POLYCYSTIC OVARY SYNDROME: PREVALENCE, CLINICAL AND ULTRASONOGRAPHIC FEATURES AMONG WOMEN WITH INFERTILITY AT MUHIMBILI NATIONAL HOSPITAL, DAR-ES-SALAAM, TANZANIA.

By

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A dissertation submitted in partial fulfillment of the requirement for the degree of Master of Medicine (Obstetrics and Gynaecology) of the Muhimbili University of Health and Allied Sciences

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CERTIFICATION

The undersigned certify that he has read and hereby recommend acceptance by Muhimbili University of Health and Allied Sciences, a dissertation entitled "Polycystic Ovary Syndrome; Prevalence, clinical and ultrasonographic features among women with infertility at Muhimbili National Hospital, Dar es Salaam, Tanzania" in partial fulfillment of the requirements for the degree of Master of Medicine (Obstetrics and Gynaecology)

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Prof.Kaisi .M

(SUPERVISOR)

Date...30/11/07.....

DECLARATION AND COPYRIGHT

I, Muzdalifat Salim Abeid, hereby declare that this dissertation is my own original work and it is a product of my own efforts and that it has not been presented and will not be presented in any other University for a similar degree award.

Signature.....

DEDICATION

To my husband Rashad, my lovely daughter Danah and my parents Salma and Salim Abeid.

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I wish to express my gratitude to a number of people who made important contributions to the accomplishment of this dissertation.

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ABSTRACT

Background: Polycystic ovary syndrome (PCOS) is a common endocrine disorder affecting women of reproductive age. Estimates regarding its prevalence are limited and unclear, this is mainly due to diagnostic criteria used. To my knowledge no local studies that have been done to establish the magnitude or clinical feature of this condition.

Objective: The aim of this study was to determine the prevalence, clinical and ultrasonographic features of PCOS among women with infertility at Muhimbili National Hospital (MNH) using the Rotterdam criteria.

Methodology: This was a cross sectional descriptive study conducted from 11th September 2006- 15th February 2007. Information collected and measurement performed included: menstrual history, anthropometric measurement, clinical examination of acne and hirsutism, USS, and biochemical analysis of LH, FSH, Testosterone.

Results: Thirty two percent prevalence of PCOS among the 100 infertile women recruited for the study was found. Among the women with PCOS 24(75%) had oligoanovulation (OA), 25(78.1%) had Polycystic Ovaries (PCO) and 18(56.3%) had hirsutism. There was a statistical significant difference in acne and menstrual irregularity between women with PCO and normal ovaries ($p < 0.05$).

Conclusion: The results of this study shows that PCOS is very common among infertile women, however presence of PCO are not necessarily associated with other symptomatology.

Large scale longitudinal studies of women with PCO are necessary to clarify any long- term risks.

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ABBREVIATIONS

ASRM	-	American Society of Reproductive Medicine
BMI	-	Body Mass Index
ESHRE	-	European Society of Human Reproduction and Embryology
F-G	-	Ferriman- Gallwey
FSH	-	Follicle Stimulating Hormone
GOPD	-	Gynaecological outpatient department
HA	-	Hyperandrogenism/Hyperandrogenemia
LH	-	Luteinizing hormone
MNH	-	Muhimbili National hospital
MUHAS	-	Muhimbili University of Health and Allied Sciences
NIH	-	National Institute of Health
OA	-	Oligoanovulation
PCO	-	Polycystic Ovaries
PCOS	-	Polycystic Ovary Syndrome
TVS	-	Transvaginal sonography
USS	-	Ultrasound
WHR	-	Waist-Hip ratio

1.0 INTRODUCTION AND LITERATURE REVIEW

1.1 INTRODUCTION

Polycystic ovary syndrome (PCOS) is a complex endocrine disorder which affects women of reproductive age and is, conventionally, defined as the association of hyperandrogenemia and chronic anovulation in women with polycystic ovaries (PCO)[1,2].

Women with PCOS are at an increased risk for infertility, preeclampsia, early pregnancy loss and endometrial cancer. The many features of this syndrome can be broadly divided into three categories: clinical, endocrine and metabolic. The clinical features include menstrual abnormality, hirsutism, acne, alopecia, anovulatory infertility and recurrent miscarriages. The endocrine features include elevated androgens, luteinizing hormone, oestrogen and prolactin levels. The metabolic aspect of this syndrome include insulin resistance, obesity, lipid abnormalities and an increased risk for impaired glucose tolerance and type 2 Diabetes Mellitus[3].

The first description of PCOS was given by the Italian scientist in 1721, "Young peasant woman, married, moderately plump and infertile, with ovaries larger than normal, like doves eggs, lumpy, shiny and whitish…". As early as 1844, Chereau described sclerotic changes in the ovary[4].

Although occasional reports on this condition continued to appear over the years, more interest was aroused in 1935 when Stein and Leventhal described bilaterally enlarged PCO, *"two to four times the normal size, sometimes distinctly globular", "tunica thickened, tough, and fibrotic", "follicle cysts near the cortex and almost entirely confined to the cortex". "The colour of the ovary was oyster gray with bluish areas*

where the cysts were superficial and appeared on the surface as sago-like bodies". Other characteristics included oligo-amenorrhea, hirsutism and infertility. The condition for a long time was called the Stein-Leventhal syndrome[5].

In the early 1970s, Rebar and coworkers observed elevated serum levels of luteinizing hormone (LH) and elevated LH to follicle stimulating hormone (FSH) ratios in women with PCOS[6]. The next important milestone was the discovery of a link between PCOS and insulin resistance[7]. The advent of high resolution ultrasound scan (USS) provided a non-invasive technique for the assessment of ovarian size and morphology. The ultrasonographic findings of PCO was described for the first time in 1981[8]. Adams and coworkers introduced a definition for the ultrasonographic appearance of PCO in 1985 as one diagnostic criteria of PCOS[9].

