was not significant.

#### **Obstetric and Gynaecology History**

She had not started getting her menses yet. She was para 0 + 0, with no history of any sexual intercourse. She therefore was not on any contraception

#### **Family and Social History**

She was the first born in a family of 6. Other siblings were normal and alive. She had finished standard 8 in 2000 but could not continue with her education due to the above complaints. There was no history of any chronic illness in the family.

#### **Physical Examination**

She was in fair general condition. She was not pale or jaundiced and had no lymphadenopathy. Her blood pressure was 110/60 mmHg, with a pulse rate of 82/minute regular and of good volume. The respiration rate was 24/minute and temperature 36.8<sup>0</sup>C.

**Breast Examination**

The breasts were symmetrical and normal in appearance. There were no masses felt and the breasts were non tender. The nipple and areolar were well developed. They were at Tanner 5.

**Abdominal Examination**

The abdomen was scaphoid and had no areas of tenderness. No masses were palpated.

**Vaginal Examination**

She had normal external genitalia with normal hair distribution. There was a buldging occluding membrane at the vulva, which was purple in colour. The swelling was cystic and tense. Rectal examination revealed a large tense cylindrical swelling filling the vagina. The uterus was of normal size.

**Diagnosis**

A diagnosis of imperforate hymen was made.

**Investigations**

|                       |                   |                 |
|-----------------------|-------------------|-----------------|
| Haemoglobin Level     | -                 | 14.0 gm/dl.     |
| Urea and Electrolytes | -                 | Urea 6.6 mmol/L |
|                       | Na <sup>+</sup> - | 128 Mmol/L      |
|                       | K <sup>+</sup> -  | 2.81mmol/L      |
|                       | Creatinine-       | 60 µmo/l        |

**Management**



The patient was fully prepared for theatre. An informed consent was given and on 3/4/1999 she was taken to theatre. She was put under general anaesthesia. She was put in lithotomy position and the vulva and perineum cleaned with antiseptic solution. The patient was draped with sterile towels. The urinary bladder was catheterised with a Foley's catheter, which was left in situ. Inspection of the vulva and rectal examination confirmed earlier findings. A cruciate incision was made on the imperforated hymenal membrane at the 2-,4-,8-,and 10- O'clock positions . Chocolate brown coloured haematocolpos drained out and about 400mls of blood was obtained. Digital examination was deferred. General anaesthesia was reversed.

### **Post Operative Care**

The patient was transferred back to the ward where she was started on oral, tetracycline 500mg 6 hourly and metronidazole 400mg 8hourly for 5 days. She was put on oral paracetamol 1gm 8 hourly for 48 hours. She recovered well from the operation and was discharged home after 4 days on oral antibiotics to be reviewed in GOPC after 4 weeks.

### **Follow Up**

She was seen in the clinic as per the appointment and found to have healed well. The cruciate incision was patent. Digital examination revealed a normal vaginal canal and uterus. She was sent back to Makindu Hospital for further follow up.

### **DISCUSSION**

A 18 years old lady who had imperforate hymen is presented. Cruciate incision was successfully done.

The hymen is a membrane of connective tissue covered by stratified squamous epithelium. The hymen has more apparent variations in structure than any other part of the female genitalia (1).

The hymen is the junction of the sinovaginal bulbs with the urogenital sinus. The hymen is usually perforated during embryonic life to establish a connection between the lumen of the vaginal canal and the vaginal vestibule. If there is no perforation through this membrane, the hymen is termed imperforate (1,2).

Although variations in hymenal development occurs, complete blockage of the vaginal orifice by the hymen is rare. Three main hymenal configurations have been observed: fenestrated, circumferential and posterior rim (3). The patient presented had complete blockage of the vaginal orifice.

Imperforate hymen is rarely diagnosed before puberty. Most patients are seen at the age of 13 to 16 years of age when symptoms begin to appear (1,2). The patient presented had symptoms at 16 years of age but only sought medical attention when she was 18 years.

The symptoms after the onset of puberty are due to the accumulation of menstrual blood. The blood first accumulates in the vagina leading to hematocolpos. Patient may feel a slight fatigue and have cramping discomfort suggesting menstruation, but will have no history of any passage of menstrual blood, through the vaginal outlet (1,2). Repeated accumulation may lead to hematometra and hematosalpinx and even hemoperitoneum may occur (1,2,4).

The most common symptoms of vaginal overdistension are low back pain, discomfort in the pelvis and pain in the lower abdomen. Pain is often aggravated by defecation. Urinary retention may occur (1, 2). Our patient had monthly lower abdominal pains with no vaginal bleeding.

A tender mass often is palpable suprapubically. This is as a result of uterine enlargement and upward displacement, bladder distension or both. Protrusion

of the hymen usually is visible and is sometimes massive and dark in colour (1,2). Our patient had no palpable abdominal masses but had protrusion of the hymen with a purple mass.

The management of an imperforate hymen is purely surgical. The aim of such a procedure is to relieve pressure on the proximal organs, create space for menstrual blood to escape and allow satisfactory coitus. The hymenal membrane is simply incised preferably at the 2, 4, 8 and 10 O'clock positions. There are no major complications. Uterine perforation can occur if instrumentation is done (1,2). Our patient had a cruciate incision done and drained the haematocolpos. A late complication of the surgery is dyspareunia which is rare. It is due to stenosis occurring at the vaginal introitus, which may occur with healing.

Follow-up evaluation of the vagina and pelvis should be deferred for 4 - 6 weeks to reduce the risk of introducing infection.

Our patient healed well and during follow-up showed no complications. She needed further evaluation, since imperforate hymen is associated with urinary tract anomalies.

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## CASE NO. 14

### SYMPTOMATIC UTERINE FIBROIDS – TOTAL ABDOMINAL HYSTERECTOMY

|                        |                       |
|------------------------|-----------------------|
| <b>Name</b> :L. W.     | <b>Parity</b> :3 + 0  |
| <b>Age</b> :45 Years   | <b>DOA</b> :13/3/2001 |
| <b>IP No.</b> :0705060 | <b>DOD</b> :19/3/2001 |

#### Presenting Complaints

She was admitted to ward 1B through the Gynaecolgy Out Patient Clinic where she had presented with complaints of lower abdominal pains, heaviness on the lower abdomen and slow growing lower abdominal mass.

#### History of Presenting Illness

She had experienced lower abdominal pains for the previous 5 years, which was followed by a feeling of heaviness on the lower abdomen. She later noted a swelling on the lower abdomen, which was slowly increasing in size. Since then she had been having normal flow of her menses with no associated dysmenorrhoea. She had sought medical attention at various health institutions until she came to Kenyatta National Hospital gynaecology Clinic and was subsequently admitted.

#### Past Obstetric and Gynaecology History

She was Para 3 + 0. Her last delivery had been in 1981. Her menarche was at 15 years. Her last menstrual period was on 19/2/2001. She had menses for 5 days. Her menstrual cycle was of 25 days, regular and of normal flow. She had no dysmenorrhea. She had used condoms between 1983 and 1985 and stopped when she divorced. She had not used any other method of family planning.

#### Past Medical History

This was not significant.

### **Family and Social History**

She was divorced. She had retired as a typist and had 3 living children.

She neither smoked cigarettes nor took alcoholic drinks. There was no history of chronic illness in the family.

### **Systemic Enquiry**

This was unrevealing.

### **Physical Examination**

She was in good general condition, not pale, and had no evidence of oedema or jaundice. The blood pressure was 120/80 mmHg, pulse rate 72/minute, regular and of good volume. Her respiratory rate was 18/minute.

The central nervous system cardiovascular and respiratory systems were normal.

### **Abdominal Examination**

The abdomen was distended in the suprapubic region, extending to the umbilical region. A mass arising from the pelvis corresponding to a 26 weeks gravid uterus was palpated. It was firm, tender, mobile and its surface was irregular. The liver and spleen were not palpable.

### **Vaginal Examination**

The external genitalia were normal. Speculum examination revealed no abnormality of the vaginal vault or cervix. On digital examination the cervix was firm, and its os closed. On bimanual palpation the mass was found to be continuous with the cervix, firm, nodular and mobile. The adnexa were free and Pouch of Douglas empty and non tender.

### **Impression**

A diagnosis of symptomatic uterine fibroids was made.

## Investigations

1. Ultrasound-. The uterus was bulky with multiple low echo masses suggestive of uterine fibroids, the largest measuring 8.2x 7.1cm. Both ovaries appeared normal.
2. Haemogram: Haemoglobin - 12.5 gm/dl  
WBC -  $8.2 \times 10^9/l$
3. Urea and Electrolytes  
Na<sup>+</sup> - 143 Mmol/l  
L<sup>+</sup> - 4.7 mmol/l  
Cl - 101 Mmol/l  
Urea - 5.7 Mmol/l
4. Pap Smear - Pap Class I(CIN-0).
5. I. V. U. was reported to have shown right hydronephrosis secondary to a pelvic mass.

