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Original Research Article

Acarbose is as effective as metformin in reducing central obesity in infertile women with polycystic ovary syndrome

Tahmida Islam, Asma Akter, Rawnok Laila, Rafikunnahar Renu, Sumyara Khatun, Shakeela Ishrat*

Department of Reproductive Endocrinology and Infertility, Bangabandhu Sheikh Mujib Medical University, Dhaka, Bangladesh

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***Correspondence:**
Dr. Shakeela Ishrat,
E-mail: shakeelaishrat@bsmmu.edu.bd

ABSTRACT

Background: Polycystic ovary syndrome (PCOS) in infertile women is frequently associated with insulin resistance and obesity. Optimization of the patient by reducing weight and insulin resistance improves clinical, biochemical & endocrine parameters and consequently increases the chance of successful ovulation and pregnancy. Acarbose is an alpha-glucosidase inhibitor which acts by reducing and slowing down intestinal absorption of glucose, with a reduction of the postprandial glucose wave and a consequent reduction of insulin secretion. The objective of this study was to evaluate the efficacy of acarbose compared to metformin, in reducing central obesity in infertile women with PCOS.
Methods: This randomized controlled trial study was conducted on a total 60 infertile, overweight and obese women with PCOS. The women were allocated randomly to two treatment arms: one group receiving acarbose 100 mg three times daily with meal for 3 months and another group receiving metformin 500 mg three times daily after meal for 3 months. The main outcome variables were changes in central obesity and insulin resistance.
Results: Mean weight, BMI, waist circumference and waist hip ratio was significantly decreased in both acarbose and metformin group. Reduction of fasting blood sugar, fasting insulin and HOMA-IR were also significant. The reduction was more in acarbose group, but the difference was not statistically significant. Gastrointestinal side effects were more in the women given metformin.
Conclusion: There is significant reduction in central obesity or insulin resistance parameters in infertile PCOS women given acarbose or metformin over three months. However, there is no statistically significant difference between the two groups. Acarbose has less gastrointestinal side effects, so can be a suitable alternative to metformin in those who are intolerant to metformin.

Keywords: PCOS, Acarbose, Metformin, Overweight, Insulin resistance

INTRODUCTION

PCOS and persistent anovulation is one of the most prevalent causes of infertility.[1] Whether women with PCOS are average weight, overweight or obese, adipose tissue tends to accumulate in the central portion of the body.[2-3] In individuals with PCOS, central adiposity exacerbates hormonal and metabolic problems.[4] Insulin resistance is highly prevalent in individuals with PCOS, with approximately 80% of them affected by it.[5] Acarbose inhibit intestinal brush border alpha-glucosidase and pancreatic alpha-amylase in a competitive and reversible manner. It slows down intestinal absorption of glucose. Thereby, it decreases the glucose wave after meal, which in turn slows down the release of insulin.[6] Women who are overweight or obese and eat a lot of carbohydrate is expected to respond well to acarbose when combined with a low-calorie diet or exercise regimen.[7] Metformin is an

oral anti-diabetic medication which is frequently used for treatment of PCOS. Most notable adverse effects of metformin include nausea, vomiting, diarrhoea, bloating and fatigue. Around five percent of people may need to stop taking the medicine because of the serious side effects and drug intolerance. Acarbose was less likely to result in gastrointestinal issues than metformin.[8] Side effects of acarbose was significantly lower than metformin.[9] Acarbose has received marginally less attention from researchers than other medications for treatment of PCOS patients. Several studies have claimed that acarbose is more effective than metformin in the management of overweight-obese PCOS women.

Non-obese patients with PCOS and hyperinsulinemia showed improvement in regularity of menses and decreased androgenic activity when given 300 mg of acarbose daily for three months.[10] Acarbose use was also linked to significantly higher blood levels of SHBG, decreased insulin resistance and lower serum levels of LH and testosterone. Compared to women those treated with metformin, PCOS women who received acarbose lost more weight and experienced more regular cycles.[11] Individuals with insulin resistance have beneficial effect from both metformin and acarbose. But there was significant decrease in the BMI and weight of those who received acarbose.[12]

Bangladesh is a country where early marriage is not uncommon. When obesity and infertility co-exist in young women, PCOS is the most likely apparent condition. The excess fat in the body aggravates insulin resistance and perpetuates the vicious cycle of anovulation and hyperandrogenism. If the aim is to establish spontaneous ovulation, optimization of these patients should be planned by reduction of weight, central adiposity and insulin resistance. The objective of the present study is to assess if acarbose is more effective than metformin in reducing central obesity of infertile women with PCOS.

METHODS

This open label parallel design randomized controlled trial was carried out in the department of reproductive endocrinology and infertility of Bangabandhu Sheikh Mujib Medical University (BSMMU), Dhaka from October 2022 to September 2023. The participants were infertile overweight and obese women with PCOS (diagnosed according to international evidence-based guideline 2018), age range 18-35 years, with primary or secondary infertility, body mass index (BMI)≥23 kg/m2, waist circumference (WC) >80 cm.[13]

The exclusion criteria were any contraindication to acarbose or metformin (e.g. diabetic ketoacidosis, colonic ulcer, acute or chronic alcoholism), medical (pulmonary, cardiac, renal or hepatic disease) or endocrine (diabetes mellitus, hypothyroidism, hyperprolactinemia) disorders and intestinal disease (e.g. inflammatory bowel disease, mal-absorption syndrome). The study was approved by institutional review board. Informed consent was taken from each participant. The participants were randomized into interventional and comparator groups. Random sequence generation was done by permuted block randomization and computer-generated random numbers. Allocation concealment was done using serially numbered closed opaque envelops. The interventional group was given tab acarbose (SUGATROL, Pacific Pharmaceuticals Limited) for 3 months at a dose of 100 mg daily for 1 week, 200 mg daily for next 1 week and 300 mg daily in 3 divided doses for last 10 weeks.