The diagnostic criteria for PCOS have long been the issue of debate. In the United states, the National Institute of Health (NIH) in 1990 recommended that the diagnostic criteria should include clinical or biochemical evidence of hyperandrogenism (HA) and ovulatory dysfunction. Other endocrinopathies must be excluded including thyroid dysfunction, hyperprolactinaemia, late onset congenital adrenal hyperplasia or cushing's syndrome. In 2003 a congress of American Society of Reproductive Medicine (ASRM) and European Society of Human Reproduction and Embryology (ESHRE) in Rotterdam, Netherlands extended the diagnosis of PCOS to include USS finding of PCO to the National Institute of Health (NIH) definition. The Rotterdam definition requires a minimum of two items out of three to make a diagnosis of PCOS. This recognizes four PCOS phenotypes:

HA + OA +PCO a full-blown syndrome; HA + OA a former NIH definition; HA + PCO an ovulatory PCOS and OA + PCO[10,11].

Despite PCOS being one of the most common endocrinopathies, a comprehensive explanation of pathophysiology is still lacking. Several theories have been proposed to explain the pathogenesis of PCOS. There is some evidence for a genetic predisposition[12]. Several studies reported on familial clustering of PCOS, which may suggest a genetic component of the disorder[13]. Hyperandrogenism is one of the important inheritable characteristics[14]. Genes involved in the regulation of steroid hormone synthesis and androgen receptor modulation have been suggested as an explanation for the genetic basis of PCOS.These genes are CYP17A gene which encodes for the P450c 17α enzyme, and CYP11A gene encoding for the P450 side-chain cleavage enzyme[15].

One hypothesis for the pathogenesis of PCOS,is that the developmental process in utero or in early postnatal life is influenced by genetic and environmental factors[16]. Female rhesus monkeys exposed prenatally to increased levels of testosterone by treating their mothers with testosterone during pregnancy exhibit abnormal LH secretion, abnormal insulin secretion, central obesity and hyper-androgenic anovulation as adult animals, and their menarche was delayed by six months[17]. Similar observations have been made in sheep. In both species, the ovaries were enlarged with multiple antral follicles. The clinical picture was equivalent to PCOS in humans. Androgens are potent gene transcription factors. They can interact with their own receptors and potentiate gene expression through serine phosphorylation of cyclic Adenosine Monophosphate[18].

Environmental factors seem to play an important role in the clinical presentation of the disorder[19]. Hence, there is a possibility that androgen excess in human fetuses results in imprinting, which later in life can result in the PCOS.

1.2 LITERATURE REVIEW

Although PCOS occurs universally, the prevalence, the time of onset of the clinical symptoms, and the severity of clinical presentation differ between ethnic and racial groups[20,21]. Carmina et al investigated Hispanic American, Japanese, and Italian women with PCOS and observed similar androgen levels, insulin resistance and prevalence of PCO among them, but the Japanese PCOS women were less hirsute and less obese than others[22]. This demonstrates that clinical expression might differ according to genetic differences in ethnic populations.

Data on prevalence of PCOS are variable due, in part, to the lack of well accepted criteria for diagnosis. If PCOS is defined by ultrasonographic appearance of PCO, the prevalence varies depending on the study settings used. PCO are seen in 92% of women with idiopathic hirsutism, 87% of women with oligomenorrhea[9], 21-23% of randomly selected women[23,24], 23% of women who considered themselves normal and who report regular menstrual cycles[19]. Up to 25% of patients with sonographic finding of PCO may be entirely asymptomatic[8]. Studies estimating the prevalence of PCOS using the NIH criteria agreed in 1990, reported an overall 4.0% prevalence of PCOS in women from the U.S[25] and a 6.8% prevalence of PCOS in the Greek island of Lesbos[26]. In a population of Caucasian women from Spain, a 6.5% prevalence of PCOS was demonstrated[27]. Prevalence studies according to Rotterdam criteria are not yet available. Probably the prevalence will be higher because the Rotterdam criteria have a wider definition of PCOS than the NIH definition.

Menstrual disturbances in form of oligomenorrhoea or infrequent menstruations are dominant symptoms of the anovulatory component of PCOS. Some women have regular

cycles at first and experience menstrual irregularity in association with weight gain[28]. The occurrence of oligomenorrhea may be explained by PCOS in approximately 85-90% of women, where as 30-40% of amenorrheic patients have been reported to have the disorder[29].

Hyperandrogenism is the second defining characteristic of PCOS. The most common clinical sign of hyperandrogenism in PCOS women is hirsutism. Hirsutism in women is male pattern of body hair growth. The modified F-G scale is most commonly used for the assessment of hirsutism[30]. The prevalence of hirsutism in PCOS women varies between 17-83% [29,31].

The prevalence of infertility, caused mainly by anovulation, in PCOS women varies between 35% and 94%[2,29,31]. In a case-control study of fertility in women with PCO, the concurrent presence of any PCOS symptom, such as obesity, hirsutism, acne, or menstrual disturbances, was associated with a 2.5 to 5 times longer time to pregnancy than that in women with normal ovaries Only 35% of the 258 cases of women with PCO did not have at least one PCOS symptom. This shows that although PCO are not independently a predictor of subfertility, they are associated with the risk of subfertility in women who have other signs and symptoms of PCOS[32].

The functional significance of PCO in ovulatory women with infertility remains unclear. A higher prevalence of PCO in ovulatory patients with infertility have been demonstrated than that in the normal population, suggesting that PCO may, perhaps by virtue of an effect of hyperandrogenemia, contribute to the causes of subfertility in women with regular menses[33]. According to Dahlgren et al, women with PCOS are as likely to have children as healthy women, although often after infertility treatment[34].

Some studies have also described an increased miscarriage rate in PCOS, the mechanism of which is poorly understood[35].