## Management

She was counselled for the type of operation planned and gave consent to the operation of total abdominal hysterectomy. Two units of compatible blood were availed.

### Total Abdominal Hysterectomy

The patient was starved from midnight on the eve of the operation day. An enema was given at 6am on the morning of operation and premedication in the form of intramuscular 0.6 mg atropine sulphate and pethidine 50 mg was given 30 minutes before theatre.

In theatre, the patient was anaesthetised and put in the dorsal position. The vulva and the vagina were cleaned. The bladder was catheterised and 50mls

of clear urine drained. The catheter was left insitu. Pelvic examination under anaesthesia confirmed earlier findings. The vagina and cervix were painted with methylene blue.

The patient was then put in the supine position and her abdomen cleaned and draped, then opened in layers through a sub-umbilical mid line incision. A self-retaining retractor was inserted and the gut was packed away using sterile abdominal packs and the pelvis was inspected. The size of the uterus was found to be 26 weeks with both the ovaries and tubes healthy. There were no adhesions. The uterus was delivered through the abdominal incision. Total abdominal hysterectomy was performed as described in the introduction.

After a correct count of the swabs and instruments the abdomen was closed in layers. The estimated blood loss was 800mls. The wound was dressed with sterile gauze. Anaesthesia was reversed.

The uterus was cut open longitudinally revealing a normal endometrium. There were multiple intramural fibroids. The specimen was taken for histology.

### **Post Operative Management**

She was observed in the recovery ward until she was fully awake then transferred back to the ward. She was put on intravenous fluids, antibiotics and pethidine. On the first post operative day she was found to have bowel sounds and hence started on oral sips. Check haemoglobin on the 3<sup>rd</sup> post operation day was 11.0gm/dl. She recovered well and on the 4<sup>th</sup> post operation day she was discharged home for removal of stitches at the nearest health institution on the 7<sup>th</sup> day. She was to come again to the gynaecology clinic after 6 weeks.

### **Histology Report**

Histology showed benign uterine leiomyoma and a normal cervix.



## Follow Up

She was seen and found to have no complaint during her review at the gynaecology clinic. The wound had healed well and the vulva and vagina were healthy. The vaginal vault was intact. She was discharged from the clinic.

## DISCUSSION

The patient presented had symptomatic uterine fibroids characterised by a huge abdominal mass and lower abdominal pain. Total abdominal hysterectomy was done and she did well post operatively and in the follow up.

Uterine leiomyomata are the commonest tumors of the uterus and the female pelvis. They are benign tumors comprised mainly of smooth muscles but containing varying amounts of fibrous tissue. The incidence of uterine fibroids is not accurately known. This is because most are asymptomatic.. The tumors are more common in blacks than in whites ie 3 - 9 times more. They grow larger and occur at an earlier age in black women. The tumors are rare below the age of 20 years. The peak incidence has been reported to be 30 - 40years (1-3). The patient presented was 45 years old though the symptoms started 5 years earlier when she was 40 years (1-3). Wanjala found uterine leiomyomata to account for 66.8% of hysterectomies done at Kenyatta National Hospital. Two thirds of the patients in his study were aged 26-40 years(4).

Their etiology is obscure. Their growth is thought to be dependent on oestrogen. Thus the tumours thrive during years of greatest ovarian activity and regress after menopause, when the ovarian oestrogen production declines (2). However, isolated cases of postmenopausal growth of new fibroids have been reported(1). It is possible that when fibroids grow postmenopausally, it is in response to oestrogen production from some source(2). The patient

presented was para 3 + 0 having delivered 20 years before. This shows she had a prolonged exposure to unopposed oestrogen release.

Most fibroids are located in the corpus of the uterus, with only a few being sited in the cervix. In our patient, the uterine corpus was massive with multiple fibroids. Fibroids may be subserous, intramural or submucous. Intramural fibroids are the commonest. Subserous and submucous fibroids may be pedunculated. Fibroids are mainly composed of spindle shaped smooth muscle cells arranged in a whorl-like or interlacing pattern, with a variable amount of fibrous tissue that increases with age or size of fibroid.(1). They are surrounded by a pseudo-capsule comprising compressed normal uterine wall.

The majority of fibroids are asymptomatic, and need only to be observed from time to time(1-4). Less than 50% of patients with uterine leiomyomata have symptoms, which include menorrhagia, metrorrhagia, abdominal swelling and spontaneous abortion. Most researchers have reported that pain is not a common thing with leiomyomata (1-3), but experience at the Kenyatta National Hospital is otherwise. Pain was found to occur in 57.6% of cases (4). Pain is thought to result from degeneration with the tumor, circulatory occlusion, infection, torsion of pedunculated tumor or myometrial contraction in attempts to expel a submucous leiomyoma from the uterine cavity (1,3,4). Abnormal uterine bleeding like menorrhagia is due to an increase in the surface area of the endometrium by submucous fibroids, increased vascularity, associated endometrial hyperplasia and compression of the veins by the intramural fibroids leading to dilation and engorgement of the venous plexuses in the endometrium and the myometrium. There may be post menopausal or intermenstrual bleeding due to ulceration and infection of the submucous (particularly pedunculated) fibroids. In postmenopausal cases, malignancy must be excluded when this occurs. The abdominal mass may cause pressure symptoms on the urinary bladder, rectum and lymphatic and venous drainage causing frequency of micturition, partial constipation and

oedema of the lower limbs respectively. Infertility or pregnancy wastage may result from impaired implantation as a result of distortion of the endometrial cavity by submucous fibroids. Our patient had an abdominal mass and lower abdominal pain.. The patient did not present with menorrhagia or pressure symptoms to the bladder and rectum, though IVU done showed features of obstructive uropathy.

The major complications of uterine fibroids include haemorrhage, infection of ulcerated submucous fibroids, torsion of subserous pedunculated fibroids, degeneration in pregnancy, compression of the ureters, infertility, habitual abortions, premature labour and malignant sarcomatous change which occurs in 0.2 – 0.7 percent of the cases. Sarcomatous change should be suspected if postmenopausal fibroids greatly increase in size and cause postmenopausal bleeding.

Fibroids may shrink after menopause with regression of ovarian oestrogen secretion. The degenerations that can occur include hyaline, cystic, fatty, red and myxomatous changes. Hyaline degeneration is the most common while red degeneration tends to occur more commonly in pregnancy. None of these changes were seen in our patient.

The mere presence of uterine fibroids does not mandate intervention. The asymptomatic patient may be managed expectantly with examination every 6 months to rule out rapid enlargement. This is especially true for women who are planning to conceive. A rapidly enlarging myoma is only rarely due to sarcoma in a premenopausal patient. It may be due to pregnancy or to the use of oral contraceptives containing large amounts of oestrogens. In the postmenopausal patient, however, growth of a uterine leiomyoma is highly suggestive of a malignancy. A uterus that is larger than 12- 14 weeks gestational size in a woman with several years prior to menopause who is



planning no further pregnancies should be considered for hysterectomy before there is further growth.

The young woman who has asymptomatic fibroids and who is prepared to attempt pregnancy should be encouraged to do so. The rationale for myomectomy is that small tumours are more likely to be successfully removed with less risk of complications. The obvious disadvantages are the morbidity of the procedure, adhesion induced impairment of fertility and a 15-45 % risk of subsequent growth of new fibroids requiring further surgery.

Medical alternatives to surgical intervention involve production of hypo-oestrogenic states. Progestins have been sporadically reported as successful. The most promising short-term results have come from the use of leuteinizing hormone releasing hormone (LHRH) analogues, which cause significant shrinkage of the fibroids. These GnRH analogues reduce the size of the fibroids by about one third of their pretreatment size after three months of treatment. A particular indication for GnRH is for pretreatment before surgery by controlling menstrual blood loss and reducing tumour size. This may avoid need for any operation, but close continued supervision will be essential. It also allows time to enable an initially low haemoglobin in the patient to be raised by use of haematinics. Disadvantages of treatment with these agents include their effect on a fibroid capsule, which becomes thinner, hence is not easily seen and removed at operation and then subsequently regrows. For our patient, who was 45 years old, the uterine size and symptoms were such that a total abdominal hysterectomy was the treatment of choice.

Both ovaries were not removed since she had not gone into menopause, though Mattingly advised the removal of both ovaries in patients undergoing total abdominal hysterectomy for uterine fibroids after the age of 40-45 years, as the ovaries' function of producing oestrogen continues minimally after this



and there is a risk of 1% developing ovarian cancer after the age of 40 years (2).

