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THE EFFICACY AND EFFICIENCY OF INTRAUTERINE DEVICE (TCU380A) AS AMEAN OF CONTRACEPTION.–AL-BAHA UNIVERSITY .K.S.A - 2015

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ABSTRACT

Objectives: The study was conducted at Elobeid Reproductive Health Clinic – January 2015. The objective of the study was to determine the effectiveness and to evaluate the complications of the Tcu380A in women who had been using the device and to compare between doctors and midlevel Care providers' skills. **Methods:** Retrospective clinical base study was obtained through client's follow up records. A total of 124 participants who had an IUD inserted during 2010-2014 were 2enrolled in the study. **Results:** No pregnancy occurs, perforation, thread loss and no ectopic pregnancy. 6.5% of users experience removal of IUD due to bleeding in early months after insertion. Two of the study population (1.6%) developed PID that occurs at 4 and 5 years after insertion. The majority planned pregnancy and removed IUD without any complications. No significant differences between doctors and midlevel provider's skill. Although the IUD is one of the most widely used contraceptive methods in the world only 4.1 % of women used it in Elobied reproductive health clinic. These data indicate that Tcu380A Intrauterine device be a better option for women wishing to practice highly effective long term reversible birth control without having to resort to hormonal Methods.

KEYWORDS: Tcu380A, IUD, PID.

1-INTRODUCTION

1-1 Historical background:- The World Health Organization (WHO) estimate that 125 Million in the world, mostly in developing countries, are not using contraception in spite of the desire to space or limit the number of children they have.[3]

The family planning needs of these women are unmet because of poor access to quality health services, limited availability of a variety of contraceptive methods, lack of birth control information, concern about safety or side effects, and cultural factors such as social, religious, or partner disapproval.[4]

Because so many women lack access to modern contraceptive, about 38% of all pregnancies worldwide are unintended.

The mortality rate from abortion is highest among developing nation; for example 680 women die/100/000 abortion in Africa. Compared with 0.7/100/000 in developed region, obviously, when women have access to family planning services, the number of women both seeking abortion and dying as a result of them is low.[3]

The inert devices may be used up to menopause, there is no need to remove before menopause if the woman is satisfied with the method and has no problem with it.[4]

Prevalence of Use

Worldwide, the IUD is the most widely used reversible contraceptive. IUD use varies from country to country, reflecting differences in culture, availability, and choice of contraceptives, attitudes and training of providers, and fertility goals of women. In Scandinavia, 20 to 40 percent of contraceptive users have IUDs, while about 60 million Chinese women use IUDs.[17]

The World Health Organization (WHO) has reported that the incidence of complications is up to 40% for some IUDs. Pain and bleeding are the most common side-effects leading to preterm removal of IUDs. Applying better IUDs and inserting them correctly are important factors in reducing the risk of complications that can lead to abandonment of the method and the risk of unwanted pregnancy.[17]

Tcu380A prevents pregnancy by combination of Mechanisms of action including

- Inhibition of sperm migration in the upper female genital tract.

- Inhibition of ovum transport.
- Inhibition of fertilization.

IUD should be provided to any woman who requests it after receiving appropriate counseling and selection and use for this method of contraception and reaching an informed decision, and who has no contraindication to its use.[5]

Tcu380A, is a T shaped frame of polyethylene, intrauterine device (IUD) is a form of birth control, it is an object, placed in the uterus, to prevent pregnancy.

The properties of the copper T 380A model are

Fig: 1

- The vertical arm is wound with copper wire.
- There are two additional copper sleeves, fixed to the side arm.
- Copper surface area is 380mm.square.
- The width is 31.85mm.
- The length is 35.85mm.[1]

Tcu380A long term reversible contraception, with an associated pregnancy (failure) rate **0.8%** in first year of use. {Trusiet, 2004} in long term international comparative trail, sponsored by the World Health Organization {WHO}, the average annual failure rate was **0.4%** or less, and after 12 years of use the cumulative failure rate **2.2%,** which is comparable to that of female sterilization {United Nations Development Program me et al, 1997}.

Because it is so effective in preventing pregnancy in the unlikely event of pregnancy in an IUD user, that pregnancy is more likely to be ectopic than is a pregnancy in a non user. Still, the pregnancy in an IUD user is far more likely to be normal than ectopic: only an estimated **1** in every **13** to **16** pregnancies or **6 – 8%** is ectopic (Fur log, 2002).[8]

For us to consider a birth control method **completely effective:** no couples will become pregnant while using this method.

Very effective: Means that between **1** and **2** out of **100** couples become pregnant.

Effective: Means that **2** to **12** out of **100** couples become pregnant.

Moderately effective: Means that **13** to **20** out of **100** couples become pregnant while using that method.

Less effective: Means that **21** to **40** out of **100** couples become pregnant.

Not effective: Means that more than **40** out of **100** couples become pregnant while using that method.[4]

Effectiveness by typical – use pregnancy rates
Very good (0 – 1%).
Good (2 – 12%) very good with perfect use.
Fair (15 – 21%) good with perfect use.

Understanding contraceptive effectiveness, especially for short time use.[23]

1-2-JUSTIFICATION

The family planning needs of these women are unmet because of poor access to quality health services, limited availability of a variety of contraceptive methods, lack of birth control information, Large – scale family planning programs are urgently needed concern about safety or side effects, and cultural factors such as social, religious, or partner disapproval in developing countries to help stem the tide of rapid population increase. However trained medical personnel are scarce, therefore training paramedical personnel in the various aspect of family planning, particularly for service in rural areas for intrauterine devices insertion.

Paramedical personnel are being used in Pakistan, Thailand, Ceylon and eastern Kentucky in the United States as well as in other countries.

Through the roll-out of the training scheme, Yemen is making great strides towards improving the quality of IUD services in the public and private sectors and expanding services in those sectors. Last year, 320 midwives from 11 governorates within Yemen successfully completed the course, with a further 150 being trained over the next 12 months, Yemen is making a real impact.[11]

Use of IUDS remains low, in spite of the need for long – term, non hormonal contraception. This may be due to, in part, to myths and misinformation regarding the safety and efficacy of IUD.

1-3-PROBLEM STATEMENT

The mortality rate from abortion is highest among developing nation; for example 680 women die/100/000 abortion in Africa. Compared with 0.7/100/000 in developed region, obviously, many women lack access to modern contraceptive, when women have access to family planning services, the number of women both seeking abortion and dying as a result of them is low.

The intrauterine device (IUD), primarily in the form of the copper IUD, is used by more than 150 million women around the world, making it the most widely used reversible method of contraception. With a remarkably low failure rate of less than 1 per 100 women in the first year of use, the Copper T-380A is in the top tier of contraceptives in terms of efficacy. Risks of utilization include perforation and an increased risk of infection in the first 20 days following insertion. Overall, the number of adverse events is low, making the Copper T-380A a very safe contraceptive method. The most common reasons for the discontinuation of this method are menstrual bleeding and dysmenorrheal.

