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A cross sectional study on, prevalence of polycystic ovarian syndrome and its health effects, in reproductive age women (15-45 years) in a rural area, Telangana, India

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Abstract
Introduction: Polycystic Ovary Syndrome causes irregular menstrual cycles, excessive body or facial hair and polycystic ovaries. Prevalence ranges from 2.2% to 26% globally, as it is not defined precisely. This is a community based study in the reproductive age women (15-45years) to correctly assess prevalence of PCOS and health effects in women with PCOS.
Material and Methods: Cross sectional study done in 624 Reproductive age women (15-45 years) in a rural area. Data collected by interview method, clinical examination of which 182 women (with signs suggestive of PCOS) got biochemical and ultrasound to establish diagnosis of PCOS and health effects were studied. Data analysed using SPSS 20.
Results: Prevalence of PCOS was 72(11.5%). Infertility followed by psychosocial problems was the most common health effects.
Conclusion: Although infertility was seen in 73.6% of women with PCOS, only 18% received treatment in the past, due to under diagnosis and lack of accessibility.

Keywords: polycystic ovarian syndrome, prevalence, reproductive women, health effects

1. Introduction
Polycystic Ovary Syndrome (PCOS) is the most common cause of infertility (not able to get pregnant- conception may take longer than in other women, or women with PCOS may have fewer children than they had planned. In addition, the rate of miscarriage is also higher in affected women) in reproductive age women attending Gynaecology out patient department.
PCOS causes irregular menstrual cycles, excessive body or facial hair and polycystic ovaries as its main symptoms. Polycystic means “many cysts” and PCOS often causes clusters of small, pearl- sized cysts in the ovaries. The cysts are fluid –filled and contain immature eggs. Women with PCOS produce slightly higher amounts of male hormones known as androgens, which contribute to some of the symptoms. Other symptoms include acne, male pattern baldness or thinning of hair.
PCOS is a genetically complex endocrine disorder of uncertain aetiology with a complicated pathophysiology. A main underlying problem with PCOS is a hormonal imbalance. In women with PCOS, the ovaries make more androgens than normal which effects ovulation process. These high androgens cause acne, excessive hair growth, weight gain and problems with ovulation [1].
The diagnostic criteria for PCOS have been offered by three groups (1): the National Institutes of Health/National Institute of Child Health and Human Disease (NIH/NICHD) [2], (2) the European Society for Human Reproduction and Embryology/American Society for Reproductive Medicine (ESHRE/ASRM) or the ‘Rotterdam Criteria’ [3] (3) and the Androgen Excess and PCOS Society [4]. Rotterdam criteria is widely accepted.
Prevalence of PCOS is highly variable ranging from 2.2% to 26% globally, as it is not defined Precisely [1]. Consideration of different endocrine or clinical criterion for each diagnosis of PCOS can influence the incidence and prevalence rate estimation of PCOS, thereby masking the gravity of the problem [5].

Early diagnosis of PCOS is needed as the women are at increased risk for developing insulin resistance, type 2 diabetes, high cholesterol, high Blood pressure (BP) [1]. Hence management of women with PCOS should include screening and simultaneous detection of other health effects associated with PCOS and inturn their management for better outcome. Previous studies in India did not cover the entire reproductive age women and few were either hospital based or done in adolescents in college. Current study is a community based study in the entire reproductive age women (15-45years) to correctly assess burden of PCOS and to understand, health effects in women with PCOS.

2. Materials and Methods

2.1 Study design and population: A cross sectional analytical community based study was done in Reproductive age women (15-45 years) in a rural area, during January 2019 to December 2020. Population size of women between 15-45 years was 2015 in study area.

2.1.1 Inclusion criteria: women of 15-45 year age group previously diagnosed with or without PCOS who gave informed consent to participate in the study.

2.1.2 Exclusion criteria: Menarche with in past 2 years, post menopausal women, pregnant and lactating women, women on oral contraceptive pills and intrauterine devices, diagnosed with cancers. Women who underwent hysterectomy or bilateral oophorectomy.