Psychosexual issues among women who have undergone hysterectomy have been analysed. Given that the uterus is a symbol of femininity, for some women loss the uterus means the end of fertility and for some women fertility is an essential aspect of being a woman. At Kenyatta National Hospital Elfenesh showed that the ability for post hysterectomy psychosexual adjustment with respect to sexual desire reduces with advancing age. She also showed that pain and depression due to loss of the uterus were the commonest cause of loss of sexual desire post hysterectomy (10). The patient presented was counselled and informed that she would not receive her menses after the operation.

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## **CASE NO. 15**

### **RUPTURED ECTOPIC PREGNANCY - RIGHT SALPINGECTOMY**

**Name** :C. M.                      **Para** : 2 + 0  
**Age** :26 Years                **DOA** : 20/5/2001  
**IP No.** :0736754            **DOD** : 25/5/2001

#### **Presenting Complaints**

The patient presented with history of lower abdominal pain for 3 weeks and lower abdominal swelling for 3 days.

#### **History of Presenting complaints**

C. M. was admitted to the acute gynaecology ward through the casualty department on 20/5/2001. She had presented there with 3 days history of lower abdominal distension, 3 weeks history of lower abdominal pain and vaginal bleeding. Since the onset of the problem, she had been seen at a private clinic and treated for amoebiasis. Since the condition did not improve, she was seen by a herbalist who applied some herbs on the lower abdomen. This did not solve her problem and therefore she decided to seek attention at the Kenyatta National Hospital because she had noted that she was becoming weaker and was now walking with difficulties due to the lower abdominal pain and distension.

#### **Past Obstetric and Gynaecological History**

She had her menarche at 15 years. Her L.M.P was on 25/3/2001 therefore she had an amenorrhea of 8 weeks. Her periods were regular, occurring every 28 days and lasted for 3 days. She had no associated dysmenorrhea and flow was moderate. She was para 2 + 0. She had her last delivery in 1998 which was normal and the baby was alive and well. She gave no history of chronic lower abdominal pain or vaginal discharge. She had not been treated for any sexually transmitted disease. She had used contraceptive pills from 1998 to

2000, when she changed to Depo Provera. She had her last injection six months before.

### **Past Medical and Surgical History**

This was not significant.

### **Family and Social History**

She was divorced in 1995. She was a casual labourer at a Kariobangi cafe. She used to drink alcohol but she had never smoked cigarettes. There was no chronic illness in her family.

### **Physical Examination**

She was sick looking and in pain. She was pale but afebrile. Temperature was 36.8°C. Her pulse rate was 102 beats per minute, regular and of good volume. The blood pressure was 97/49 mmHg. The respiratory rate was 20/min. There was no leg oedema, or lymphadenopathy.

The central nervous, cardiovascular, and respiratory systems were normal.

### **Abdominal Examination**

The abdomen was slightly distended at the hypogastrium and in the flanks. The abdomen was moving with respiration. There were multiple therapeutic marks in the hypogastric region. On palpation, she had marked tenderness in the suprapubic region, accompanied by guarding and rebound tenderness. Shifting dullness and fluid thrill were demonstrated. The liver and spleen were not palpable.

### **Vaginal Examination**

The extended genitalia and vagina were normal. The cervix was long, soft and the os closed. Cervical excitation was positive. There was tenderness and fullness of both adnexa and pouch of Douglas. It was difficult to determine the uterine size due to tenderness. Blood was noted on the examining fingers.



Paracentesis was done and it was positive for non- clotting blood.

### **Diagnosis**

A diagnosis of ruptured ectopic pregnancy was made and patient prepared for emergency laparotomy.

### **Management**

An intravenous line with a normal saline was established using a wide bore cannula. Blood samples for grouping and cross-matching and haemoglobin estimation was taken. Informed consent was obtained and the patient was shaved in the pubic region. She was premedicated with intramuscular atropine sulphate 0.6mg and taken to theatre.

### **Laparotomy and Right Salpingectomy.**

In theatre, the patient was anaesthetised and put in the semilithotomy position. Vulvo-vaginal toilet was done and the patient aseptically catheterised. Clear urine was obtained.

The patient was then put in supine position and the abdomen cleaned with savlon and surgical spirit and draped with sterile towels. A sub-umbilical midline incision was made. The abdomen was opened in layers. Haemoperitoneum was encountered and 2000mls of blood evacuated. Massive old clots were found in the pouch of Douglas and adherent to the left ovary and left fallopian tube. The Right fallopian tube was ruptured and bleeding at the ampullary region. The right ovary was healthy. The uterus looked healthy but was bulky.

There was no evidence of previous pelvic inflammatory disease. The intestines were packed away from the operation area using a sterile abdominal pack. A curved haemostatic clamp was applied about 1 cm proximal to the

ruptured gestational sac. Another clamp was applied 2 cm distal to it. The tube was divided just distal to the proximal clamp and proximal to the distal clamp. The part containing the ectopic gestation sac was removed and sent for histology. The mesosalpinx, the cut end of the tube and the bleeding vessels were ligated with chromic catgut No. I and haemostasis achieved. The abdominal cavity was cleaned with warm saline, and the abdomen closed in layers after the instruments and swabs count was found to be correct. Anesthesia was then reversed.

### **Post Operative Care**

The vital signs were observed half hourly until the patient was fully awake and then 4 hourly. She continued with intravenous 5% dextrose and alternated with normal saline until the bowel sound returned to normal. Intravenous crystalline penicillin 2 mega units 6 hourly and gentamycin 80 mg 8 hourly were given for 48 hours.

Intramuscular Pethidine 100mg 6 hourly was given for 24 hours for analgesia. Her fluid input and output chart was normal. Her post operative recovery was uneventful. Her check Hb on the third postoperative day was 7g/dl. She was discharged on her 5th post operative day for removal of stitches at the nearest health centre. She was advised to come for review at the gynaecology clinic in 6 weeks time. She was discharged home on haematinics and antibiotics.

### **Follow Up**

She was seen in the gynaecology out patient clinic and had no complaints. The incision had healed well and pelvic examination was normal. She was counselled on family planning methods and referred to the family planning clinic.

## DISCUSSION

The patient presented was a 25 year old para 2 + 0 who presented with lower abdominal pain and vaginal bleeding for three weeks and was diagnosed to have a ruptured tubal pregnancy for which laparotomy and right partial salpingectomy was done.

Ectopic pregnancy is the implantation of a blastocyst, anywhere else other than the endometrial lining of the uterine cavity. More than 95% of ectopic pregnancies involve the oviduct (1). Ectopic pregnancy was first recognised in 1693 by Busiere, when he was examining the body of a prisoner executed in Paris. Gifford of England made a more complete report in 1731 (2).

The etiology of ectopic pregnancy is not known, but there are factors associated with increased incidence of ectopic pregnancy. These include mechanical factors e.g. salpingitis, peritubal adhesions, developmental abnormalities of the tube, previous ectopic pregnancy, previous pelvic operations including abortion and tumors that distort the tube (1).

Functional factors that delay passage of the fertilised ovum into the uterine cavity also lead to increased incidence of ectopic pregnancy (1). Cigarette smoking at the time of conception had been shown to increase the incidence of ectopic pregnancy (3). Several forms of assisted reproduction have been reported to increase the incidence of ectopic pregnancy. In a study by Webala at Kenyatta National Hospital, he found that 69% of the patients with ectopic pregnancy had associated chronic pelvic inflammatory disease (PID) (4). The patient presented had no evidence of (P I D).

Failed contraception increases the incidence of ectopic pregnancies. With the use of any contraceptives the actual number of ectopic pregnancies is decreased because pregnancy occurs less often (5). At Kenyatta National Hospital it was shown that overall, use of IUCDs does not increase the



incidence of ectopic pregnancy, but if used for over 2 years there is a 5 - 6 times increase in the risk (6).

The incidence of ectopic pregnancy in rural Kenya is 1:81 deliveries (7), as compared to that found in Nigeria of 1:84 deliveries (8).

Various studies have been done to determine the site of ectopic pregnancy. About 95% of extra uterine implantations occur in the oviduct, 55% of these occur in the ampulla, 20% in the isthmus, 17% in the fimbria, while the interstitial segment accounts for about 2-4% (2). At Kenyatta National Hospital, ampullary ectopic pregnancy accounted for 60% of all ectopic pregnancies admitted in the hospital. 13% were fimbrial, 12% were isthmal and 7% were cornual (9).

Clinical manifestations of a tubal pregnancy are diverse and depend on whether rupture has occurred. Most patients present with pelvic and abdominal pain and amenorrhoea with some degree of vaginal spotting or bleeding. Dizziness and light headedness may occur (12). The patient presented had all the above symptoms, though the symptoms progressed slowly until they were severe at the time of admission.