Complications of intrauterine devices (IUDS) are a key concern in midwifery.[19]

RESEARCH QUESTIONS

1. What are the main complications of intrauterine device copper T380A among client user?
2. Are service providers in Elobeid Reproductive Health clinic had skill in inserting Tcu380A. To avoid potential complications?

1- 4- HYPOTHESES

H1: Potential risks may occur due to IUD insertion like: PID.

H2: The main complication among IUD users may be excessive bleeding.

H3: Health care providers who provide IUDs insertion were skilled and had good experiences to avoid risk of uterine perforation.

2- OBJECTIVES

2-1.GENERAL

To determine the effectiveness of intrauterine device (Tcu380A) among clients user.

2-2. SPECIFIC

1. To calculate failure rate in clients who inserted (Tcu380A). During 2002 -2006.
2. To identify nature of complications occur among clients user.
3. To compare between doctors and midlevel care providers skills during 2002 –2006.

3- METHODOLOGY

3-1. Study design: - non intervention retrospective cohort clinical base study.

3-2. Study area: - North Kordofan State, Elobied Reproductive Health Clinic, which established in 2001.

Elobied is the capital of the state, this clinic located central in the City. Population in Elobied is about 345.126.[18] This clinic provide many services such as ante natal follow up and booking , family planning counseling and IUDS insertion, maternal and child vaccination, ultra sound, doctor clinic for referral cases, HIV counseling, mother classes, early detection of ca.cervix, laboratory tests, post abortion care.

3-3. study Population: - all clients who inserted copper T380A during 2002 -2006. At study clinic total coverage.

3-4. Inclusion criteria: - clients who inserted copper T380A during 2002-2006 in the clinic.

3-5 .Exclusion criteria: - clients who used other methods of contraception, or came for other services in the clinic.

3-6 .Variables:- Age, parity, educational level, level of service providers and years of experience, duration of insertion till removal and complications that occurred during 2002-2006 will be analyzed.

3-7.Data Collection

Tools: - Check list.

Technique: - data collected by principal investigator through clients follow up records and their telephone numbers using check list.

3-8. Analysis: - Computerize analysis using - social packages statistic analysis (SPSS) version 14, Age, parity, educational level, level of service providers, duration of Insertion, occurrence of complications analyzed and put in frequency tables and graphs. Chi- square and T. test were used.

3-9. Data management: Data was collected, cleaned inside the clinic and kept confidentially until analyzed and put in frequency tables, graphs.

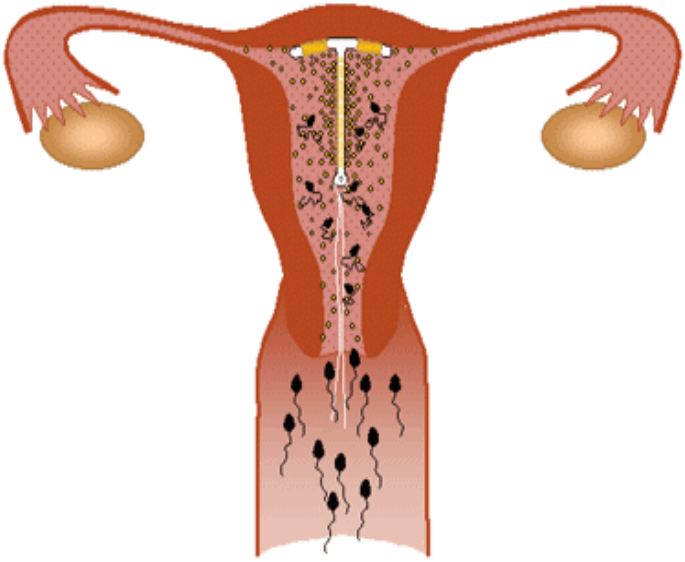
4- LITERATURE REVIEW

4-1. Introduction to Literature Review

The ParaGard Intrauterine Device (IUD) copper T 380A is a small, "T-shaped" contraceptive device, about 1-1/4 inches wide by 1-3/8 inches long, made of flexible plastic and wrapped in copper. The ParaGard IUD must be inserted by a qualified healthcare professional (such as an ob/gyn or nurse practitioner). It is hormone-free, Tube, obstructing the fertilization (that is, when the male sperm fertilizes the female egg so it does not alter a woman's natural menstrual cycle. The ParaGard IUD releases a tiny amount of copper (which acts as a spermicidal continuously over a 10-year period as a way to prevent pregnancy.[17]

How OPTIMA IUD TCU 380A works as a contraceptive method?

The contraceptive efficacy of an IUD is obtained by the ongoing release of copper inside the uterine cavity. This interferes with the number and transport of sperms, making it difficult for the egg to move through the fallopian egg). IUD does not avoid ovulation and do not cause abortion.[23]



The intrauterine device {IUD} is a safe and effective method of reversible contraception. Tcu380A has proved to be highly effective for at least 12 years with a cumulative pregnancy rate of 2.2% per 100 women.[2] Many researches were conducted among user of Tcu380A.

4-2. Review of the previous studies

Research title: performance of the frameless IUD (flexi gard prototype inserter) and the Tcu380A after six years as part of multicenter randomized comparative clinical trial in porous women. Shanghai Institute of Planned Parenthood research, China.[4]

comparative trail sponsored by the(WHO), the average annual failure rate was 0.4% or less, and after 12 years of the use the cumulative failure rate 2.2% , which is comparable to that of female sterilization.

Life span after insertion of Tcu380A

Long – term studies have shown that Tcu380A is effective for at least 12 years after insertion. *United Nations Development Program et.al. 1997.[7]

PERFORATION

Perforation of the uterus during insertion has been shown to be quiet rare, with fewer than 1.5 perforations per 1,000 IUD insertions occurring in large clinical trial (Treiman et.al., 1995); United Nations Development Program me et.al. 1997.[7]

The skill and experience of the provider is the most important factor that minimizes the risk of perforation (Harrison – Woolrych et.al. 2003).[7]

EXPULSION

expulsion of the IUD is uncommon , the skill and experience of the provider is the most important factor that minimizes the risk of expulsion(Chi, 1993).cumulative expulsion rate of 2.4 , 3.4 and 4.4% at one two and three years of use ,respectively, have been reported among copper IUD user(UNDP et.al., 1995) in the first year of use.[8]

Expulsion rates vary from 2 – 8%

(Treiman et.al., 1995) based on clinical experience, women are usually aware when they have expelled their IUD such expulsion is not dangerous for the user; however, the women is no longer protected against pregnancy. Expulsion rate tend to be slightly higher for nulliparous women (compared to porous women) and for post partum insertions (compared to interval insertions (Grimes 2004).