The prevalence of obesity varies largely among PCOS women, depending on the population studied and the diagnostic criteria used. Most investigators have found that 30-50% of women with PCOS are obese[2]. Women with PCOS usually present with the so called "central obesity",which is associated with insulin resistance, increased risk of cardiovascular disease and type 2 diabetes mellitus[36].

Acantosis nigricans manifests as skin pigmentation and papillomatosis. It is associated with insulin resistance and increased insulin secretion. It has been suggested that the skin lesion is due to increased insulin stimulated melanin synthesis in the melanocytes of the dermis. Acantosis nigricans is typically seen in areas with increased mechanical exposure, such as the neck, the armpits and the groin. It has been reported to be present in 3% of women with PCOS and is more frequent in dark-skinned populations[10].

To my knowledge there is no study which have been done in Tanzania to show the magnitude or clinical feature of PCOS. However, in a private hospital (TMS) in Dar-es-Salaam the record shows that a total of 127 patient had ovarian drilling for PCOS from January-August 2006. This remarkable figure simply shows how common may PCOS be in Tanzania.

1.3 Statement of the problem and Rationale of the study

Infertility among women is a major problem in Tanzania. Many divorces and domestic conflicts may arise out of infertility. With the advent, widespread, and availability of ultrasound machines as a diagnostic tool in poor countries, including Tanzania, along with the evolution of fast hormonal assays, the local gynecologist have awaken up to the fact that chronic anovulation is increasingly becoming a common recognized disorder among infertile women in Tanzania.

However, as far as we could establish, to date no studies have been carried out to establish what proportions of cases of anovulation is due to PCOS in Tanzania and since the main problem has been the diagnostic criteria to be use to diagnose PCOS, therefore this study using the Rotterdam criteria has identify the magnitude of PCOS, this will enable us either to adapt to the Rotterdam criteria or establish a modified criteria.

Todate the mainstay of infertility management in women has been one or the other form of tubal surgery, or stimulation of ovaries with clomiphene citrate. Knowing the magnitude of PCOS in our country is bound to have a significant impact on female infertility management generally, and increase awareness on the role of quality sonography in identification of PCO.

Since PCOS is now known to be part of complex metabolic syndrome involving insulin, carbohydrate and lipid metabolism, and hence closely related to the lifestyle, and since urbanization in Africa is rapidly taking place, sedentary lifestyle and obesity are likely to parallel the changes and may turn PCOS into major reproductive health problem. Early identification is very likely to have a major impact on increase awareness among the

patients and the local professionals alike. There is a need to objectively assess and quantify its magnitude.

2.0 OBJECTIVES

2.1 Broad Objective

To determine prevalence, clinical and ultrasonographic features of PCOS among women attending gynaecological outpatient department (GOPD) for infertility at Muhimbili National Hospital (MNH).

2.2 Specific Objectives

1. To determine the prevalence of PCOS using Rotterdam criteria among women attending GOPD for infertility
2. To compare levels of sex hormones (LH, FSH, testosterone) between women with PCOS and without PCOS
3. To compare clinical features and hormonal profile among women with PCO and those without PCO.

3.0 METHODOLOGY

3.1 Study design

Descriptive cross-sectional study.

3.2 Study area

MNH is the largest referral, consultant and teaching hospital located in Dar es salaam. The city is organized into three municipal councils namely Ilala, Kinondoni, and Temeke. Each municipal has a district hospital which provide gynaecological outpatient services. Gynaecological patients with complications or needing further investigations are referred to MNH-GOPD. Therefore MNH-GOPD receive patients from district

hospitals, private hospitals, health centres and dispensaries of Dar-es-salaam, also from nearby coast region and the whole country.

The GOPD services run throughout all working days of the week from 8.00 a.m to 12 noon except for Tuesday. GOPD services are run by four firms conducted by a team of doctors which include consultants, specialists, residents, registrars and intern doctors. For fast track patients the clinics usually run in the afternoon from 2.00pm to 5.oo pm. Fast track patients are free to choose any doctor who is of specialist cadre. The clinic has five rooms. Patients attending GOPD per day range from 10 to 25, among which at least two are presenting with the problem of infertility.

3.3 Study duration

The study was conducted from 11th September 2006 to 15th February 2007.

3.4 Study population

All women who attended GOPD at MNH during the study period.

3.5 Study sample

All women who presented at GOPD with infertility during the study period were recruited.

3.6 Pretesting and research assistants training

Pretesting was done one week prior to data collection to test the flow of the questionnaire, to avoid repeatitions, to see if there were any forgotten questions which are relevant and to make corrections of any mistakes. Few changes were made to the questionnaire before it was used for data collection. The researcher conducted a one day

training to the two research assistants. Introduction to the research topic and the purpose of the study was done. The procedures of data collection were elaborated.

3.7. Data collection procedure

3.7.1 Recruitment

Those patients who fulfilled the inclusion criteria were identified by the research assistants as they came to GOPD. Data were collected using the structured questionnaire (Appendix11).The researcher and research assistants arranged themselves so that all the patients including the fast track patients were included in the study. The principal investigator counter-checked all the questionnaires filled by the research assistants, any missing information was obtained from the participants in the following visit.

The collected information included social demographic characteristics, menstrual pattern, family history of infertility, and duration of infertility. Physical examination included assessment of acne, hirsutism, weight, height, waist and hip circumferences. The researcher used F-G method to score the extent of hirsutism (Appendix I11).

3.7.2 Laboratory investigations

Blood for hormonal analysis was taken after physical examination irrespective of the menstrual cycle. Serum samples were analyzed for levels of total testosterone, FSH and LH. A double antibody technique on an Elecys 2010 analyzer (Roche Diagnostic GmbH, Manheim, Germany), using reagents and calibrators supplied by the manufacturers was used. All analyses were performed on the same day blood was taken.