Early response to moderate haemorrhage many range from no change in pulse and blood pressure to a slight rise in blood pressure or a vasovagal response with bradycardia and hypotension. The temperature may be normal or low (1). Our patient was found to be hypotensive, with a rapid pulse and normal temperature.

Abdominal palpation may reveal tenderness. Vaginal examination shows tenderness on movement of the cervix (Cervical excitation). Paracentesis or culdocentesis may show non-clotting blood aspirated from the peritoneal cavity (1,2). The patient presented had abdominal tenderness and cervical



excitation was positive. Paracentesis done was positive for non-clotting blood.

Other investigations which may aid in the diagnosis of ectopic pregnancy include laboratory test such as urinary pregnancy test, serum beta-HCG levels and abdominal ultrasonography may be used to confirm a diagnosis of rupture/or unruptured ectopic pregnancy (1, 2). Our patient never needed these since she had a positive paracentesis and hence needed an urgent laparotomy.

Total salpingectomy is required when a tubal pregnancy has ruptured, causing intra-abdominal haemorrhage that must be quickly controlled. There is no room for conservative management if there is rupture (2). The patient presented had intra-peritoneal bleeding and hence needed urgent laparotomy. Salpingectomy was done.

In centres with good monitoring facilities enabling early diagnosis of ectopic pregnancy, expectant treatment of tubal pregnancy can be offered (2). The natural history of ectopic pregnancy suggests that a majority of these tubal pregnancies can resolve without treatment. Fernandez observed spontaneous resolution of ectopic pregnancy in 64% of patients as confirmed by beta HCG levels less than 10 mIU./ml (10). The expectant management of tubal pregnancy is appropriate only under rigidly controlled conditions.

Methotrexate can be used systemically or by local injection into the unruptured tubal gestational sac. Candidates for methotrexate therapy should be hemodynamically stable, with normal liver and renal functions. The patient on treatment is instructed that the medical therapy fails in 5 to 10% of the patients and this is higher in pregnancies above 6 weeks gestation or with a tubal mass greater than 3.5 cm in diameter. Failure of medical treatment means surgery must be resorted to. If treated as an out patient, rapid

transportation must be available at all times. Signs of rupture should be reported promptly. Sexual intercourse is prohibited until after serum beta HCG is undetectable. No alcohol can be consumed and multivitamins with folic acid should not be taken (1).

Following resection of an ectopic pregnancy approximately 15% of women ovulate by 19 days and 65% by 24 days. By the 30<sup>th</sup> postoperative day, almost 75% have ovulated. Contraception should ideally be commenced at the time of hospital discharge (11).

There is chance of a recurrence of ectopic pregnancy and therefore our patient was counselled on her future fertility. In Kenya it has been shown that the recurrence rate of ectopic pregnancy is 8.1% (4), while Nigeria it was 3.8% (8).

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## **GYNAECOLOGY LONG COMMENTARY**

**THE ROLE OF MEFENAMIC ACID IN CONTROL OF  
IRREGULAR UTERINE BLEEDING FOLLOWING  
NORPLANT USE AT THE FAMILY WELFARE CLINIC,  
KENYATTA NATIONAL HOSPITAL**



## **ABSTRACT**

**OBJECTIVE:** The possibility of control of irregular uterine bleeding following Norplant use by mefenamic acid (500mg twice daily orally) was investigated.

**DESIGN:** This study was a prospective randomized placebo controlled clinical trial.

**SETTING:** The study was conducted at the Family Welfare Clinic, Kenyatta National Hospital, Nairobi.

**SUBJECTS:** 85 Norplant users attending the family welfare clinic, Kenyatta National Hospital were included from January to March, 2002. All had irregular uterine bleeding.

**MAIN OUTCOME MEASURES:** Number of days of bleeding or spotting and bleeding free interval per month.

**RESULTS:** The women were randomly allocated into 2 groups. 41 received mefenamic acid 500mg twice a day for 5 days. The remaining 44 were given placebos in the same manner. The total days of bleeding and spotting and the fraction of women in whom bleeding was stopped were analysed at the end of weeks 1 and 4. The percentage of women in whom bleeding was stopped during week 1 was significantly higher in the mefenamic acid group than the placebo group (63.4%, 22.7%,  $p<0.001$ ). 4 weeks after onset of treatment, a bleeding free interval of 21 or more days was found in 63.4% of women treated with mefenamic acid compared to 18.1% treated with placebo ( $P<0.001$ ). The mean number of days of bleeding and spotting were lower with mefenamic acid treatment (9.2 and 15.3 days,  $p=0.0085$ ).

**CONCLUSION:** Mefenamic acid is more effective than placebo in control of irregular uterine bleeding associated with the use of Norplant implants.

## **INTRODUCTION**

Norplant contraceptive implants system is an effective contraceptive method that provides protection from pregnancy for up to 5 years (1,2). It was developed by the Population Council, an international organisation established in 1952 to improve contraceptive technology.

In this study, women with uterine bleeding following the use of Norplant were followed up to determine whether they would benefit from mefenamic acid to minimize or eliminate this side effect of Norplant. Norplant was introduced in Kenya through a pilot study in 1986 and was released for use in family planning programs in 1989 (3).

## **LITERATURE REVIEW**

The Norplant implant system is one of the available methods of contraception. It was introduced into family planning programmes worldwide in 1983 after rigorous research that began in 1966 (1). There are two systems. One consists of six small flexible capsules made of silastic tubing filled with a synthetic progestin, levonorgestrel (LNG). Each capsule is 3.4mm long and 2.4mm in diameter. The capsules are inserted subdermally on the inner side on a woman's upper arm by a minor surgical procedure. They provide effective contraception for up to five years.

The second system is called Norplant -2. It consists of two solid silastic rods each 44mm long and containing 70mg LNG. Its contraceptive effect lasts three years. Return of fertility after removal of the implants is prompt.

LNG is a steroid with potent progesterone - like activity and weak androgenic properties. It is a synthetic derivative of testosterone. Each capsules contains 36mg LNG in a dry crystalline form, this continuously passes through the capsules' wall into the bloodstream at a fairly constant rate for up to 5 years.

Blood levels of LNG sufficient to prevent pregnancy are reached within 8-24 hours of insertion. During the first few weeks of use, the rate of release is about 85mg/day, falling to 50mg/day by 9 months, 35mg/day by 18 months and finally a steady level of 30mg/day for the rest of the 5 year period (1,2)

Circulating levels of LNG in individuals varies with rate of metabolism, weight and fat to muscle ratios, and levels of sex hormone binding globulin (SHBG). SHBG binds lightly to LNG to maintain higher LNG levels in blood (2).

Local factors affecting LNG release include thickness of the fibrous capsules forming around each implant and the vascular pattern and amount of adipose tissue around the implants (1,2).

Pregnancy is prevented by a combination of mechanisms:

- ◆ Production of thick, scanty cervical mucus which prevents sperm penetration.
- ◆ Inhibition of ovulation in about a half of menstrual cycles. By decreasing secretion of follicle stimulating hormone (FSH) and Luteinizing Hormone (LH), and blocking the midcycle LH Surge.
- ◆ Suppression of natural progesterone production by the ovary during the initial phase in cycles where ovulation occurs (2,7). Oestrogen secretion is unaffected.

Norplant is one of the most effective contraceptive methods developed. 1<sup>st</sup> year pregnancy rate is 0.2 per 1000 women - years, with a 5-year cumulative rate of just 1.6/1000 women years (7). It's failure rate is 0.2 for the 1<sup>st</sup> 2 years, and 0.5, 0.9 and 1.1 per 1000 women years for the 3<sup>rd</sup> to 5<sup>th</sup> years respectively (10).

Efficacy is reduced in women concomitantly on:

- ◆ Antiseizure drugs e.g. phenobarbitone, phenytoin and Carbamazepine.
- ◆ Antibiotics e.g. Rifampicin.
- ◆ Antifungals e.g. Griseofulvin.

This is due to increased hepatic metabolism of circulating LNG following enzyme induction (3).

Continuation rates reported in several multicentre studies range from 76-95% in 1<sup>st</sup> year, falling to 25-78% by year 5, with an average duration of use of 3-5 years (4-6,10).

The main reason for discontinuation of Norplant use is due to changes in menstrual bleeding patterns, this is responsible for up to 40% of removals in the 1<sup>st</sup> year, decreasing to 3% in the 5<sup>th</sup> year (7). Change in menstrual bleeding patterns is the commonest side effect in Norplant users (4-6,10). Oestrogen levels in Norplant users vary from day to day. Therefore the cycle control that occurs in combined pill users does not occur, i.e. lack of breakthrough bleeding and spotting. These are common in Norplant users especially in the first 6 to 9 months of use. This problem is similar to that occurring with progestin-only pills and injectables (8).