Ectopic pregnancy:- Because they are so effective in preventing pregnancy in the unlikely event of pregnancy in an IUD user, that Pregnancy is more likely to be ectopic than is a pregnancy in a non user. Still, the pregnancy in an IUD user is far more likely to be normal than ectopic: only an estimated 1 in every 13 to 16 pregnancies or 6 – 8% is ectopic (Fur log, 2002).[8]

Pelvic inflammatory disease(PID):- Rate of clinical PID are very low among IUD user – lower than previously thought and much lower than providers may realize 1.6 cases per 1000 women per year, that is 998.4per 1000 women per year did not get PID (Farley et.al; 1992).[8]

Long-term reversible contraception

Twelve years of experience with the TCu380A and TCu220C: Few data on the long-term efficacy of intrauterine devices (IUD) are available, and this article reports on the final 12-year experience with the TCu220C and TCu380A devices from two randomized, multicenter trials conducted in 24 centers. A total of 3,277 and 1,396 women, respectively, were recruited for use of each device between 1981 and 1986 and followed at 3, 6, years. Volume 74, Issue 6, Pages 483-486 (December 2006).

Continuation rates and reasons for discontinuing TCu380A IUD use in Tabriz, Iran

Continuation of TCu380A IUD use by women at 1 month, 6 month, 1 year, 2 years, 3 years, 4 years and 5 years was 98.2, 89.3, 79.3, 68.3, 57.6, 49.5 and 45.0 per 100, respectively. Among women using the TCu380A IUD, the rate of termination due to pain/bleeding was significantly higher than the rate of termination due to other causes. Overall, two pregnancies were reported within 5 years after insertion. A third pregnancy Occurred on Year 6.[9]

TCU 380A IUD: a reversible permanent contraceptive method in women over 35years of age:- The concept that women who have insertion of a TCU 380A IUD at the age of 25 years or older could use this IUD as a reversible but permanent method of contraception up to the menopause continues to be supported by the accumulation of evidence, although definitive evidence remains to be obtained.[9]

Little information is available about the relationship:- Between retention of the IUD and the training of the inserter.

Two reports of early studies presented contradictory Finding. One of these reports, which Presented preliminary findings from a *study in a Korean rural area* revealed that expulsion rates were slightly higher and removal rates were slightly lower. When the insertions were done by paramedical personnel. On the other hand, a study in Barbados gave suggestive evidence that the mean retention time was higher.

Insertion of IUDS by rural midwives in Iran

Non physician personnel learn to insert the IUD. WHO.1st phase, a training method was created with competence comparison of the assistant to physician following in the 2nd phase, the 3rd phase of the project.

Studied the use of non- physician services throughout country, it was found that assistant – nurse -midwives were equally capable of IUD. Insertion and check – up and that service can now reach rural areas of the country beyond the range of traditional medical services.[10]

Safety of intrauterine device insertion by trained nurse - midwives in the Sudan. *F.A. Aziz and A.A. Osman*

Insertion of intrauterine devices (IUDs) by trained health workers other than physicians. Twenty nurse-midwives in government service in the Sudan, called health visitors (HVs), were trained to provide intrauterine contraceptives in a research project designed to evaluate

the safety of insertion of IUDs by Medical personnel who are not physicians. After training, they inserted 763 IUDs. Independent evaluation of 520 clients was conducted by gynecologists who found that only six devices (1.2%) had been incorrectly inserted. Outcomes for clients of the health visitors, with respect to perforations, infections, expulsions, and pregnancies, compared well with those of eight physicians who participated in the study. The research strongly supports the concept of nurse- Midwife training for IUD insertion. This would greatly expand the availability of family planning services and would conserve physician time and skills for problem cases.[10]

Midwives deliver family planning as well as babies

Sana´a – Yemen is increasing the number and quality of IUD services provided in the public and private sectors through its successful countrywide training scheme.

Through the roll-out of the training scheme, Yemen is making great strides towards improving the quality of IUD services in the public and private sectors and expanding services in those sectors.

Last year, 320 midwives from 11 governorates within Yemen successfully completed the course, with a further 150 being trained over the next 12 months.[11]

RESULTS

No pregnancies occurred prior to or at the first follow-up visit, making CuT380A 100% effective as emergency contraception in this study. The pregnancy rate over the 12-month period was 0.23 per 100 women. In all, 29 (1.5%) women experienced a difficult IUD insertion process, requiring local anesthesia or prophylactic antibiotics. No uterine perforations occurred. The main side-effects were increased menstrual bleeding and

menstrual disturbances. The 12-month post insertion continuation rate was 94.0 per 100 woman-years.[12]

Long-term safety, efficacy, and patient acceptability of the intrauterine Copper T-380A:- Bliss Kaneshiro Tod Aeby, department of obstetrics and Gynecology, John A Burns school of medicine, University of Hawaii, Honolulu, Hawaii, USA. Several investigators have examined the efficacy of various Copper IUD devices. A Cochrane review published by Kulier in 2007 examined 35 randomized controlled trials that all together included more than 50,000 women and made 16 different Comparisons of efficacy from the scientific Literature. The Authors concluded that the Copper T-380A was more effective in preventing pregnancy than the other devices including the Multiload 375, Multiload 250, Copper T-220, and Copper T-200.[13]

Comparative study on contraceptive efficacy and clinical performance of the copper/low-density polyethylene nanocomposite IUD and the copper T220C IUD. Family Planning Research Institute, Tongji Medical College, Huazhong University of Science and Technology, Wuhan 430030, PR China. Publication date & source: 2008-10, Contraception. 78(4):319-23. Epub 2008 Jul 11.

RESULTS: Follow-up rate was 100% at the 12th month. In the experimental group and control group, the cumulative continuation rates were both 92.0 per 100 women at the 12th month and there was no difference between them ($p > .05$). The pregnancy rate, removal rate and expulsion rate were low with the difference being not statistically significant ($p>.05$). The most common side effects were excessive menstrual bleeding, spotting and pain. The rates of side effects were lower in the experimental group than in control group, especially during the initial 3 months after insertion with the differences being statistically significant ($p < .05$).[14]

Copper-containing, framed intrauterine devices for contraception: a systematic review of randomized controlled trials. West side Contraceptive Services, Westminster Primary Care Trust, Raymede Clinic, London, UK. Publication date & source: 2008-05, Contraception. 77(5): 318-27. Epub 2008 Mar 18.