3.7.3 Ultrasound examination

Transvaginal ultrasound was performed by an experienced (more than 15 years) physician-sonologist, using Esaote Biomedica AU3 Partners, Italy and GE Logiq Pro 100, South Africa, with 7.5 MHz. USS measurements were taken in real time. USS was performed one week later after clinical evaluation.

3.8 Data management and analysis:

Each questionnaire was assigned with an identification number. The data were precoded and entered into the computer and cleaned by the researcher using EPI INFO 6 and analysed by SPSS 10.0 computer programme. Data are presented as median plus range for non- parametric data or as number and percentages. Differences between two groups were evaluated with the Mann- Whitney U test or Chi-square test as appropriate. When more than two groups were compared Kruskal-Wallis-Test was used. P values < 0.05 were considered significant.

3.9 Ethical issues

Ethical clearance was obtained from Research and Publication committee of Muhimbili University of Health and Allied Science (MUHAS). Permission to conduct the study was obtained from the Executive Director of MNH. Participants were not exposed to any risks in the study and they were informed about the importance of the study and its purpose to improve future management of other patients with infertility. Consented participants signed a consent form (Appendix IV).

For those patients who were diagnosed with PCOS were treated according to the hospital guidelines. Patients who wished to withdrawn from the study were offered standard treatment according to the hospital protocol.

3.10 Study limitations

Lack of adequate finance made it impossible to perform other biochemical tests to exclude other causes of hyperandrogenemia, and this somehow influenced the study results. Also the blood samples which were taken could not be timed to the woman's menstrual cycle for practical reasons.

Male factors were not taken into consideration as a cause of infertility. Fewer patients coming to GOPD since they have to pay and time limitation contributed to small study sample.

3.11 Definition of terms

1. Infertility - inability to conceive for one year or more.
2. Oligo/Anovulation – determined by menstrual pattern (oligomenorrhoea (cycle length over 35 days and under six months) or amenorrhoea (absence of menstruation for the last three months or longer)).
3. Acne - presence of comedones on the face, neck, upper chest, upper back, or upper arms.
4. Hirsutism –F-G method was applied and a score of 6 or more was taken as significant.
5. Hyperandrogenemia - serum level of Testosterone > 0.6ng/ml.
6. BMI- overweight was defined as BMI>25 kg/m2 and obese BMI >30kg/m2.

4.0 Results.

One hundred and two women with infertility who attended the GOPD during the study period were recruited and consented for the study. Two women were excluded after discovering were pregnant by hormonal assay and USS remaining with 100 women for analysis, there were no declines. The recruitment profile is shown in Figure 1.

The proportion of women diagnosed with PCOS was found to be 32(32%). Among these 25(78.1%) had polycystic ovaries identified in the USS, 24(75%) had signs of oligoanovulation, and 18(56.3%) had hirsutism.

Among the non- PCOS, 7(10.3%) had polycystic ovaries identified by USS, 15(22.1%) had signs of oligoanovulation and 6(8.8%) had hirsutism.

Of the 100 women included in the study, 20% were overweight (BMI, 25.0-29.9kg/m2), and 14% were obese (BMI >= 30.0 kg/m2). Among women diagnosed with PCOS, 6 were overweight and 6 were obese.

Hyperandrogenemia was demonstrated in 11% of the population, 12% (4/32) were diagnosed to have PCOS.