2.2 Sample size: Sample size was calculated using formula for finite population.

Z α is the standard normal deviate, which is equal to 1.96 at 95% confidence interval.

p is the prevalence in the population of the factor under study 9.13%. (as per National Health portal prevalence in south India given was 9.13%) [1]

e = Absolute precision taken as 2% (<5% is acceptable)

p = 9.13%

-p = (1-0.0913)

N = Population to be studied (women of reproductive age group 15-45 years). = 2015

$$Sample\ size(n) = \frac{\frac{z^2 X\, p(1-p)}{e^2}}{1 + \frac{z^2 X\, p(1-p)}{e^2 N}}$$

$$Sample\ size(n) = \frac{\frac{(1.96)^2 X\ 0.0913(1-0.0913)}{(0.02)^2}}{1 + \frac{(1.96)^2 X\ 0.0913(1-0.0913)}{(0.02)^2\ 2015}}$$

$$Sample\ size(n) = 571(around)$$

Corrected sample size for non response rate as 15% calculated and rounded up to 660.

2.3 Sampling method: simple random sampling method was used to select study participants

2.4 Data collection: After obtaining institutional ethical committee approval and informed consent from study participants. Data collected by face to face interview method, clinical examination, biochemical investigations (Basic lab investigations in Sensa Core ST 200 Pro/Plus/CL (full auto analyzer) and Hormonal assessment in Beckmann access 2) and ultrasound examination (Done with Phillips affinity Trans vaginal or trans abdominal sonography with probe frequency 5-7.5Hertz)

2.5 Procedure: Step 1: House to house community survey done. Data on socio demographic details, history on present illness, menstrual history, past and present medical and surgical illness, gynaecological illness, family history of PCOS, hirsutism score based on ferriman gallwey scoring method,[6] history of acne and alopecia were collected in a semistructed questionnaire. Vital signs and anthropometric measurements (height, weight, BMI = Weight (Kg)/ height (m^2), waist circumference,) were recorded by trained interviewers.

Step 2: For 182 study participants with menstrual irregularities and moderate to severe hirsutism (suggestive of PCOS – 218 women out of which 24 women were excluded based on exclusion criteria and 12 dropped) biochemical investigations and ultrasound examination done on either day 2 or 3 of menstrual cycle or to establish the diagnosis of PCOS based on Rotterdam's criteria at the institute.

The waist circumference was measured at the midpoint between the lower margin of the last palpable ribs and the top of the iliac crest, using a stretch-resistant tape that provides a constant 100 g tension [7].

Fasting venous blood sample of (182 women with signs suggestive of PCOS) about 10 ml collected on day 2 or 3 of menstrual cycle for basic laboratory investigations (blood sugars and serum lipid profile) and hormonal assessment for confirming PCOS and excluding other etiologies {follicle stimulating hormone (FSH -Normal range 5-20mIU/ml), Luteinizing hormone (LH -Normal range 5-20mIU/ml), prolactin (< 25 ng/ml), TSH (thyroid stimulating hormone 0.5 to 5.0 mIU/L), total testosterone (Normal range 6.0-86 ng/dl), Free testosterone (Normal range - 0.7-3.6 pg/ml), androstenedione (Normal range - 0.7-3.1 ng/ml), 17OH-progesterone, dehydroepiandrosterone-sulfate (DHEAS) and Serum hormone binding globulin (SHBG <41nmol/l) }.

2.6 Operational definition

Definition of PCOS according to Rotterdam Revised 2003 criteria (2 out of 3): 1) Oligo-anovulation was defined as a cycle length 35 days or amenorrhoea. 2) Clinical hyperandrogenism was defined as the presence of acne, alopecia and hirsutism recorded as m-FG score ≥ 8. Biochemical hyperandrogenism was defined as elevated free Testosterone levels (>0.034 nmol/l) or raised free androgen Index (Formula: Total testosterone/SHbg × 100). 3) polycystic ovaries on ultrasound - The finding of polycystic ovaries was defined as ≥15 follicles measuring 2– 10 mm in diameter or ovarian volume 10 ml in at least one ovary. Other aetiologies must be excluded such as congenital adrenal hyperplasia, androgen secreting tumours, Cushing syndrome, thyroid dysfunction and hyperprolactinaemia [8].

Hirsutism severity score was done based on ferriman gallwey scoring method. The modified Ferriman-Gallwey (mFG) score grades 9 body areas from 0 (no hair) to 4 (frankly virile), including the upper lip, chin, chest, upper abdomen, lower abdomen, thighs, back, arm, and buttocks. A total score of 8 or more is diagnostic for hirsutism [6].