RESULTS: We included 35 trials, resulting in 18 comparisons of 10 different IUDs in approximately 48,000 women. TCu380A was more effective in preventing pregnancy than

MLCu375 (RD 1.70%, 95% CI 0.07-2.95% after 4 years of use). TCu380A was also more effective than MLCu250, TCu220 and TCu200. There tended to be fewer pregnancies with Cu380 S compared to TCu380A after the first year of use, a difference which was statistically significant in the fourth year (RD -1.62%, 95% CI -3.00% to -0.24%). This occurred despite more expulsions with Cu380S (RD 3.50%, 95% CI 0.36-6.63% at 4 years). MLCu375 was no more effective than TCu220 at 1 year of use, or MLCu250 and Nova T up to 3 years. Compared to TCu380A or Cu380S, none of the IUDs showed any benefits in terms of bleeding or pain or any of the other reasons for early discontinuation. None of the trials that reported events at insertion found one IUD easier to insert than another or caused less pain at insertion. There is no evidence that uterine perforation rates vary by type of device. There are minimal randomized data on IUD use in nulliparous women.[15]

BLEEDING

The amount of excess bleeding is (50-60 ML) with the smaller copper devices such as the copper T series. Clinical trials demonstrate that particularly the small Gyne Fix® version reduces the incidence of heavy blood loss due to the small size of the foreign body. Menstrual blood loss studies suggest that the small Gyne Fix® does not increase menstrual blood loss when compared to the period prior to IUD use.[22]

RESULTS

Age

		Frequency	Percent	Valid Percen	Cumulative Percent
Valid	<20	9	7.3	7.3	7.3
	20-35	88	71.0	71.0	78.2
	>35	27	21.8	21.8	100.0
	Total	124	100.0	100.0	

Figure (1): Shows Distributions of Participants'- Age -Elobied Reproductive Health Clinic {R.H.C.} 2011

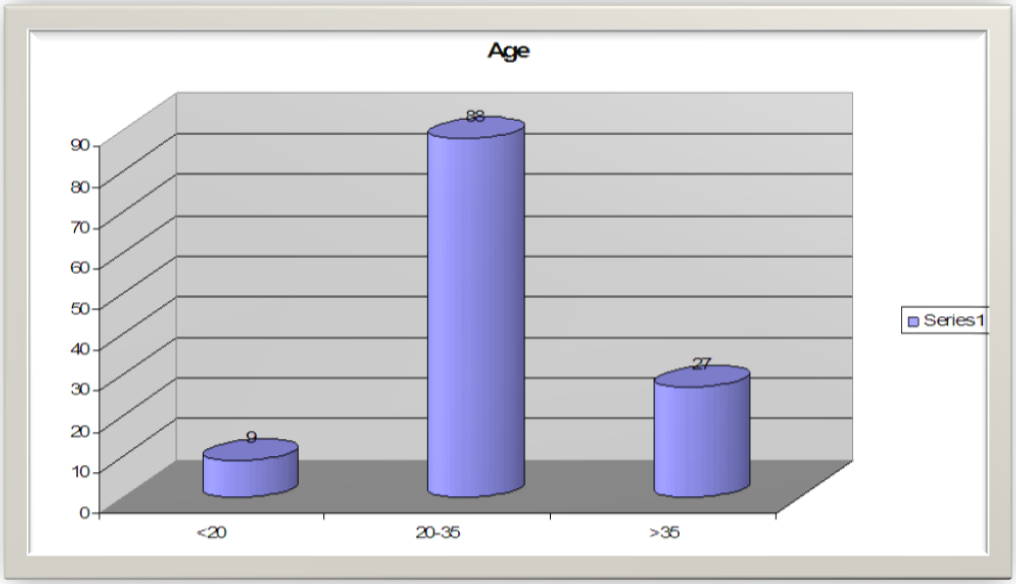
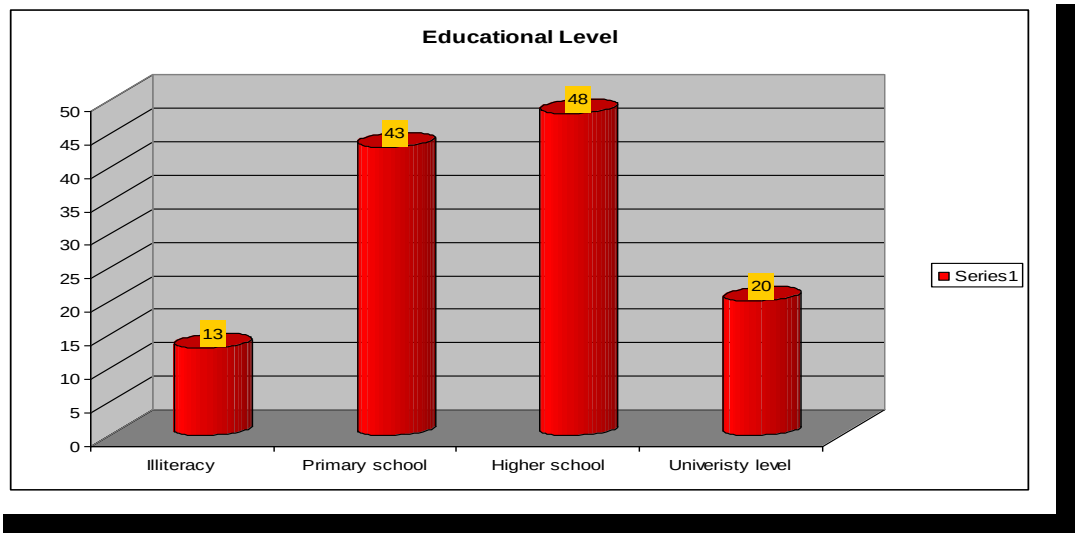


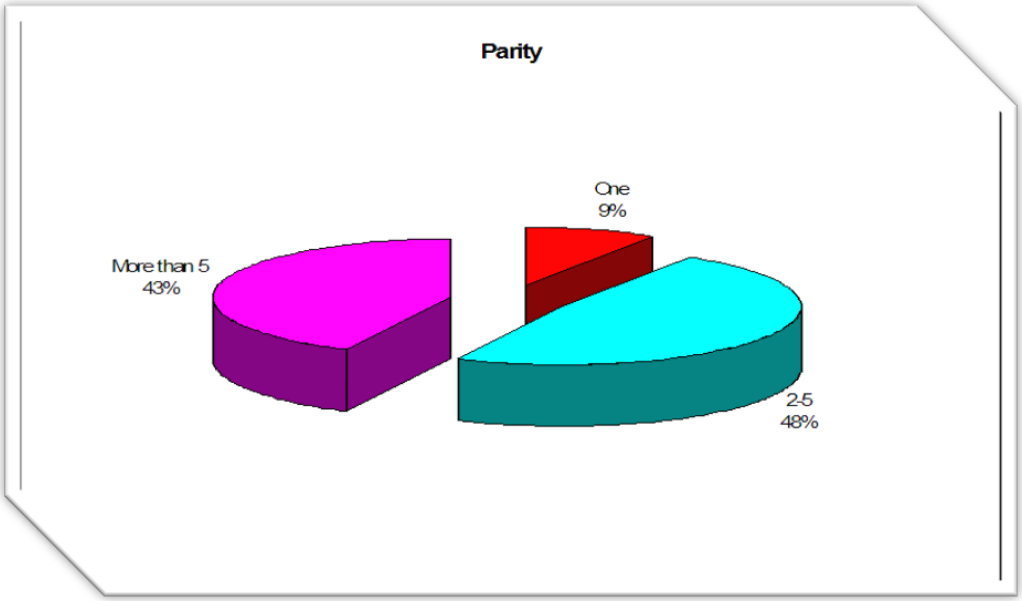
Figure (2): shows Educational level of Study Group– Elobied R.H.C 2011



Educational Level

		Frequency	Percent	Valid Percen	Cumulative Percent
Valid	Illiteracy	13	10.5	10.5	10.5
	Primary sch	43	34.7	34.7	45.2
	Higher scho	48	38.7	38.7	83.9
	Univeristy le	20	16.1	16.1	100.0
	Total	124	100.0	100.0	