FIGURE 1: FLOW CHART

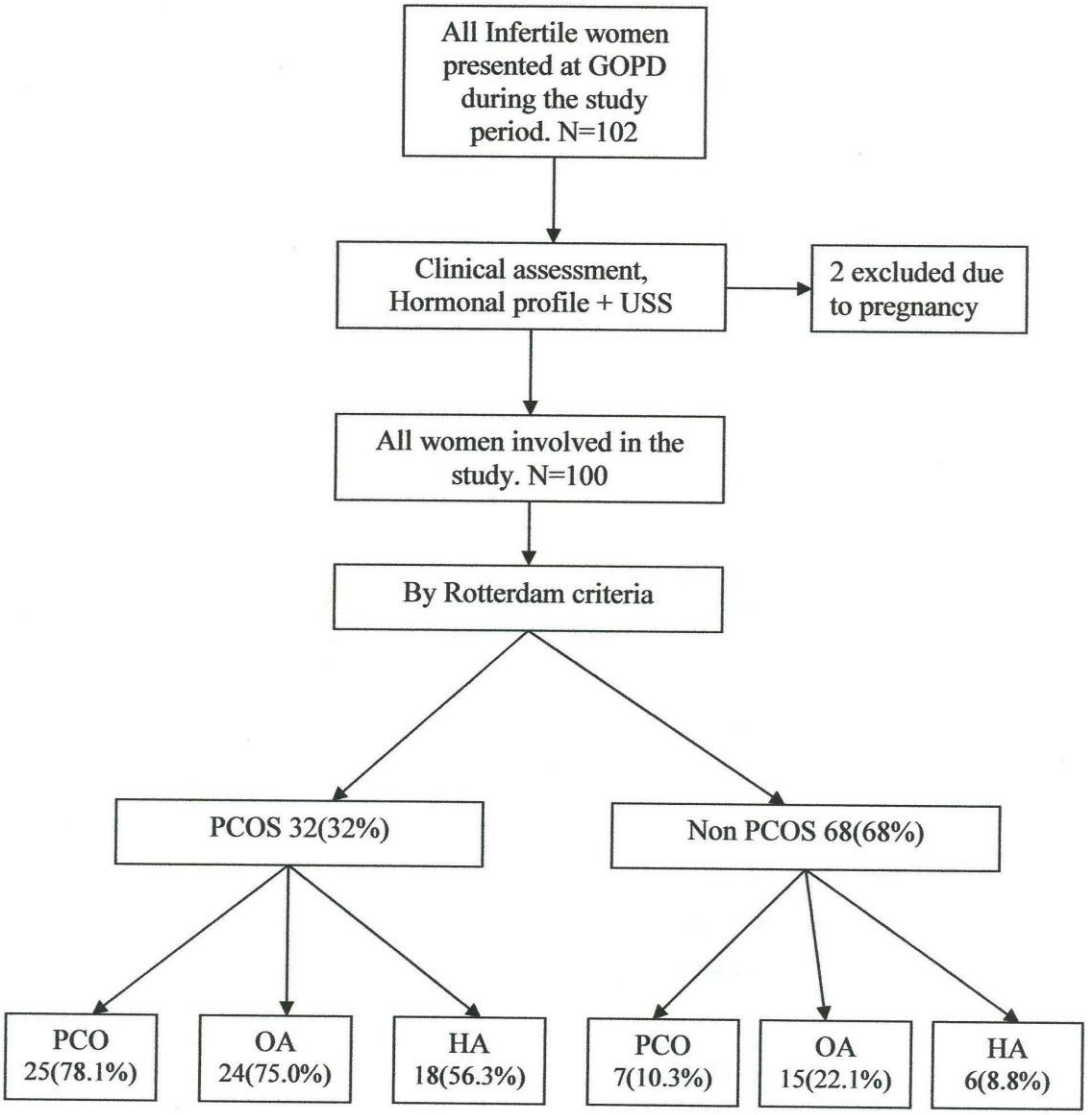

Table 1: Socio-demographic characteristics and fertility status of women with PCOS and without PCOS (n=100)

Characteristics	**PCOS n=32** n(%)	**Non-PCOS n=68** n(%)
Age of patient:(Years)		
<20	-	2(100)
20-30	20(40.8)	29(59.2)
31-40	12(24.9)	37(75.1)
Parity:		
0	21(33.3)	42(66.7)
1	9(33.3)	18(66.7)
2	1(12.5)	7(87.5)
3	1(50.0)	1(50.0)
Marital status:		
Single	3(33.3)	6(66.7)
Married	28(31.5)	61(68.5)
Unstable relationship	1(50.0)	1(50.0)
Education:		
No formal education	1(33.3)	2(66.7)
Primary education	14(29.1)	34(70.9)
Secondary + above	17(34.6)	32(65.4)
Occupation:		
Student	2(50.0)	2(50.0)
House wife	10(23.3)	33(76.7)
Employed	7(33.3)	14(66.7)
Petty businesswoman	11(36.7)	19(63.3)
Peasant	2(100)	-
Infertility status:		
Primary	15(35.7)	27(64.3)
Secondary	17(29.3)	41(70.7)

Table 1 shows that women with PCOS and without PCOS had comparable socio-demographic characteristics.

Table 2: Hormonal profile between women with PCOS and without PCOS

Hormones	**PCOS** **Median(Range)**	**Non-PCOS** **Median(Range)**	**P-Value**
Testosterone	0.26(0.02-0.88)	0.21(0.02-1.25)	p=0.69
LH(miu/ml)	7.04(0.29-41.78)	6.65(0.2-72.04)	p=0.59
FSH(miu/ml)	5.13(0.41-44.42)	5.48(0.50-98.90)	p=0.12
LH/FSH ratio	1.18(0.52-4.98)	1.21(0.09-11.06)	p=0.605

There were no statistical differences in levels of, LH, FSH and LH/FSH ratio between women with PCOS and those without PCOS.

Table 3: Comparison of demographic, clinical feature and hormonal profile among phenotypes of PCOS.

Characteristics	HA+OA n=7	HA+PCO n=8	OA+PCO n= 14	HA+OA+PCO n=3	P-VALUE
Age(yrs)*	28.1 ± 4.9	31.5 ± 3.3	28 ± 5.8	29 ± 3.0	NS
BMI(kg/m2)*	23.9 ± 2.6	24.5 ± 5.1	27 ± 6.4	25 ± 2.5	NS
WHR†	0.7(0.6-0.8)	0.7(0.6-0.8)	0.8(0.5-0.9)	0.6(0.6-0.8)	NS
HIR.Score*	8.1 ± 1.5	8.3 ± 1.7	3.6 ± 1.5	7.3 ± 0.5	p<0.001
Parity*	0.5 ± 1.1	0.6 ± 0.5	0.3 ± 0.6	0.00	NS
Abortions †	0.0(0-6)	1.0(0-2)	0.0(0-3)	0.0(0-1)	NS
Menarche(yrs)*	16.4 ±1.8	14.3 ± 1.7	13.5 ± 1.9	14 ± 2)	p<0.05
Dur.infert.(yrs)*	5.1 ± 2.9	3.8 ± 2.1	4 ± 2.1	3 ± 1.0	NS
T (ng/dl)†	0.09(0.02-0.8)	0.2(0.02-0.5)	0.2(0.2-0.7)	0.4(0.2-0.8)	NS
LH (miu/ml)†	3.6(0.3-13.6)	5.0(3.1-26.2)	10.2(2.7-41.8)	14.0(6.6-20.4)	NS
FSH (miu/ml)†	4.7(0.4-8.5)	6.1(4.0-8.4)	6.1(1.9-44.4)	4.1(2.9-5.6)	NS
OVA VOL*	-	17 ± 8.6	32.7 ± 21	33.3 ± 24.4	NS

*Mean (sd)
† Median (range)
HIR.score-hirsutism score; Dur.infert- duration of infertility; T-testosterone; OVA VOL- ovarian volume, NS- not significant. Kruskal-Wallis test was used.

With exception of menarche and hirsutism score, where there was statistical difference, PCOS phenotypes did not differ statistically in terms of clinical and laboratory as well as demographic findings ($p > 0.05$).

Table 4: Comparison of demographic, clinical feature and hormonal profile among women with both OA and PCO and women with either OA/PCO.