Menstrual bleeding changes include:

- ◆ Prolonged bleeding during the first few months of use or menorrhagia.
- ◆ Bleeding or spotting between menstrual periods.
- ◆ Reduced number of days of bleeding or spotting.
- ◆ Amenorrhea
- ◆ A combination of any of the above.

These disorders occur in 21-66% of users (1,2,6,7). Frequency of bleeding changes decreases with increase in duration of use of Norplant. With adequate counselling, most women will tolerate these menstrual changes quite



well. Rarely, irregular bleeding after Norplant insertion may mask cancer of the genital tract (10). Other side effects include weight gain, headache, mood changes, nausea, increase in body hair and acne.

In several studies the effects of LNG on the endometrial cells has been examined. The histological appearance was one of mixed proliferative and secretory activity with mostly a considerable decrease in endometrial activity (hypoplasia or atrophy). No important pathological changes were noted.

Various means of controlling the irregular bleeding have been tried (10,13,19). Archer et al in 1996 found that Ethinyl Estradiol (EE) (50mg/day) reduced bleeding over a 1-year period by 52 days while Ibuprofen (800mg 8 hourly) reduced bleeding by 35 days. Levonorgestrel 30mg twice daily reduced bleeding by 28 days. EE was given for 20 days whereas ibuprofen was given for only 5 days. EE is expensive and associated with undesirable hormonal effects (12).

Kaewrudee and others, working at a family planning clinic of a university teaching hospital in Thailand found mefenamic acid to be more effective than placebo in controlling irregular uterine bleeding following Norplant use. Their subjects were mostly young, married women of low parity (20).

Non-steroidal anti-inflammatory drugs (NSAIDS) such as mefenamic acid act by blocking prostaglandin synthesis, thereby reducing uterine contraction and reducing blood flow to the endometrium (11). Combined pills and EE control or stop bleeding by rebuilding the endometrium (12). Combined pills are preferred over EE because oestrogen per se reduces the contraceptive effect of Norplant on cervical mucus (12,13).

Changes in endometrial perfusion may contribute to vascular fragility and breakdown of endometrial perfusion in Norplant users. It is unclear

whether local changes in endometrial haemostasis are involved in Norplant induced menstrual irregularities. Au and others in 1994 (14) found that menstrual disturbances associated with Norplant are likely to be due to changes in Von-Willebrand factor (VWF) levels in endometrial epithelial cells.

Endothelin (ET), a potent vasoconstrictor is reduced in the endometrium of Norplant users. Levels of ET vary across the menstrual cycle in normal endometrium. It has been proposed that ET has a paracrine role in regulation of uterine blood flow. Neutral endopeptidase (NEP) is a membrane - bound ectoenzyme that can inactivate stroma. Local increase in NEP activity in Norplant users may explain the reduced ET activity. It remains unclear whether endometrial epithelial cell Endothelin ET acts as a mitogen in endometrial repair and regeneration or as a vasoconstrictor important in stoppage of bleeding following menstruation (17).

Endometrial biopsies from Norplant users have shown an increase in microvascular density after 3 to 12 months. Morphological changes in endometrial capillaries following progestogen exposure have suggested an increase in vascular fragility (21).

Progestin induced breakthrough bleeding is often focal, suggesting endometrial microvascular heterogeneity. Progestins alter the balance of angiogenic promoters and inhibitors, in the endometrium, thus leaving the vessels in a perpetually weakened state (22). This may result in poor repair and regeneration of endometrium, resulting in irregular bleeding (21).

## **MEFENAMIC ACID**

### **Pharmacology**

Mefenamic acid belongs to a family of aspirin -like drugs called fenamates which are derivatives of N-phenylanthranilic acid.

**Pharmacological properties.**

It has analgesic and anti-inflammatory properties. Studies in Asia have shown it to reduce irregular bleeding following Norplant use (20). These properties are mediated by its capacity to inhibit cyclooxygenase enzyme which cyclises and oxygenates arachidonic acid to form prostaglandins. These then cause uterine contractions that increase blood flow towards the endometrium.

**Pharmacokinetics**

Mefenamic acid is rapidly absorbed following oral intake. Peak plasma concentrations are reached in about 2 hours. Plasma half-life is 3 to 4 hours. In man, 50% of the ingested dose is excreted in urine. Of this, half is excreted as the conjugated B-hydroxymethylmetabolite and its conjugates and the remaining 25% mainly as conjugated mefenamic acid. 20% of the drug is recovered in faeces mostly as the unconjugated Beta-Carboxyl metabolite.

**Preparations, routes of administration and dosage.**

Mefenamic acid is available as tablets, capsules or suspension. The adult dose is 1-2g / day, given in two to four divided doses. It is not recommended for use in pregnancy, nor should it be given for longer than seven days.

**Adverse effects**

The commonest involve the gastrointestinal system, usually as dyspepsia, diarrhoea or constipation as well as steatorrhea. There have been reports of bleeding ulcers. Others include transient abnormalities in hepatic and renal function, CNS effects and skin rashes. A potentially serious side effect is haemolytic anaemia, which may be of an autoimmune type. Mefenamic acid is contraindicated in patients with a history of gastrointestinal disease and asthma.

### **Drug interactions**

Mefenamic acid binds strongly to plasma proteins thus can displace other drugs from nonspecific binding sites on Plasma albumin. Thus it potentiates oral anticoagulants by displacing them from plasma protein binding sites and though its antiplatelet activity (23).

### **RATIONALE**

Norplant implants have gained increasing acceptance among family planning service users in Kenya. Irregular uterine bleeding remains a big problem and accounts for a large proportion of discontinuations. There is need to identify a cheap, readily available means of controlling this phenomenon.

Studies done in the United States of America and Asia have suggested non steroidal anti-inflammatory drugs could be useful in controlling such irregular bleeding. No such studies had been done in our set up.

### **NULL HYPOTHESIS**

There is no difference in bleeding patterns following administration of mefenamic acid in clients having irregular bleeding after Norplant insertion.

### **BROAD OBJECTIVE**

Determine the role of mefenamic acid in controlling irregular menstrual bleeding in clients on Norplant.

### **SPECIFIC OBJECTIVES**

- ◆ Determine sociodemographic characteristics of Norplant users.
- ◆ Determine obstetric and gynaecological histories of Norplant users.
- ◆ Determine differences in cost of treatment
- ◆ To determine the efficacy of mefenamic acid in controlling irregular menstrual bleeding.



- ◆ Determine acceptability of tolerability of mefenamic acid in Norplant users experiencing irregular menstrual bleeding.

## **STUDY DESIGN**

This was a prospective double-blind placebo-controlled clinical trial.

## **STUDY AREA AND POPULATION**

The study was carried out at the family welfare clinic (FWC), Kenyatta National Hospital on women using Norplant and experiencing irregular uterine bleeding. The FWC provides family planning services. These were free of charge until October 2000. Now a fee is charged that varies with the service sought. Anyone is welcome to use the facility.

## **MATERIALS AND METHODS**

A sample of women with irregular menstrual bleeding after Norplant use were subjected to treatment with 500mg mefenamic acid twice daily for five days. A similar number of women were subjected to treatment with a placebo in a similar manner in a randomized double blind fashion. The mefenamic acid and placebo looked alike and were coded. This code was broken after the desired sample size was attained and data analysed to determine who got what, and the effect of each. Each patient was reviewed after one week, and again after four weeks.

The amount of bleeding before, one week after treatment onset and four weeks after onset of treatment were recorded in terms of number of days of bleeding per month and bleeding free interval per month.

A sampling frame was created using a table of random numbers. The treatment and placebo were packaged in like containers each labelled A or B. The subjects from the sampling frame were allocated to each at random.

## **SAMPLE SIZE AND SAMPLING FRAME**

Sample size was calculated using EPI-Info version 5 based on a confidence interval of 95%, power of 80% an expected rate of irregular bleeding in Norplant users of 70%, and ratio of treatment: placebo groups A and B of 1:1, using the formula:

$$\text{Sample size } N = Z^2(1-\alpha) \frac{P_1(1-P_1) + P_2(1-P_2)}{(P_1-P_2)^2}$$

$$P_1 = 0.7$$

$$P_2 = 0.49$$

$$N = 40$$

$$2N = 80$$

The sample size was increased to by 10% to 88 to cover for any patients being lost to follow up. Using this, the calculated sample was 44 for each group.

Categorisation of the women was done using a table of random numbers into either group A or B. After decoding, it was found that group A received mefenamic acid and group B placebo. The mefenamic acid and placebo were coded by the manufacturer (Laboratory & Allied) who released the code after data analysis.

## **RECRUITMENT**

Recruitment was done from women attending the family planning clinic at KNH. Those with irregular uterine bleeding exceeding 8 days per month were selected and subjected to complete physical and pelvic examination including speculum examination.