Figure (3): shows percentage of participants' parity - Elobied R.H.C 2011



Parity

		requenc	Percent	alid Percer	Cumulative Percent
Valid	One	11	8.9	8.9	8.9
	2-5	60	48.4	48.4	57.3
	More tha	53	42.7	42.7	100.0
	Total	124	100.0	100.0	

Table (1): cross tabulation * educational Level vs. parity - Elobied R.H.C 2011

Educational Level * Parity Crosstabulation

Count

		Parity			
		One	2-5	More than 5	Total
Educational Level	Illiteracy	1	4	8	13
	Primary schoc	6	20	17	43
	Higher school	2	25	21	48
	Univeristy leve	2	11	7	20
Total		11	60	53	124

Chi-Square Tests

	Value	df	Asymp. Sig. (2-sided)
Pearson Chi-Square	5.150[a]	6	.525
Likelihood Ratio	5.264	6	.510
Linear-by-Linear Association	.299	1	.584
N of Valid Cases	124		

a. 4 cells (33.3%) have expected count less than 5. The minimum expected count is 1.15.

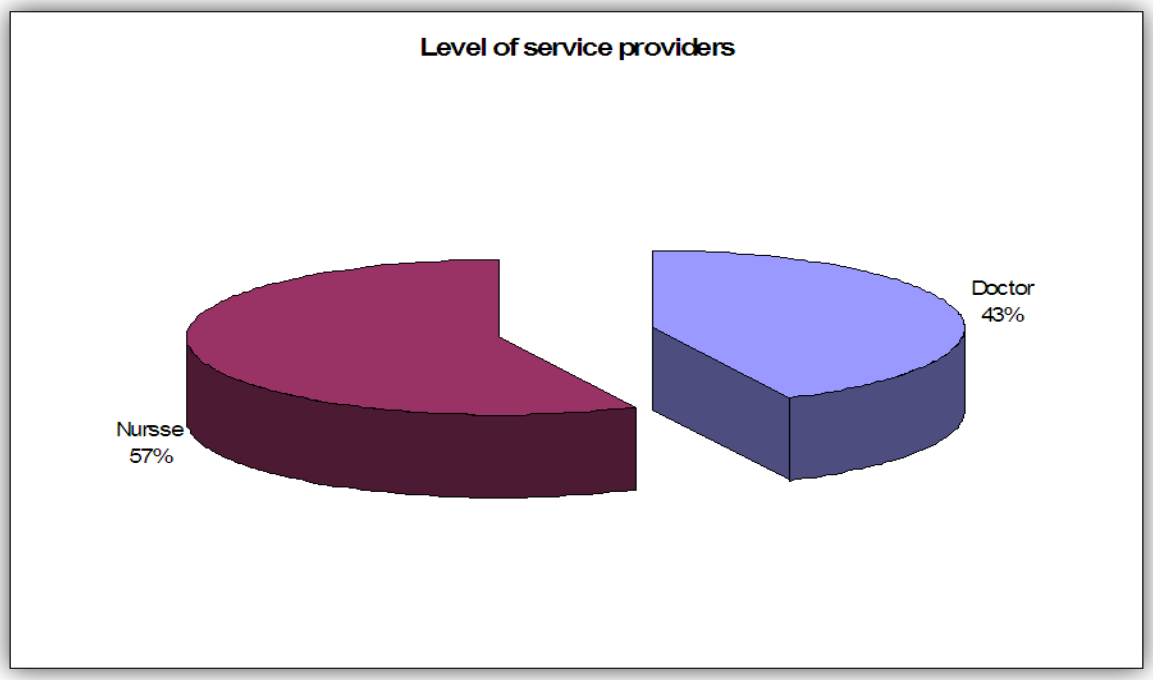


Figure (4) shows level of service providers- Elobied R.H.C. 2011

Level of service providers

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Doctor	53	42.7	42.7	42.7
	Nursse	71	57.3	57.3	100.0
	Total	124	100.0	100.0	