Variable	OA/PCO	OA+PCO	P-VALUE
Age(yrs)*	29.93(4.3)	28.41(5.36)	NS
BMI(kg/m2)*	24.2(4.0)	26.8(5.9)	NS
WHR†	0.7(0.6-0.8)	0.8(0.5-0.9)	NS
HIR.Score*	8.3(1.6)	4.3(2.5)	p<0.001
Parity†	0(0-3)	0(0-2)	NS
Abortions †	0.0(0-6)	0.0(0-3)	NS
Menarche(yrs)*	15.3(2.0)	13.6(1.9)	NS
Dur.infert.(yrs)*	4.4(2.5)	3.8(2.0)	NS
T (ng/dl)†	0.24(0.027-0.88)	0.20(0.20-0.80)	NS
LH (miu/ml)†	4.8(0.29-26.17)	10.9(2.67-41.78)	p<0.05
FSH (miu/ml)†	5.0(0.4-8.50)	5.2(1.88-44.42)	NS
OVA VOL*	17.0±8.6	33.3 ± 22.7	NS

*Mean (sd)
† Median (range)
HIR.score-hirsutism score; Dur.infert- duration of infertility; T-testosterone; OVA VOL- ovarian volume, NS- not significant.

Women with both feature of OA and PCO appears to have high levels of LH as compared to women with either OA/PCO and the difference is statistical significant ($p< 0.05$). This suggests that women who have both characteristics that is OA and PCO are more likely to have PCOS.

Table 5: Association of clinical data and Hormonal profile among women with PCO and Normal Ovaries

Characteristics	**PCO n(%) n=32**	**Normal ovaries n(%) n=68**	**P-Value**
Menstrual pattern:			
Oligomenorrhoea	17(53.1)	22(32.4)	p<0.05
Regular menses	15(46.9)	46(67.6)	
Hirsutism	11(34.4)	13(19.1)	NS
Acne	13(40.6)	12(17.6)	p<0.05
BMI*	25.78±5.2	24.16±4.0	NS
WHR*	0.74±0.08	0.75±0.09	NS
Testosterone**	0.223(0.02-1.25)	0.196(0.20-0.88)	NS
LH**	7.42(0.2-72.04)	6.49(0.29-50.27)	NS
FSH**	5.67(0.50-44.42)	5.16(0.41-98.90)	NS

*Body mass index, waist to hip ratio expressed in means±SD, t-test was used for comparison.
** Testosterone, luteinizing hormone and follicle stimulating hormone are expressed in medians(range). NS- not significant.

There were significant differences in irregular periods and acne among women with polycystic ovaries compared to women with normal ovaries (P< 0.05). (table 5).

The mean BMI did not differ significantly between the groups (25.78kg/m2 in women with polycystic ovaries vs. 24.16kg/m2 in women with normal ovaries P> 0.05).

There were no significant difference in hormone levels among women with polycystic ovaries and those with normal ovaries.

5.0 DISCUSSION

PCOS is believed to be one of the most common endocrine disorders of women, however there is very limited data regarding its prevalence. As stated above, the present definition of PCOS is based on the congress of ESHRE/ASRM in Rotterdam, Netherlands, 2003[37]. To our knowledge prevalence defined by Rotterdam criteria have never been previously determined. Due to lack of financial support, in this study some of the investigations were not done which would have probably rule out other endocrinopathies which are clinically similar to PCOS and thus changing the prevalence of PCOS.

In this cross-sectional study of a sample of 100 infertile women attending MNH-GOPD, using the Rotterdam criteria a 32% prevalence of PCOS among infertile women was found. This rate is exceptionally high if you compare to those reported by other investigators in Greece, US, and Spain[25,26,27]. However this discrepancy was expected since the study population is different and also because Rotterdam criteria have a wider definition of PCOS than the previously NIH criteria.

It is possible that prevalence of PCOS in this study was underestimated since clinical hyperandrogenism was defined only by the presence of hirsutism and ovulatory dysfunction was estimated from menstrual history only. Since the optimum system for acne scoring remains highly disputed[38], its presence was simply recorded without a grade. In this population 4 women had evidence of acne, and their consideration would have increased the overall incidence of PCOS to 36%. Moreover, as total testosterone was the only androgen measured, the prevalence of PCOS would have been even higher if other serum androgens (Androstenedione, dehydroepiandrosterone sulfate) were measured.

It should be noted that it was not possible to control precisely for the time of the day of the menstrual cycle of serum sampling. As we all know that levels of LH and FSH varies at different phases of menstrual cycle. However this was also observed in previous studies, but as Knochenhauer et al pointed out clearly that none of these factors appears to have a significant impact on the clinical value of circulating androgens[25].

In this studied population 61.5% (24/32) of patients with menstrual dysfunction had PCOS, raising questions regarding the high proportion of PCOS suggested to affect women with oligoovulatory infertility[39].

In this study population, overrall prevalence of hirsutism was 24% with the chosen F-G score of 6 or more as indicating the presence of significant hirsutism. Seventy-five percent of women with hirsutism were estimated to suffer from PCOS. It should be noted that prevalence of hirsutism in PCOS varies by ethnicity. In comparative studies, the rate of hirsutism in Japanese patients was lower than in Hispanic and Italian women living in the United States[22]. In the present study there was a statistical difference in hirsutism among different phenotypes of PCOS.

In this population of infertile women, 32% were documented to have PCO detected by ultrasound. This prevalence is considerably higher than the reported prevalence of 21-23% among normal female population [19,23,24]. Alternatively, 53.1% prevalence of PCO among the women with OA is comparatively small to the prevalence of 83% among

anovulatory infertile women reported by E.Kousta et al[40], but the difference could be explained by the small sample size and limited time used in this study.