2.6.1 Phenotypes of polycystic ovary syndrome as per the Rotterdam criteria were calculated

1. Frank or classic polycystic All the three - chronic anovulation, polycystic ovaries and hyperandrogenism
2. Classic non-cystic - Anovulation, hyperandrogenism with normal ovaries
3. Non-classic ovulatory - Regular menses, polycystic ovaries and hyperandrogenism
4. Non-classic mild or normo-androgenic Anovulation, - anovulation polycystic ovaries with normal androgens [9]

2.6.2 Metabolic syndrome (International harmonization definition)

Any three of the following criteria (i) waist circumference ≥80 cm, (ii) serum triglyceride ≥1.7 mmol/L, (iii) serum high-density lipoprotein cholesterol <1.3 mmol/L, (iv) blood pressure ≥130/85 mm Hg, and (v) fasting blood sugar of >100 g/dL. [10]

2.7 Data analysis: Data for 624 (660 women out of which 36 excluded and dropped out) women entered in Microsoft excel, analysed using mean and proportions and SPSS version 20 was used for statistical tests (t test and chi square test used) and P<0.05 was considered significant.

3. Results

Data on Socio demographic details and clinical examination was analysed for 624 study participants. Analysis on Biochemical and ultrasound was done in 182 women with signs suggestive of PCOS.

Based on Revised Rotterdam criteria, women with PCOS in this study were diagnosed and various phenotypes were classified. Prevalence of PCOS was 72 (11.5% of reproductive women) with 44(61%) out of 72 with Frank or classic polycystic PCOS with all the three criteria present, where as Classic non Cystic, Non-classic ovulatory and Non-classic mild or normo-androgenic were seen in 13(2.1%), 11(15.3%) and 4(0.6%) women with PCOS (shown in Table 1)

Table 1: Phenotypes of polycystic ovary syndrome as per the Rotterdam criteria

Phenotype	Rotterdam criteria	Frequency n= 72(100%)
Frank or classic polycystic (All the three criteria)	chronic anovulation, polycystic ovaries and hyperandrogenism	44 (61%)
Classic non Cystic	Anovulation, hyperandrogenism with normal ovaries	13(2.1%)
Non-classic ovulatory	Regular menses, polycystic ovaries and hyperandrogenism	11(15.3%)
Non-classic mild or normo-androgenic	Anovulation, polycystic ovaries with normal androgens	4(0.6%)

Mean age of the study participants were 28.5±5.3, majority of the patients belong to age group 15-25 years (46.3%). Majority of the women studied up to high school (40.5%) followed by Primary school (28.4%). Almost 50.9% women belong to upper middle class followed by upper class (31.4%) according to BG Prasads classification of Socioeconomic status. Married women were 74.2% and having children were 53.8% (shown in table 2).

Table 2: Distribution of women based on socio demographic data Verses PCOS (n=624)

Sociodemographic variables		PCOS (72/11.5%)	No PCOS (552/88.5%)	Total (624/100%)	X^2 or t test / p value
Age	15-25 years	28(4.5%)	261(41.8%)	289(46.3%)	X^2 = 1.8182/ p - 0.402896*
	26-35 years	34(5.4%)	227(36.4%)	261(41.8%)	
	36-45 years	10(1.6%)	64(10.3%)	74(11.9%)	
Mean Age± SD		25.9±4.6	31.3±6.3	28.3±5.3	t =7.03 / p = <0.0001#
Literacy status	Illiterate	7 (1.1%)	75(12%)	82(13.1%)	X^2 = 5.1845/ p - 0.268881*
	Primary school	18(2.9%)	159(25.5%)	177(28.4%)	
	High school	28(4.5%)	225(36%)	253(40.5%)	
	Undergraduate	16(2.6%)	84(13.5%)	100(16.1%)	
	Postgraduate	3(0.5%)	9(1.4%)	12(1.9%)	
Socio Economic status (As per BG prasads classification)	i. Upper class	5(0.8%)	80(12.8%)	84(13.6%)	X^2 = 6.0965. / p - 0.10701* Note: excluding lower class as it is 0.
	ii. Upper middle class	37(5.9%)	281(45%)	318(50.9%)	
	iii. Middle class	29(4.6%)	167(26.8%)	196(31.4%)	
	iv. Lower Middle class	1(0.2%)	24(3.8%)	25(4%)	
	v. Lower class	0(0%)	0(0%)	0(0%)	
Marital status	Married	56(9%)	407(65.2%)	463(74.2%)	X^2 = 0.5446. / p - 0.460532*
	Unmarried	16(2.6%)	145(23.2%)	161(25.8%)	