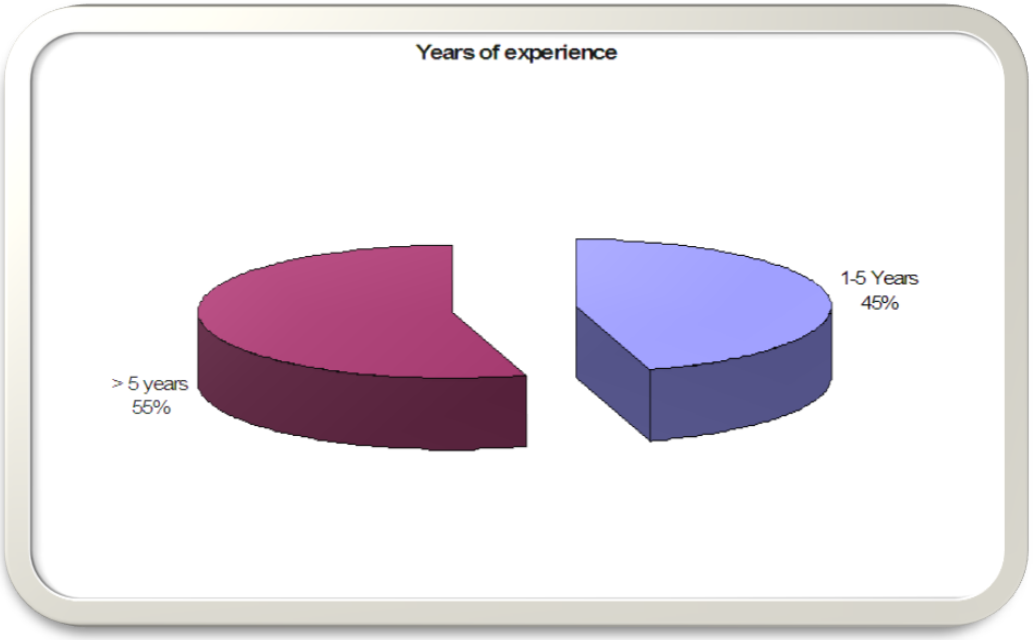


Figure (5): shows service providers' Years of experience ElobiedR.H.C.2011

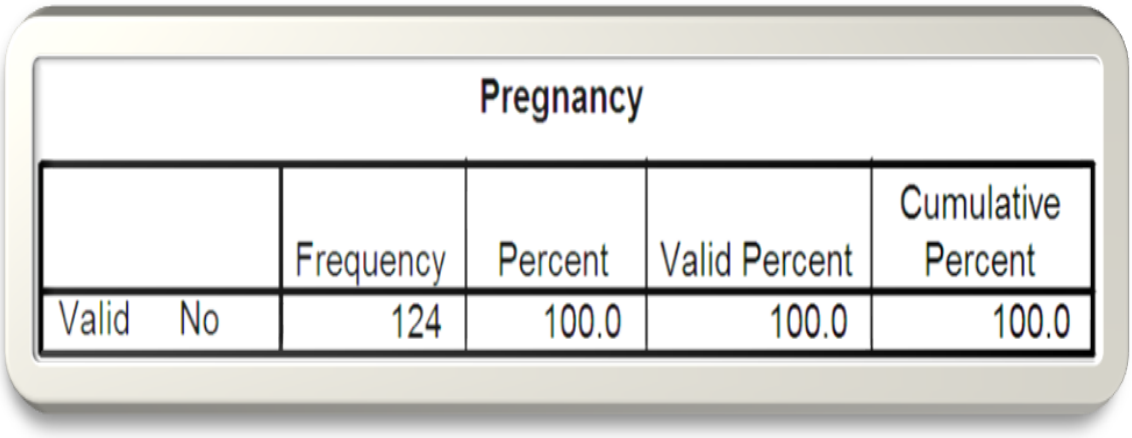
Years of experience

		Frequency	Percent
Valid	1-5 Years	56	45.2
	> 5 years	68	54.8
	Total	124	100.0

Table (2): T. test between doctors and midlevel Care Provider's skill - Elobied R.H.C. 2011

Independent Samples Test

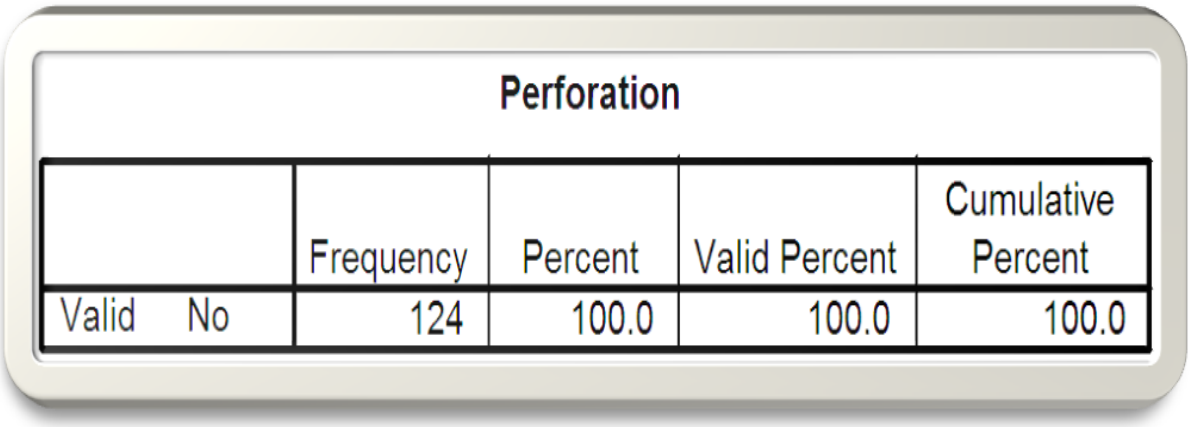
		vene's Test f ality of Variar		t-test for Equality of Means					
									% Confiden nterval of the Difference
		F	Sig.	t	df	g. (2-taile	Mean ifferenc	td. Erro ifferenc	Lower Upper
duration	Equal var assumed	.359	.550	1.553	122	.123	.5590	35992	7147 5355
	Equal var not assur			1.536	7.468	.127	.5590	36381	8013 6221



Pregnancy

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	No	124	100.0	100.0	100.0

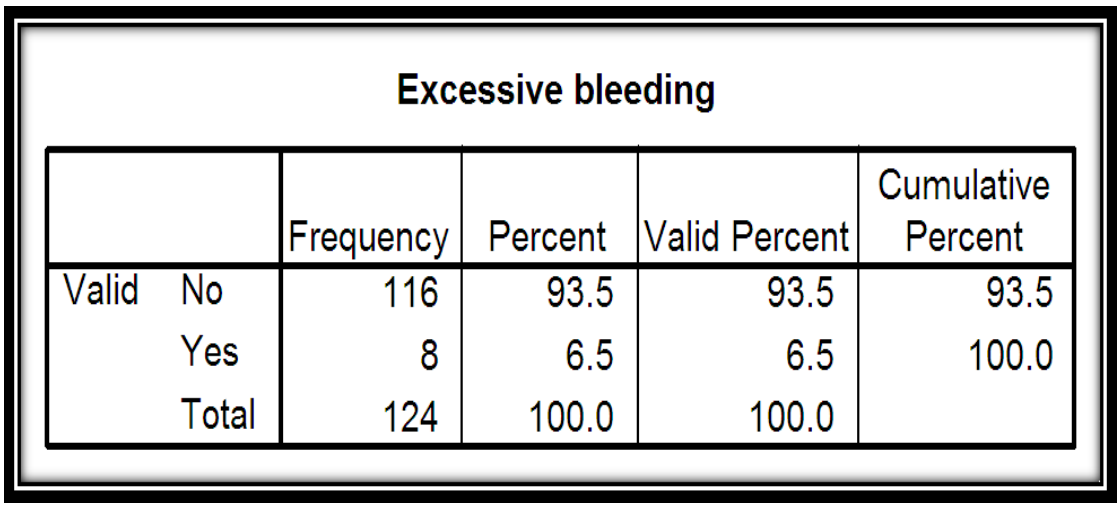
Figure (6): shows occurrence of pregnancy after Tcu380A insertion - Elobied R.H.C. 2011



Perforation

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	No	124	100.0	100.0	100.0

Figure (7): shows occurrence of perforation after Tcu380A insertion - Elobied R.H.C. 2011



Excessive bleeding

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	No	116	93.5	93.5	93.5
	Yes	8	6.5	6.5	100.0
	Total	124	100.0	100.0	

Figure (8): Occurrence of excessive bleeding after Tcu380A insertion- Elobied R.H.C. 2011