Polycystic ovaries in this population were associated with irregular menstrual cycles more frequently than in women with regular menstrual cycles.This finding is not suprising since several hospital based studies have shown menstrual irregularities to be commonly associated with PCO[10,29]. The frequency of irregular cycles reported in the women with normal ovaries however, was 32.4% higher than expected when compared with the frequency reported in community studies by Clayton et al., Farquhar et al., in which the rates were 20% and 27% respectively[23,24]. This discrepancy may be due to the study population and study design. Previous studies dealt with normal female population.

Presence of PCO has been shown to have no significant impact on fertility in asymptomatic women[32]. Moreover it is important to consider that normally ovulating women with the isolated finding of PCO on ultrasound and the absence of hyperandrogenism are not considered to have PCOS. The role of PCO in ovulating PCOS women remains unclear. On the other hand, the relevance of PCO on reproductive therapeutic interventions is well-known. Takahashi and colleagues found that PCOS women with multiple follicles and enlarged ovarian volume failed to respond to ovulation induction with clomiphene citrate[41].

Elevated serum testosterone concentration have been frequently associated with PCO [10]. Of the women with PCO in this population however, only 12.5% (4 of 32) had elevated serum testosterone concentration (> 0.6 ng/ml). In this study, the presence of PCO was not associated with any biochemical feature, this is in accordance to other study groups[22].

It should be noted that defining overweight as a BMI > 25kg/m^2 and obese as a BMI > 30kg/m^2, 20% of subjects were overweight and 14% were obese. The prevalence of overweight and obesity was similar among women with PCOS (18.7%) and this rate is lower than Spanish patients[27]. These data suggest that there are significant ethnic differences in the prevalence of obesity in PCOS and that obesity per se is not a universal feature of the syndrome.

In this study levels of LH was significantly higher in the group with both PCO and oligoanovulation versus the group with either oligoanovulation or PCO. This implies that combination of OA and PCO is more likely to be PCOS. Elevated values of LH have been associated with a significant impairment of fertility. It has been suggested that a high LH in the mid-follicular phase directly and adversely affects the timing of maturation of the oocyte, resulting in release of an 'aged' oocyte[35].

Although this study has demonstrated a higher prevalence of PCOS among infertile women and that PCO is not necessarily associated with PCOS, however these findings should be regarded as approximate and in need of verification by further studies. It should be noted that MNH-GOPD is a predominantly secondary referral centre and is the main provider of infertility services in the city with exception of private hospitals. Therefore, most of the patients are secondary referrals with only a few tertiary referrals.

6.0 CONCLUSION

PCOS is a common reproductive-endocrinological disorder in our set up with a prevalence of 32% among infertile women. Additionally, ultrasound detected PCO has no clinical significance since presence of PCO are not necessarily associated with other symptoms of PCOS.

7.0 RECOMMENDATIONS

Doctors should understand that it is unwise to advocate metformin treatment in patients with PCO only, because having PCO does not mean you have PCOS.

Therefore, application of the Rotterdam criteria in diagnosing PCOS would be advise.

Large scale longitudinal prospective studies of women with polycystic ovaries are necessary to clarify any long term risks.

8.0 References.

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9.0 APPENDIX I

9.1 ROTTERDAM ESHRE/ASRM 2003 CRITERIA.

Two of the following three criteria must be fulfilled for the diagnosis of PCOS:

1.Polycystic ovaries; 12 or more follicles in each ovary, each follicle measuring 2-9 mm in diameter and/or ovarian volume > 10ml, verified by transvaginal ultrasound. One polycystic ovary is sufficient for the diagnosis.

2.Oligo-/anovulation; clinically diagnosed as oligo-/amenorrhea, that is menstrual cycle longer than 35 days or less than 10 menstruations per year.

3.Hyperandrogenism; clinical or biochemical.

And exclusion of other aetiologies (congenital adrenal hyperplasias, androgen-secreting tumours, Cushing's syndrome).

APPENDIX II

9.2 QUESTIONNAIRE:

Prevalence, Clinical and Ultrasonographic features of PCOS among infertile women attending GOPD at MNH.

Identification No: ..... Registration No: .....

Name of Interviewer.....

Date of Interview.....

Part I: Social Demographic Characteristics:

No:	ITEM	TO BE FILLED BY RESEARCH ASSISTANT	TO BE CODED BY MAIN RESEARCHER
1.	Age of patient	[ ]	1.[ ]
2.	Parity	[ ]	2.[ ]
3.	Marital status	1. Single 2. Married 3.Unstable relationship	3. [ ]
4.	No. of yrs spent at school by patient	1. 0 2. 1-4 3. 5-7 4. 8-14	4. [ ]
5.	Occupation of patient	1. Student. 4. Employed 2. Housewife 5. Peasant 3. Businesswoman.	5. [ ]

Part II: Details on antropometric measurement:

o:	ITEM	TO BE FILLED BY RESEARCH ASSISTANT	TO BE CODED BY MAIN RESEARCHER
6.	Waist Circumference (cm) [ ] Hip Circumference (cm) [ ] W/H.	[ ]	6. [ ]
7.	Body weight (kg) [ ] Height (m2) [ ] BMI	[ ]	7. [ ]

Part III: Details on menstrual history:

No:	ITEM	TO BE FILLED BY RESEARCH ASSISTANT	TO BE CODED BY MAIN RESEARCHER
8.	Menarche onset.	[ ] .	8. [ ]
9	Menstrual pattern.	1. Eumenorrhea 2. Oligomenorrhea 3. Amenorrhoea 4. Polymenorrhea	9. [ ]

Part IV: Details on obstetrics Hx:

No:	ITEM	TO BE FILLED BY RESEARCH ASSISTANT	TO BE CODED BY MAIN RESEARCHER
10.	Abortions	[ ]	10. [ ]
11	Subfertility	1. Primary 2. Secondary	11. [ ]
12	Duration of Subfertility	[ ]	12. [ ]

Part V: Details on Family history:

No:	ITEM	TO BE FILLED BY RESEARCH ASSISTANT	TO BE CODED BY MAIN RESEARCHER
13.	Hx of infertility in the family.	1.Yes 2. No	13. [ ]
14	Hx of Diabetes in the family .	1.Yes 2. No.	14. [ ]

Part VI: Details on clinical hyperandrogenism

No:	ITEM	TO BE FILLED BY RESEARCH ASSISTANT	TO BE CODED BY MAIN RESEARCHER
15.	Hirsutism Chin. Upper lip. Chest. Abdomen. Pubic area. Legs. Back. Buttocks.	Score[ ]	15. [ ]
16	Acne	1. Yes 2. No	16. [ ]

Part VII: Investigations.