The patients were informed of the purpose of the study by the principal investigator and written consent for participation obtained. They were

recruited if they met the inclusion criteria. The treatment group received 500mg mefenamic acid, with the control group receiving 500mg starch (placebo), both twice daily for 5 days. All prospective clients underwent a physical examination including pelvic and speculum examinations.

### **INCLUSION CRITERIA**

- Patients on Norplant with irregular bleeding not attributable to other cause willing to participate in the study.
- Physically fit with no other medical condition.
- Normal recent PAP smear within 1 year of admission into the study.

### **EXCLUSION CRITERIA**

Clients with:

- ◆ Hypersensitivity to mefenamic acid
- ◆ History of Asthma/ peptic ulcer disease
- ◆ Vaginal bleeding due to cause other than Norplant.
- ◆ Heavy bleeding
- ◆ Amenorrhea
- ◆ Presence of severe illness that would preclude participation in the study.

### **DEFINITIONS**

**Amenorrhea:** Absence of menses for at least 6 months

It is primary if the patient has never had menses and secondary if the patients had previously had menses.

**Dysmenorrhea** Refers to painful menses.

**Menorrhagia:** Refers to heavy menses, normal menstrual flow is 20-80ml per cycle.

**Polymenorrhea:** Menses occurring at intervals of less than 21 days.

**Metrorrhagia:** Uterine bleeding between menses.

### **TREATMENT PROTOCOL**

After recruitment, patients were assessed. At the 1<sup>st</sup> visit demographic characteristics were recorded, complete history was taken and physical examination carried out. Medication was then given with instructions on how it should be taken.

### **FOLLOW UP**

The patients were seen after one week, then 4 weeks after start of treatment.. They were advised to report back earlier if the bleeding got heavier. None of the patients reported heavier bleeding after recruitment. Bleeding was monitored in terms of days of bleeding per month and bleeding free interval per cycle.

### **DATA COLLECTION**

This was done by the principal investigator by filling in the attached questionnaire. The data was later coded and entered into a computer for analysis. Comparison between the 2 groups was made using the Mann-Whitney test.

### **ETHICAL CONSIDERATIONS**

1. The study was approved by the Kenyatta National Hospital ethical & research committee
2. Written informed consent was obtained from the clients after the purpose of the study was explained to them.



3. All information gathered was treated with utmost confidentiality with questionnaires not bearing any names and only identifiable by numbers.
4. The principal investigator assisted in treatment of the patients for other coexisting conditions.

## **RESULTS**

At the end of the study, 85 women with irregular uterine bleeding after Norplant insertion had been recruited. 41 of these were allocated to the treatment group, with the remaining 44 being allocated to the control group. After data analysis and breaking of the code 41(48.2%) of the women had been treated with mefenamic acid while 44(51.8%) had been treated with placebo.

Table 1 DEMOGRAPHIC CHARACTERISTICS

|                               | treatment<br>(n=41) | controls (n=44)  | significance<br>( p value) |
|-------------------------------|---------------------|------------------|----------------------------|
| <b>AGE</b>                    |                     |                  |                            |
| 15-19                         | 2(4.9%)             | 3(6.8%)          |                            |
| 20-24                         | 23(56.1%)           | 24(54.5%)        |                            |
| 25-29                         | 10(24.4%)           | 11(25.0%)        |                            |
| 30-34                         | 6 (14.6%)           | 7 (13.7%)        |                            |
| range                         | 17-32               | 18-34            |                            |
| mean $\pm$ sd                 | 24.29 $\pm$ 3.44    | 24.50 $\pm$ 3.42 | 0.37 (NS)                  |
| <b>MARITAL<br/>STATUS</b>     |                     |                  |                            |
| Single                        | 8(19.5%             | 10(22.7%         |                            |
| Married                       | 28 (68.3%           | 30 (68.2%)       |                            |
| separated /<br>divorced       | 5 (12.2%)           | 5 (9.1%)         | 0.56                       |
| <b>LEVEL OF<br/>EDUCATION</b> |                     |                  |                            |
| none                          | 2 (4.9%)            | 3(6.8%)          |                            |
| primary                       | 5 (12.2%)           | 7 (13.7%)        |                            |
| secondary                     | 29 (70.7%)          | 26 59.1%)        |                            |
| college /<br>university       | 5 (12.2%)           | 8 (20.4%)        | 0.07                       |
| <b>OCCUPATION</b>             |                     |                  |                            |
| none                          | 8 (19.5%)           | 9 (20.4%)        |                            |
| student                       | 5 (12.2%)           | 6 (13.6%)        |                            |
| self-employed                 | 9 (21.9%)           | 8 (18.4%)        |                            |
| employed                      | 15 (36.6%)          | 18 (40.8%)       |                            |
| professional                  | 4 (9.8%)            | 3 (6.8%)         | 0.45.                      |

The majority (56.1%, 54.5%) of the patients in both groups were aged 20-24 years . Most of the patients (68.3%, 68.2%) were married. Majority of

the patients (70.7%, 59.1%) had attained a secondary school level of education. In terms of occupation, the highest proportion of patients was in the employed group. The differences in age, marital status, level of education and occupation were statistically insignificant ( $p= 0.37, 0.56, 0.07, 0.45$ ) respectively

Table 2: clinical parameters

|                                              | treatment group (n=41) | control group n=44 | significance (p value) |
|----------------------------------------------|------------------------|--------------------|------------------------|
| <b>PARITY</b>                                |                        |                    |                        |
| 0                                            | 5 (12.2%)              | 7 (16.9%)          |                        |
| 1                                            | 13 (31.7%)             | 15 (35.1%)         |                        |
| 2                                            | 18 (43.9%)             | 16 (36.4%)         |                        |
| 3                                            | 2 (4.9%)               | 3. (6.9%)          |                        |
| 4 or higher                                  | 3(7.3%)                | 2 (4.6%)           |                        |
| mean +/- sd                                  | 1.4+/-1.1              | 1.6+/-1.1          | 0.36(NS)               |
| <b>DURATION OF USE OF NORPLANT IN MONTHS</b> |                        |                    |                        |
| <6                                           | 2 (4.9%)               | 4 (9.2%)           |                        |
| 7-12                                         | 20 (49%)               | 24 (55.2%)         |                        |
| 13-18                                        | 15 (36.4%)             | 14 (31.0%)         |                        |
| 19-24                                        | 3 (1.35%)              | 2 ((4.6%)          |                        |
| >24                                          | 1(2.45%)               | 0(0%)              |                        |
| range                                        | 5-26                   | 4-24               |                        |
| mean $\pm$ sd                                | 12.3 $\pm$ 4.4         | 12.5 $\pm$ 4.2     | 0.67(NS)               |

Most patients (75.4%) were of low parity, either 1 or 2. The mean parity was 1.4 for the treatment group and 1.6 for the control group. The differences were not statistically significant. The mean duration of use of Norplant was 12.3 months for the treatment group, with a range from 5 to 26 months . In the control group, this was 12.5 months with a range from 4 to 24 months . The differences were not statistically significant ( $p = 0.67$ ).

Table 3: Information concerning irregular bleeding at insertion.

| TOLD<br>INSERTION | OF IRREGULAR         | BLEEDING           | AT        |
|-------------------|----------------------|--------------------|-----------|
|                   | Treatment group n=41 | Control group n=44 |           |
| YES               | 33 (80.5%)           | 36 (81.8%)         |           |
| NO                | 8 (19.5%)            | 8 (18.2%)          | 0.41 (NS) |

During the pre-insertion counselling most of the patients had been told that irregular bleeding may occur (80.5%, 81.8%). The differences were statistically insignificant (p= 0.41).

Table 4. Bleeding patterns before treatment.

|                                                            | Treatment group<br>n=41 | control group n=44 | significance(p value) |
|------------------------------------------------------------|-------------------------|--------------------|-----------------------|
| <b>DURATION OF<br/>IRREGULAR BLEEDING<br/>(MONTHS)</b>     |                         |                    |                       |
| 0-3                                                        | 19 (46.3%)              | 16 (36.4%)         |                       |
| 4-6                                                        | 17 (41.5%)              | 20 (45.4%)         |                       |
| >6                                                         | 5 (12.2%)               | 8 (18.2%)          |                       |
| range                                                      | 1-14                    | 2-16               |                       |
| mean+/-sd                                                  | 4.3+/-2.2               | 4.7+/-2.7          | 0.07(NS)              |
| <b>NATURE OF BLEEDING</b>                                  |                         |                    |                       |
| spotting                                                   | 19 (46.3%)              | 15 (34.1%)         |                       |
| prolonged light bleeding                                   | 16 (41.5%)              | 24 (54.6%)         |                       |
| light bleeding on - off                                    | 5 (12.2%)               | 5 (11.3%)          | 0.42 (NS)             |
| <b>DAYS OF BLEEDING<br/>PER MONTH BEFORE<br/>TREATMENT</b> |                         |                    |                       |
| 9-14                                                       | 5 (12.2%)               | 7 (15.9%)          |                       |
| 15-20                                                      | 24 (58.5%)              | 27(61.4%)          |                       |
| 21 or more                                                 | 12 (29.3)               | 10 (22.7%)         |                       |
| range                                                      | 9-24                    | 9-22               |                       |
| mean +_sd                                                  | 18.8 +_ 3.62            | 17.9 +_ 2.81       | 0.36 (NS)             |



The highest proportion of patients with irregular bleeding in the treatment group had had it for 3 months or less (46.3%) whereas in the control group it had been for 4-6 months (45.4%) (p=0.07). Irregular bleeding occurred mostly as spotting or prolonged light bleeding in both groups (17.8%, 88.7%). The differences were statistically insignificant (p= 0.42).