Chisquare test (X^2 test)= denoted as * and t test denoted as #

Mean age of women with PCOS (13.3years) was slightly higher than women without PCOS which was statistically significant. Oligomenorrhoea and family history suggestive of PCOS was seen in 84.7% and 47.2% of women with PCOS, which was significantly high when compared to women without PCOS (it was 16.7% and 16.5% respectively). Only 18% of women with PCOS had infertility treatment which was high compared with women without PCOS (3.4%). Proportion of clinical hyperandrogenism is more in women with PCOS (63.9%) than without PCOS (22.8%) and it was statistically significant. BMI, Waist circumference ≥ 0.80 and Blood pressure ≥ 130/85 were seen in more proportion of women with PCOS than without PCOS and was significant statistically (shown in table 3).

Table 3: Distribution based on history and anthropometric measurements Versus PCOS (n=624)

Variables		PCOS present (72)	PCOS absent (552)	Total (624)	X^2 or t test / p value
Mean age at which menarche attained		13.3±1.7 years	12.1±2.1years	13.1±2.4 years	t test = 4.6529 p value < 0.0001#
Oligomenorrhoea	Present	61(84.7%)	92(16.7%)	153(24.5%)	p -value is < .00001*
	Absent	11(15.3%)	460(83.3%)	471(75.5%)	
Family history of either hyperandrogenism or PCOS	Present	34(47.2%)	91(16.5%)	125(20%)	p -value is < .00001*
	Absent	38(52.8%)	461(83.5%)	360(80%)	
Received infertility treatment in the past	Yes	13(18%)	19(3.4%)	32(5.1%)	p -value is < 0.00001*
	No	43(59.7%)	388(70.3%)	431(69.1%)	
	Not applicable	16(22.2%)	145(26.3%)	161(25.8%)	
Clinical hyperandrogenism {Hirsutism(mFGSscore > 8), acne, alopecia}	Present	46(63.9%)	126(22.8%)	172(27.6%)	p -value is < 0.00001*
	Absent	26(36.1%)	426(77.2%)	452(72.4%)	
BMI (Body Mass Index)	Normal and underweight	28(38.9%)	446(79.7%)	474(76%)	p -value is < 0.00001*
	Overweight and obese	44(61.1%)	106(19.2%)	150(24%)	
Waist circumference	≤ 0.80	22(30.6%)	452(81.9%)	474(75.9%)	p -value is < 0.00001*
	≥ 0.80	50(69.4%)	100(18.1%)	150(24.1%)	
Blood pressure ≥ 130/85	Present	19(3.1%)	77(12.3%)	96(15.4%)	p -value is .005931*
	Absent	53(8.5%)	475(76.1%)	528(84.6%)	

Chisquare test (X^2 test)= denoted as * and t test denoted as #

Hyperglycaemia from fasting or 2 hour OGTT (17.6%) and dyslipidaemia (14.8%) was found in more proportion of PCOS women than women without PCOS. Biochemical hyperandrogenism (94.4%) and polycystic ovaries (81.9%) was proportionately high in women with PCOS (shown in table 4).

Table 4: Distribution based on Biochemical investigations and Ultrasound examination in patients suggestive of PCOS (n=182)