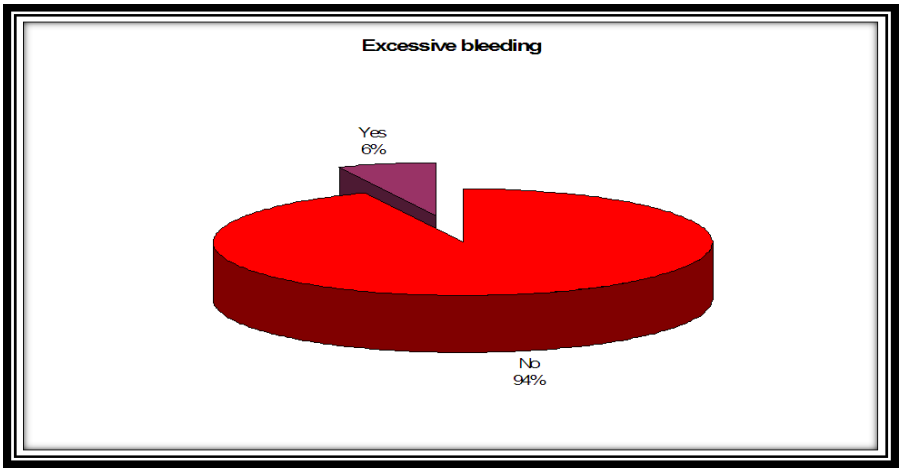
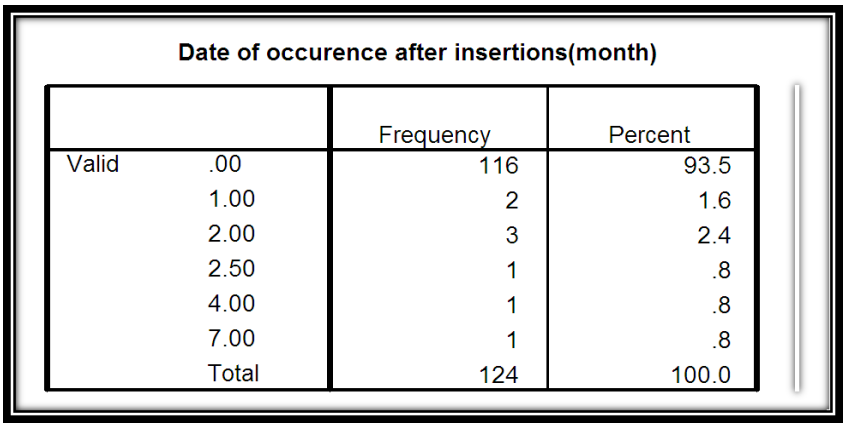


Figure (9): shows level of service providers and occurrence of excessive bleeding- Elobied R.H.C. 2011

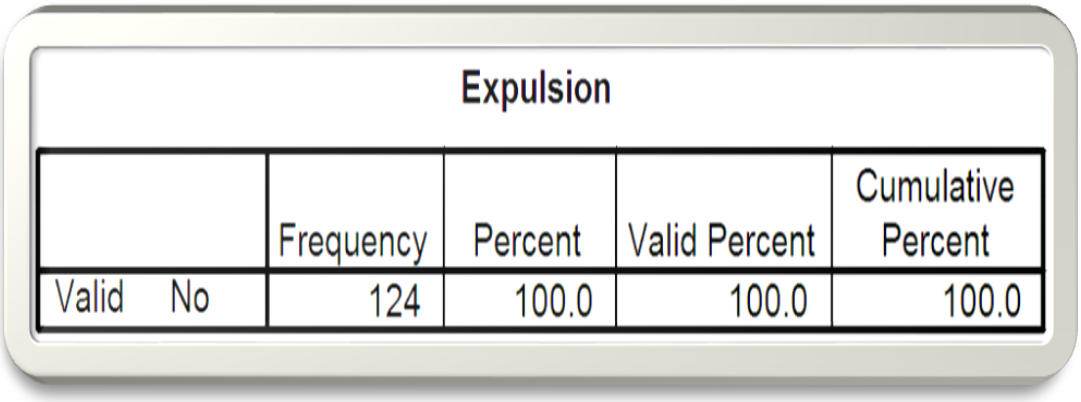
Valid	Frequency	Percent
Doctor	6	4.8
Nurse	2	1.6
Total	**8**	**6.4**



Date of occurence after insertions(month)

		Frequency	Percent
Valid	.00	116	93.5
	1.00	2	1.6
	2.00	3	2.4
	2.50	1	.8
	4.00	1	.8
	7.00	1	.8
	Total	124	100.0

Figure (10): shows duration of Tcu380A removal due to Excessive bleeding - Elobied R.H.C. 2011



Expulsion

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	No	124	100.0	100.0	100.0

Figure (11): shows expulsion rate after Tcu380A insertion- Elobied R.H.C. 2011

Thread loss

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	No	124	100.0	100.0	100.0

Figure (12): shows rate of thread loss after Tcu380A insertion- Elobied R.H.C. 2011

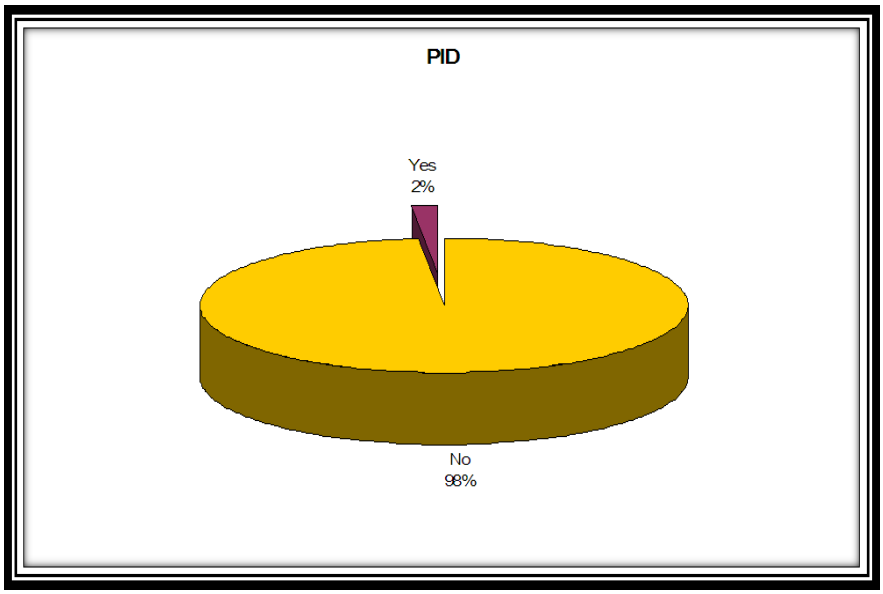


Figure (13): Occurrence of PID after Tcu380A insertion- Elobied R.H.C. 2011

PID

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	No	122	98.4	98.4	98.4
	Yes	2	1.6	1.6	100.0
	Total	124	100.0	100.0	