Table 5. Bleeding patterns after treatment.

|                                                | Treatment group<br>n=41 | Control group n=44 | P value(significance) |
|------------------------------------------------|-------------------------|--------------------|-----------------------|
| STOPPAGE OF BLEEDING AFTER 5 DAYS OF TREATMENT | 25 (62.4%)              | 10 (22.7%)         | 0.002(S)              |
| DAYS OF BLEEDING PER MONTH AFTER TREATMENT     |                         |                    |                       |
| <9                                             | 25(62.4%)               | 3 (6.8%)           |                       |
| 9 -14                                          | 9(21.9%)                | 10 (22.7%)         |                       |
| 15-20                                          | 5 (12.2%)               | 23 (52.3%)         |                       |
| 21 or more                                     | 2(4.9%)                 | 8 (18.2%)          |                       |
| range                                          | 4-21                    | 7-23               |                       |
| mean $\pm$ sd                                  | 9.2 $\pm$ 3.84          | 15.3 $\pm$ 4.36    | 0.0085 (S)            |

The bleeding was stopped in 63.4% of patients in the treatment group within 5 days of therapy, as compared to only 22.7% of patients in the control group (p=0.002). The mean number of days of bleeding during the month of follow up were reduced from 18.8 to 9.2 in the treatment group and from 17.9 days to 15.3 days in the control group (tables 3,4). These differences were statistically significant (p=0.0085).

The bleeding free interval during the month of follow up increased to a mean of 20.3 days from 12.9 days in the treatment group and from 11.6 to 12.9 days in the control group . 63.4% of patients in the treatment group had a

control group (table 4). These differences were statistically significant (p<0.001)

Table 6. Bleeding free interval per month

| BLEEDING FREE<br>INTERVAL (DAYS) | treatment (n=41)    |                    | control (n=44)      |                    | significance(p value) |                    |
|----------------------------------|---------------------|--------------------|---------------------|--------------------|-----------------------|--------------------|
|                                  | before<br>treatment | after<br>treatment | before<br>treatment | after<br>treatment | before<br>treatment   | after<br>treatment |
| < 8                              | 14 (34.1%)          | 6(14.6%)           | 10(22.7%)           | 12(27.3%<br>)      | 2.48                  | 0.002              |
| 9-20                             | 22(53.71%)          | 9(22.0%)           | 29(65.9%)           | 24(54.6%<br>)      |                       |                    |
| >20                              | 5(12.2%)            | 26(63.4%)          | 5(11.4%)            | 8(18.1%)           |                       |                    |
| range                            | 7-26                | 4-28               |                     |                    |                       |                    |
| mean ± sd                        | 12.9 ± 2.91         | 20.3 ± 3.2         | 11.6 ± 4.32         | 12.5 ± 4.5         | 0.43                  | <0.001(S)          |

Table 7. Side effects of treatment

| SIDE EFFECTS                       | treatment (n=41) | control (n=44) | significance(p value) |
|------------------------------------|------------------|----------------|-----------------------|
| none                               | 39 (90.2%)       | 42 (95.5%)     |                       |
| heartburn                          | 4 (9.8%)         | 2 (4.5%)       | 0.002 (S)             |
| CONTINUATION<br>OF NORPLANT<br>USE |                  |                |                       |
| yes                                | 36 (87.8%)       | 25 (56.8%)     |                       |
| no                                 | 5(12.2%)         | 19 (43.2%)     | 0.001 (S)             |

The mefenamic acid was well tolerated with the only adverse effect experienced being heartburn that occurred in 9.8% of patients in the treatment group as compared to 4.5% of patients in the control group. The differences were statistically significant ( p=0.002). The heartburn experienced with the

were statistically significant (  $p=0.002$ ). The heartburn experienced with the placebo could have arisen from the preservative used during their manufacture.

After treatment ,87.8% of the patients in the treatment group still wished to continue using Norplant as compared to 56.8% in the control group (table 5). The differences were statistically significant ( $p<0.0$

## **DISCUSSION**

Irregular uterine bleeding remains the commonest side effects occurring after insertion of Norplant implants. It has been found to be responsible for up to 40% of Norplant removals (6). It occurs in up to 83% of Norplant users during the 1<sup>st</sup> year (10)

This phenomenon is important because it consumes the resources of family planning service providers in terms of time, supplies and manpower It may also discourage potential users of the method from adopting it.

This study has shown Norplant users to be mostly young, married, low parity women with at least a secondary school level of education. The commonest irregular bleeding patterns were prolonged light bleeding and spotting. Despite the fact that most of the time medical treatment for irregular bleeding or spotting is usually not necessary, many clinicians feel an obligation to give some medication so as to appear to be doing something about the condition and improve continuation rates of the method.

To date, several studies have been published that address this problem of irregular bleeding. In one study various medications were used. Levonorgestrel tablets 30mg orally twice daily, ethinyl estradiol 50mg daily and ibuprofen 800mg three times daily were compared to a placebo (11). In another study carried out on family planning clinic clients in Thailand (20),



Mefenamic acid 500mg twice daily for 5 days was compared to placebo. All treatment groups performed better than placebo. Ethinyl estradiol reduced bleeding over a 1 year period by 52 days, ibuprofen by 35 days and levonogestrel by 28 days. Ethinyl estradiol had been given for 20 days on average 2.2 times during the 1 year period while ibuprofen had been given for only 5 days on average 2.7 times during that year. The Thai study (20) found that mefenamic acid stopped bleeding in 76% of subjects after a week as compared to 27% subject on the placebo ( $p<0.001$ ). On the follow up visit 4 weeks after initiation of therapy, 68% of subjects treated with mefenamic acid had a bleeding free interval of more than 20 days compared to 33% of those treated with the placebo. The mean duration of bleeding and spotting per month was also lower in mefenamic acid treated subjects (11.6 days) as compared to placebo treated subjects (17.2 days,  $p<0.05$ ). In my study bleeding and spotting was stopped after 5 days of therapy in 63.4% of subjects on mefenamic acid as compared to only 22.7% of the subjects on the placebo ( $p=0.002$ ). Mean duration of bleeding or spotting fell from 18.8 days to 9.2 days in the mefenamic acid treated group and from 17.9 days to 15.3 days in the placebo treated group. The bleeding free interval also increased to more than 20 days in 63.4% of mefenamic acid treated subjects. Only 12.2% of these had a bleeding free interval greater than 20 days before onset of treatment. A bleeding free interval of more than 20 days was found in 18.1% of placebo treated subjects up from 11.4% before treatment.

The treatment was generally well tolerated. Most of the subjects had no side effects to treatment. The only adverse effect noted was heartburn. This occurred in 9.8% of mefenamic acid treated subjects compared to 4.5% of placebo treated subject ( $p=0.002$ ). Antacids effectively treated the heartburn in these patients. Following treatment, 87.8% of the mefenamic acid treated subjects elected to continue using Norplant as compared to only 56.8% of the placebo treated subjects ( $p=0.01$ )



From the findings of this study it can be deduced that mefenamic acid is a cheap, effective and well tolerated treatment for irregular uterine bleeding that follows Norplant use. It also has the advantage that it is devoid of hormonal effects that may induce weight gain, fluid retention or glucose intolerance among other adverse effects. It does not interfere with the contraceptive effect of Norplant, unlike ethinyl estradiol that may make cervical mucous less viscid hence encourage sperm penetration.

In the few patients who appear to be unresponsive to mefenamic acid, refractoriness may be due to failure of attainment of adequate therapeutic levels in the endometrium. Irregular bleeding problems are commonest during the 1<sup>st</sup> year of use because the endometrial vasculature is profoundly altered in the early months of Norplant use (24).