Variables		PCOS Present (72)	PCOS absent (110)	Total (n=182)
Hyperglycaemia in Fasting or 2hour glucose from OGTT	Present	32(17.6%)	12(6.6%)	44(24.2%)
	Absent	40(22%)	98(53.8%)	138(75.8%)
Dyslipidaemia (serum triglyceride ≥1.7 mmol/L or serum high-density lipoprotein cholesterol <1.3 mmol/L,)	Present	27(14.8%)	29(15.9%)	56(30.8%)
	Absent	45(24.7%)	81(44.5%)	126(69.2%)
FSH (follicle stimulating hormone)	Mean ± SD	8.1±1.4	6.4±1.9	7.1±1.5
LH (luteinizing hormone)	Mean± SD	16.2±2.4	7.2±3.6	11.1±3.7
FSH/LH ratio	≥ 3:1	58	24	82
	< 3:1	14	86	100
Raised Free testosterone > 0.034nmol/l	Present	45	25	70
	Absent	27	85	112
Raised Androstenedione (>8.9nmol/l)	Present	56	12	68
	Absent	16	108	124
Low SHBG (sex hormone binding globulin <41nmol/l)	Present	52	2	54
	Absent	20	118	128
FAI (free androgen index)	Median (IQR)	7.2(0.8- 52.2)	4.2(0.3-22.1)	-
Biochemical hyperandrogenism	Present	68(94.4%)	9(16.3%)	77(42.3%)
	Absent	4(5.6%)	101(55.5%)	105(57.7%)
Polycystic ovaries	Present	59(81.9%)	8(7.3%)	67(36.8%)
	Absent	13(18%)	102(92.7%)	115(63.2%)

Of the 72 women with PCOS most common health issue was infertility (53 women/73.6%). Psychosocial problems were found in 47(65.3%) women with PCOS. The various psychosocial issues were anxiety and depression due to infertility, hirsutism, alopecia, acne, negative body image and other associated medical conditions like DM type 2 and hypertension. Diabetes mellitus Type 2, hypertension and Metabolic syndrome were seen in 32(44.4%), 19(26.4%), 12(16.7%) of PCOS women respectively (shown in figure 1)

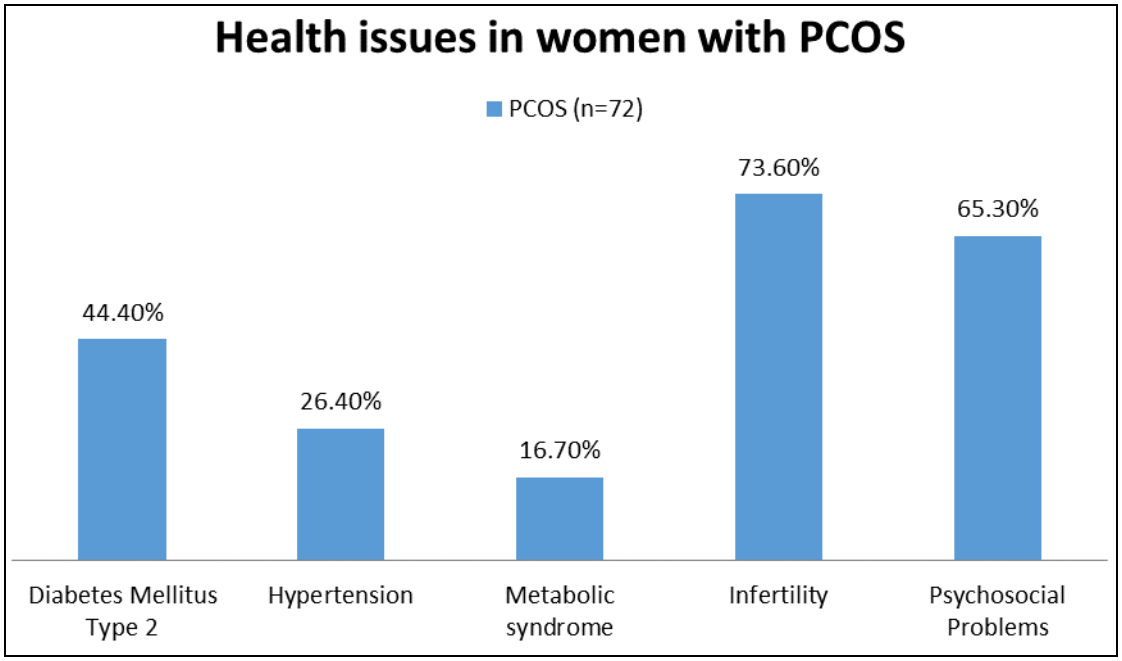

Fig 1: Health Issues in women with PCOS

4. Discussion

The prevalence of PCOS in the current study (15-45 years) was 11.5% which was high when compared with study by Vidya Bharati *et al.* and Nidhi *et al*, where the prevalence in young women (18-24yrs) was 6% and college girls (15-18 yrs) was 9.13% respectively [11, 12]. where as it was low when compared with study by Balaji *et al* in young adolescents(12-19years) and Joshi *et al*, in young adolescents (15-24 years) it was 18% and 22.5% respectively [13, 14]. The variation in prevalence can be due to different age groups of the study participants in various studies undermining the true prevalence.