Level of service providers

		Frequency	Percent
Valid	Doctor	1	50.0
	Nursse	1	50.0
	Total	2	100.0

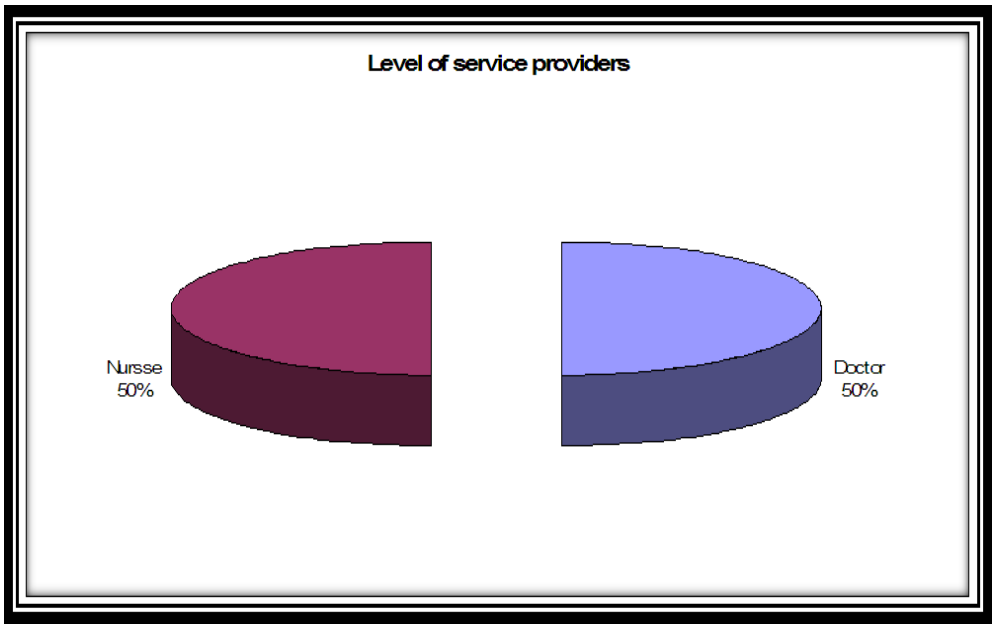


Figure (14): Occurrence of PID. And level of service providers who inserted Tcu380A. Elobied R.H.C. 2011

	frequency	Percent
Valid. 00	122	98.4
4	1	.8
5	1	.8
Total	124	100

Figure (15): Shows removal rate per year due to PID. Elobied R.H.C. 2011 Date of removal / (years)

Ectopic pregnancy

	Frequency	Percent	Valid Percent	Cumulative Percent
Valid No	124	100.0	100.0	100.0

Figure (16): Rate of ectopic pregnancy after Tcu380A insertion - Elobied R.H.C. 2011

DISCUSSION

The major objectives of this study were to evaluate the effectiveness of Tcu380A intrauterine device in term of pregnancy rate and identify nature of complications that occur after insertion and to compare between service provider's skills.

124 participants were enrolled in the study, although this population was not large enough to have higher power in detecting complications; however IUD effectiveness can vary greatly requiring ongoing skills of both doctors and midlevel providers to achieve correct and consent use.

From study‘s findings the majority of the Participants their age between 20- 35years 71%, and only 7%, of them their age less than 20 years figure (1).

Regarding educational level of participants fortunately only10.5% were illiterate and the majority of study group were higher secondary school level 38.7% and20% university level figure(2).

The parity of lady play a major role in her decision about seeking long term contraceptive methods, the study revealed that 48% of study group their parity between 2- 5 deliveries and only 9% were Para one, figure (3), but there was no relationship between educational level and parity in this study P value (0.299), in spite of many researchers suggested that there was strong relationship between parity and educational level. Table (1).

Lobe insertion needs proper fundamentals and perfect skills.

From study’ findings 57% of lobe insertion, inserted by nurses and 43% inserted by Doctors.

Figure (4).55% of these care providers fortunately their experience years more than 5 years. Figure (5). Table (2) shows T. tests between Doctors and midlevel provider’s skills, they are equal in lobe insertion there was no significance difference between Doctors and midlevel provider’s skills.

The study’s results highlighted the efficacy of Tcu380A as a perfect tool regarding occurrence of pregnancy as a complication100% (the rate of pregnancy was zero among study population). Figure (6).

This result was similar with a result of recent randomized controlled trails study done in Raymede clinic, London, UK. In 2008 which aimed to measure the effectiveness of Tcu380A in compare with ML cu375 in preventing pregnancy which approved the effectiveness of Tcu380A in preventing pregnancy.[15]

Another recent study conducted in department of Obstetrics & Gynecology, John A burn School of medicine university of Hawaii, Hondulu, Hawaii, USA. Several investigators' have examined the efficacy of various copper IUDS. The authors concluded that the copper Tcu380A was more effective in preventing pregnancy than the other devices including the multiload 375 & 250, copper T220 and copper T200.[13]

Another recent study in China, September 2010, no pregnancies occurred prior to or at first follow up visit, making Tcu380A 100% effective as emergency contraception.[12]

Occurrence of excessive bleeding during early insertion of IUCDs is suspected and from study's results the most common complication occurred and noticed was excessive bleeding, about 6.5% of the study population suffered from it. Figure (8). Compared with recent study done in Tongji Medical College, university of science & technology, China. The result shows that the most common side effects were excessive menstrual bleeding, spotting and pain although no percentage put in excessive bleeding.[14]

Appearance of complications can increase removal rate of IUD, but among study population only 6.5% registered removal rate of Tcu380A due to excessive bleeding, 1.6% of participants removed it after first month, 3.4% after 2 month, .8% after 4 months, .8% after 7months, Figure (10). In compared with study done in Tabriz, Iran, among women using Tcu380A the rate of termination due to pain/ bleeding was significantly higher than the rate of others causes.[9]

Study had done in United Nations Development Program me et.al. 1997 aimed to identify the rate of perforation of the uterus during insertion of Tcu380A has been shown to be quiet rare, with fewer than 1.5 perforations per 1,000 IUD insertions occurring in large clinical trial. The skill and experience of the provider is the most important factor that minimizes the risk of perforation (Harrison – Woolrych et.al. 2003).[7] But from study's results fortunately no perforation occur among the participants. Figure (7).

Expulsion of the IUD is uncommon, the skill and experience of the provider is the most important factor that minimizes the risk of expulsion (Chi, 1993).cumulative expulsion rate of 2.4, 3.4 and 4.4% at one two and three years of use, respectively, have been reported among copper IUD user (UNDP et.al., 1995) in the first year of use in one study done in China.[8]

But from study findings, no expulsion rate after insertion and also no thread loss were noticed.Figure (11 & 12).

PID is a serious complication associated with lobe insertion, study results showed that about 1.6% (two cases) of study group had an incidence of PID, which developed in late years as a complication, one case after 4 year and another one at 5 year respectively, Figure (13). This result Compared with another study done in U.S.A which reported that the rate of clinical PID was very low among IUD user –lower than previously thought and much lower than providers may realize 1.6 cases per 1000 women per year, that is 998.4per 1000 women per year did not get PID (Farley et.al; 1992).[8]

No ectopic pregnancy was reported among study group (the result was zero) Figure (16). Compared with other study the pregnancy in an IUD user is far more likely to be normal than ectopic: only an estimated 1 in every 13 to 16 pregnancies or 6 – 8% is ectopic (Fur log, 2002).[8]

In summary, the result of this study provides evidence base practice for the efficacy of Tcu380A in term of pregnancy rate, perforation of the uterus, expulsion, thread loss and ectopic pregnancy and from study findings also the researcher noticed that no differences or Varity in skills and fundamentals among health care providers regarding the insertion of Tcu380A.

7-1.CONCLUSION

The study concluded that, Tcu380A intrauterine device had no big serious complications like: pregnancy rate, expulsion rate, perforation, thread loss, ectopic pregnancy and these results were related to quality of care given and provided by expertise and skilled health care personnel in Elobied Reproductive Health Clinic and as researcher noticed even that two cases developed PID in late period (not related to insertion technique). Doctors and midlevel providers had equal skills in inserting intrauterine device.

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