No:	ITEM	TO BE FILLED BY RESEARCH ASSISTANT	TO BE CODED BY MAIN RESEARCHER
21.	Testosterone	[ ]	21. [ ]
22	LH	[ ]	22. [ ]
23	FSH	[ ]	23. [ ]
24	USS	1.Ovarian volume [ ] 2.Number of follicles [ ] 3.Diameter of follicles [ ]	24. [ ]

APPENDIX III

9.3 MODIFIED F-G SCALE

Definition of Hair Gradings at Each of 19 Sites (Ferriman-Gallwey Scale)*

Site	Grade	Definition
1 Upper lip	1	A few hairs at outer margin
	2	A small mustache at outer margin
	3	A mustache extending halfway from outer margin
	4	A mustache extending to midline
2 Chin	1	A few scattered hairs
	2	Scattered hairs with small concentrations
	3 & 4	Complete cover, light and heavy, respectively
3 Sideburns	1	Few nonterminal hairs
	2	More nonterminal hairs
	3	Terminal hair on side of face
	4	Terminal hair extending to mandible
4 Neck	1	Few hairs on neck
	2	More hairs on neck
	3 & 4	Complete cover, light and heavy, respectively
5 Chest	1	Circumareolar hairs
	2	With midline hair in addition
	3	Fusion of these areas, with three-quarter cover
	4	Complete cover
6 Upper back	1	A few scattered hairs
	2	Rather more, still scattered
	3 & 4	Complete cover, light and heavy, respectively
7 Lower back	1	A sacral tuft of hair
	2	With some lateral extension
	3 & 4	Three-quarter cover or complete cover, respectively
8 Buttocks	1 & 2	Few or many hairs, respectively, over lower buttocks
	3 & 4	Hair extending to upper buttocks, light and heavy, respectively
9 Upper abdomen	1	A few midline hairs
	2	Rather more, still midline involvement
	3 & 4	Half and full cover, respectively
10 Lower abdomen	1	A few midline hairs
	2	A midline streak of hair
	3	A midline band of hair
	4	An inverted V-shaped growth
11 Inguinal area	1	Pubic hair extending to inguinal area
	2	A few hairs below inguinal area
	3 & 4	Complete cover below inguinal area, light and heavy, respectively
12 Perianal area	1	Hair encircling introitus and anus
	2	Hair extending to inner thigh
	3 & 4	Hair on inner thigh and buttocks, light and heavy, respectively
13 Arm	1	Sparse growth affecting no more than a quarter of the limb surface
	2	More than this; cover still incomplete
	3 & 4	Complete cover, light and heavy, respectively
14 Forearm	1, 2, 3, 4	As for arm
15 Thigh	1, 2, 3, 4	As for arm
16 Leg	1, 2, 3, 4	As for arm
17 Foot	1	A few hairs on dorsum of foot
	2	More hair on dorsum of foot
	3 & 4	Hair over one-half or three-quarters or more, respectively, of dorsum
18 Toes	1 & 2	Few hairs or many hairs, respectively, on big toe
	3 & 4	Few hairs or many hairs, respectively, on other toes
19 Fingers	1	Few hairs on proximal phalanx—dorsal surface
	2	Many hairs on proximal phalanx—dorsal surface
	3	Few hairs on 2nd phalanx—dorsal surface
	4	Many hairs on 2nd phalanx—dorsal surface
Total score	_____	

APPENDIX IV

9.4 CONSENT FORM TO PARTICIPATE IN THE STUDY.

TITLE: PCOS: PREVALENCE, CLINICAL AND ULTRASONOGRAPHIC FEATURES AMONG WOMEN WITH INFERTILITY AT MNH IN DAR-ES-SALAAM.

Greetings! My name is Dr. Muzdalifat , a senior resident in the department of obstetrics and gynaecology . I would like to conduct a study mentioned above for my dissertation.

Purpose of the study.

The aim of the study is to determine the magnitude of PCOS among Infertile women. This will help in improving future management of other patients with PCOS.

How to participate.

Person who meet the inclusion criteria will be recruited into the study.

They will be interviewed using a questionnaire, which will include their social demographic characteristics, menstrual history, obstetrics history, medical history and anthropometric measurements. Then they will be given appointment for the necessary investigations to be taken.

Risks.

There are no risk associated with taking these measurements, although there is an invasive procedure i.e venopuncture which might cause little pain, and a non-invasive procedure TVS which will involve introducing a vaginal probe into your vagina, but both procedures are not dangerous.

Benefits:

Patients found to have PCOS will be followed up for probable better options of management.

Confidentialilty:

Any patient's results will not be revealed to anybody except attending doctors and person himself.

Cost.

No any payment is requested from you. The researcher covers for all the costs.

Person to contact in questions or problems:

Prof. M. Kaisi (Tel:0754-267082) Department of obstetrics and gynaecology.

Dr. Muzdalifat (Tel: 0754-262411) Department of obstetrics and gynaecology.

I..... have read/been told of the contents of this form and understood its meaning. I agree to participate in this study.

Signature..... (Participant) Date.....

Signature..... (Researcher) Date.....