In this study Frank or classic polycystic PCOS with all the three criteria present were in 44(61%) women, Where as Classic non Cystic, Non-classic ovulatory and Non-classic mild or normo-androgenic were seen in 13(2.1%), 11(15.3%) and 4(0.6%) women with PCOS. Where as in study by Sachdeva G *et al.* it was 67.7%, 11%, 17.7% and 3.6% respectively [15].

Mean age at menarche in women with PCOS in this study was 13.3 years and was slightly high compared with women without PCOS similar to study by Ganie *et al.* (13.1years) [16]. Oligomenorrhoea was seen in 24.5% of women in this study and was statistically high in women with PCOS (84.7%) which was high compared with study by Ramanand SJ *et al.* where oligomenorrhoea seen in 65% of women with PCOS [5]. Family history with signs suggestive of PCOS was present in 47.2% in this study which was similar to study by Tehrani FR *et al.* [17]

Infertility treatment in the past in this study was received by only 18% of patients with PCOS similar to study by Lauritsen *et al*. (19.1%) [8]. This wide gap in receiving treatment can be attributed to lack of awareness to approach for treatment, underdiagnosis and if diagnosed also, unable to afford and lack of satisfaction with the treatment outcomes. Clinical hyperandrogenism in this study was seen in 63.9% of PCOS women, whereas in study by Ramanand *et al.* it was present in 51.7% of women with PCOS [5].

FSH and LH in present study was 8.1±1.4 and 16.2±2.4 which is slightly high compared with study by Ganie *et al.* it was 6.67 ± 2.14 7 and 8.23 ± 4.99 respectively [16]. Biochemical hyperandrogenism was seen in 94.4% of women with PCOS in this study which was low compared with study by Lauristen *et al*. (51.5%) [8] FAI was high in PCOS women in this study similar to study by Joshi *et al.* [14]

As per BMI, the prevalence of obesity and overweight in our study group together was 61.1% in patients with PCOS which was lower when compared with study by Abid K *et al.* it was 27% and 53%, respectively. [18] Blood pressure ≥ 130/85 was seen in 26.4% of women with PCOS in this study which was slightly lower than study by Lo JC *et al.*, women with PCOS were 40% more likely to have elevated blood pressure than the non-PCOS women, independent of age, BMI, diabetes or dyslipidemia [19].

In our study 12 out of 72 (16.6%) of women with PCOS has metabolic syndrome where as in study by Joshi *et al.* it was 1 out of 135 and in study by Deswal *et al.* it was 6.01% [14, 20].

In our study infertility and depression was seen in 73.6% and 65.3% where as in study by Deswal *et al.* it was 18.1% and 61.7% respectively [21]. Although psychosocial problem was the second most common comorbidity in women with PCOS it was least addressed. In this study Diabetes mellitus was seen in 44.4%, where as in study by Sachdeva G *et al*, seen in 40.2%(66 out of 164) women with PCOS [15].

Strengths: this was a community based study covering entire reproductive age women (15-45 years).

Limitations: The study though community based was done in rural area. Women with cancers were excluded, which is also a comorbidity associated with PCOS due to limitation in establishing the diagnosis and treatment at our institute.

5. Conclusions

Prevalence of PCOS in reproductive age women (15-45 years) in rural area was 11.5%. Frank or Classic PCOS phenotype was the most common phenotype (61%) followed by nonclassic ovulatory (15.3%). Higher mean age at menarche and family history of PCOS are significantly present in women with PCOS. Although infertility was seen in 73.6% of women with PCOS, only 18% received treatment in the past, due to under diagnosis, lack of accessibility and if diagnosed also, unable to afford and lack of satisfaction with the treatment outcomes. Psychosocial problems (65.3%) though present were poorly addressed.

6. Recommendations: Further research on screening tools at

community and early diagnosis with appropriate interventions. As PCOS can give long term complications services should be included under National health programmes.

7. Acknowledgement
Department of radiology and Department of Biochemistry RVM medical college. Study paticipants

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