## CONCLUSIONS

1. Accumulated data from this and other studies show that mefenamic acid is effective in the control of irregular uterine bleeding following Norplant use.
2. Control of this side effect of Norplant results in improvement of continuation rates.
3. The study shows mefenamic acid to be a cheap and well tolerated medication.
4. The small fraction of non responders to mefenamic acid suggests that prostaglandins may not be the only pathogenetic mechanism involved in irregular uterine bleeding following Norplant use.
5. The optimal dosage and duration of use of mefenamic acid have not been conclusively determined from studies so far published.

## RECOMMENDATIONS

1. Data from this and other studies support the incorporation of mefenamic acid into the armamentarium of drugs available for control of irregular bleeding following Norplant use.
2. Further studies are needed to determine the optimal dosage and duration of treatment with mefenamic acid.

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## OBSTETRIC STUDY QUESTIONNAIRE

Serial No: .....IP: .....

1. Age
2. Parity
3. Marital Status:
  1. Married
  2. Single
  3. Widowed
  4. Divorced
  5. Other (Specify)
4. Highest level of education
  1. None
  2. Primary
  3. Secondary
  4. College
  5. Other ( Specify)
5. Occupation
  1. None
  2. Unskilled
  3. Skilled
6. Occupation of partner
  1. None
  2. Unskilled
  3. Skilled
7. Antenatal Care
  - (a) Place
    1. None
    2. City Council Clinic
    3. PMH
    4. Other (Specify)
  - (b) Gestation at booking  
Total number of visits
  - (c) Highest recorded blood pressure
    - Systolic
    - Diastolic
8. Gestation at diagnosis of hypertension

9. Gestation at admission
- (a) Blood pressure
- |              |                      |
|--------------|----------------------|
| 1. Systolic  | <input type="text"/> |
| 2. Diastolic | <input type="text"/> |
- (b) Oedema at admission
- |                |                      |
|----------------|----------------------|
| 1. Generalized |                      |
| 2. Pedal       | <input type="text"/> |
| 3. None        |                      |
- (c) Proteinuria at admission
- |               |                      |
|---------------|----------------------|
| 1. +          | <input type="text"/> |
| 2. 2+         | <input type="text"/> |
| 3. 3+ or more |                      |
- (d) Goecke score
- |  |                      |
|--|----------------------|
|  | <input type="text"/> |
|--|----------------------|
- (e) Category
- |             |                      |
|-------------|----------------------|
| 1. Mild     |                      |
| 2. Moderate |                      |
| 3. Severe   | <input type="text"/> |
10. (a) Occurrence of fits
- |                                |                      |
|--------------------------------|----------------------|
| 1. Before admission / delivery |                      |
| 2. Intrapartum                 |                      |
| 3. After delivery              | <input type="text"/> |
| 4. None                        |                      |
- (b) Treatment at admission
- |                                 |                      |
|---------------------------------|----------------------|
| 1. Sedation only                |                      |
| 2. Sedation + Aldomet           |                      |
| 3. Sedation + Hydrallazine drip | <input type="text"/> |
| 4. Other (Specify)              |                      |
11. Previous medical history
- Hypertension
- |        |                      |
|--------|----------------------|
| 1. Yes |                      |
| 2. No  | <input type="text"/> |
- Diabetes
- |        |                      |
|--------|----------------------|
| 1. Yes |                      |
| 2. No  | <input type="text"/> |
- Kidney Disease
- |        |                      |
|--------|----------------------|
| 1. Yes |                      |
| 2. No  | <input type="text"/> |
12. Family history of hypertension
- |        |                      |
|--------|----------------------|
| 1. Yes |                      |
| 2. No  | <input type="text"/> |

- If Yes
1. Mother
  2. Sister
  3. Other (Specify)
13. Labour
- (a) Gestation at delivery
  - (b) Fundal height at delivery
  - (c) Reason for delivery
    1. Fetal Death
    2. Severe hypertension
    3. Deteriorating renal function
    4. Other (Specify)
  - (d) Labour
    1. Spontaneous
    2. Induced
  - (e) Duration of labour
    1. Less than 8 hours
    2. 8 – 12 Hours
    3. More than 12 hours
14. Mode of delivery
1. SVD
  2. Vacuum extraction
  3. Caesarean section
  4. Other (Specify)
15. Fetus
- (a) Weight
  - (b) Apgar score at
    - (a) 1 Minute
    - (b) 5 Minutes
    - (c) 10 Minutes
  - (c) Complications
    1. Yes
    2. None
  - (d) Baby taken to nursery
    1. Yes
    2. No
  - (e) State of baby in nursery after 24hrs.
    1. Alive
    2. Dead
  - (f) Baby Death:
    1. FSB
    2. MSB
    3. Early NND

(g) Neonatal Death: Reason:

1. RDS
2. Birth asphyxia
3. Birth trauma
4. Other

16. Placenta

(a) Weight

(b) Presence of infarcts

(c) Abruptio

1. Yes
2. No

17. Mother

(a) Days in hospital

(b) Complications

1. Yes
2. No

If Yes

1. CVA
2. Sepsis
3. Other (Specify)

(c) Blood pressure reading at discharge

Systolic  
Diastolic

(d) Maternal Death

Clinical Diagnosis

1. Renal Failure
2. Pulmonary Oedema
3. CVA

18. Proteinuria

Discharge

1. Nil
2. 1-2+
3. >, 3+



# GYNAECOLOGY STUDY QUESTIONNAIRE

Identification .....Group.....

## Sociodemographic data

1. Age

2. Marital status

- 1) single
- 2) Married
- 3) Other specify

3. Level of education

- 1) None
- 2) Primary
- 3) Secondary
- 4) Other specify

4. Occupation

- 1) None
- 2) Student
- 3) Self employed
- 4) Employed
- 5) Professional
- 6) Other (specify)

## Obstetric and gynecological history

5. Parity

6. Duration of use of Norplant (months)

7. Were you told about irregular bleeding at insertion?

1) Yes

2) No

8. Duration of irregular bleeding

1) 0 – 3 months

2) 3 – 6 months

3) > 6 months

9. Nature of bleeding

1) Heavy menses normal duration

2) Spotting

3) Prolonged light bleeding

4) Other (Specify)

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14. Total days of bleeding per month

1) Before treatment

2) After 5 days of treatment

3) Bleeding free interval(days) before  after

15. Side effects from the treatment (enumerate)

16. Would you consider continuing with Norplant?

1) Yes

2) No

**CONSENT FOR PARTICIPATION IN STUDY**

**I hereby consent to participate in the study ‘The Role of mefenamic acid in control of irregular uterine bleeding following Norplant use. It has been explained to me that there are other treatments for this condition but I still wish to take part in this study.**

*Signed.....Witness.....*

...

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Fax: 725272  
Telegrams: "MEDSUP", Nairobi



KENYATTA NATIONAL HOSPITAL  
P.O. Box 20723, Nairobi

Ref.....KNH-ERC/01/1242

Date..10th January 2002

Dr. Josephat Wangwe  
Department of Obs/Gynae  
Faculty of Medicine  
University of Nairobi

Dear Dr. Wangwe,

RE: **REVISED RESEARCH PROPOSAL " ROLE OF MEFENAMIC ACID IN CONTROL OF  
IRREGULAR BLEEDING SECONDARY TO NORPLANT USE AT THE FAMILY WELFARE  
CLINIC".** (P51/6/2001)

This is to inform you that the Kenyatta National Hospital Ethical and Research Committee has reviewed and approved the revised version of your above cited research proposal.

On behalf of the Committee I wish you fruitful research and look forward to receiving a summary of the research findings upon completion of the study.

This information will form part of data base that will be consulted in future when processing related research study so as to minimize chances of study duplication.

Thank you.

Yours faithfully,

PROF. A.N. GUANTAI  
SECRETARY, KNH-ERC

c.c. Prof. K.M. Bhatt,  
Chairman, KNH-ERC,  
Dept. of Medicine, UON.

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Ref: KNH-ERC/01/1334

15 April 2002

Dr. Josephat Wangwe  
Dept. of Obs/Gynae  
Faculty of Medicine  
University of Nairobi

Dear Dr. Wangwe,

RE: RESEARCH PROPOSAL "PREGNANCY OUTCOME IN PATIENTS WITH HYPERTENSIVE DISEASE AS SEEN AT PUMWANI MATERNITY HOSPITAL" (P12/2/2002)

This is to inform you that the Kenyatta National Hospital Ethical and Research Committee has reviewed and approved the revised version of your above cited research proposal.

On behalf of the Committee I wish you fruitful research and look forward to receiving a summary of the research findings upon completion of the study.

This information will form part of data base that will be consulted in future when processing related research study so as to minimize chances of study duplication.

Thank you.

Yours faithfully,

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SECRETARY, KNH-ERC

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The Dean, Faculty of Medicine, UON