The comparator group was given tab metformin (COMET, Square Pharmaceuticals Limited) 500 mg daily for 1 week, 1000 mg daily for next 1 week and 1500 mg daily in 3 divided doses for last 10 weeks. They were called every month to check for compliance or any side effects. Second visit was scheduled at the end of 3rd month. Second follow up visit included measurement of waist circumference, waist hip ratio, fasting insulin and HOMA-IR. Any adverse event was noted.

Waist circumference was measured in centimetre by placing a tape horizontally midway between the lower border of costal margin and iliac crest on the mid axillary line. Cut-off point for central obesity was the waist circumference of 80 cm according to The Western Pacific Region Office of WHO recommendation for Asian population.[14] Hip circumference was the measurement using a measuring tape to assess the largest circumference around the buttocks. Waist- hip ratio was the dimensionless ratio of the circumference of the waist to that of the hips. This was calculated as waist measurement divided by hip measurement. Cut off point for WHR was >0.80 according to the Western Pacific Region Office of WHO recommendation for Asian population.[14] Fasting blood glucose estimation was done using commercially available reagent kits plasma FLUORIDE. Serum fasting insulin level was determined by using a radio immune assay kit. (Medico, Montreal, Canada). HOMA –IR is used to determine insulin resistance. HOMA-IR calculated by the formula: HOMA-IR=fasting glucose (mmol/l)×Fasting insulin mIU/ml divided by 22.5. HOMA-IR>1.7 was accepted as insulin resistance.[15]

Statistical analysis

Sample size of participants was calculated as 30 in each group, for a power of 0.95, a significance level of 0.05. Statistical analyses were carried out by using the Statistical Package for Social Sciences version 26.0 for Windows (SPSS Inc., Chicago, Illinois, USA). The mean values were calculated for continuous variables. The qualitative observations were indicated by frequencies and percentages. Chi-Square and Fisher's exact test was used to analyse the categorical variables, shown with cross tabulation. Student t-test and paired t-test was used for continuous variables. The p value <0.05 was considered as statistically significant.

RESULTS

A total number of 60 infertile overweight and obese women with PCOS were included and were randomly assigned into 2 groups; the intervention (acarbose) group had 30 participants and the comparator (metformin) group had 30 participants. In acarbose group, there was 4 pregnancies and 1 lost to follow up. In metformin group, there were 2 pregnancies and 2 cases lost to follow up. After the attrition or drop out the final analysis was done on 25 participants in acarbose group and 26 participants in metformin group.

Table 1: Baseline socio-demographic characteristics of study participants (n=60).

	Acarbose (n=30)		Metformin (n=30)		P value
	N	%	N	%	
Age (years)					
18-21	7	23.3	5	16.7	
22-25	12	40.0	13	43.3	
26-29	9	30.0	8	26.7	
30-35	2	6.7	3	10.0	
Mean±SD	24.33±3.52		25.30±3.97		0.323^{ns}
Occupational status					
Housewife	14	46.7	18	60.0	
Student	10	33.3	6	20.0	0.472^{ns}
Service	6	20.0	6	20.0	
Husbands occupational status					
Service	16	53.3	19	63.3	0.432^{ns}
Business	14	46.7	11	36.7	
Monthly income (Taka)					
<10,000	1	3.3	0	0.0	
10,000-30,000	17	56.7	16	53.3	0.553^{ns}
>30,000	12	40.0	14	46.7	
Type of sub fertility					
Primary	24	80.0	25	83.3	0.500^{ns}
Secondary	6	20.0	5	16.7	

Numerical variables are described as mean ± standard deviation or categorical variables as frequency (%). P-values were calculated using Student's t- test/ unpaired t-test and Chi-square test, p<0.05 is expressed as significant (s); ns=not significant.

Table 2: Baseline clinical and biochemical parameters of study participants (n=60).

	Acarbose (n=30)	Metformin (n=30)	P value
	Mean±SD	Mean±SD	
Weight (kg)	62.6±7.7	63.2±4.6	0.664^{ns}
BMI (kg/m^2)	27.8±3.7	28.5±2.0	0.327^{ns}
Waist circumference (cm)	89.6±5.4	89.8±5.8	0.927^{ns}
Waist hip ratio	0.94±0.02	0.95±0.03	0.516^{ns}
Fasting glucose (mmol/l)	5.5±1.2	5.5±0.4	0.930^{ns}
Fasting insulin (µIU/ml)	16.2±7.1	17.6±4.9	0.377^{ns}
HOMA-IR	4.0±2.2	4.3±1.2	0.546^{ns}

ns=not significant.

Table 3: Comparison between pretreatment and post treatment clinical and biochemical parameters in acarbose group.

Variable	Pretreatment (n=30) Mean±SD	Post treatment (n=25*) Mean±SD	Mean difference (95% confidence interval)	P value
Weight (kg)	62.6±7.7	58.8±7.4	3.88 (3.13 to 4.62)	0.001^{s}
BMI (kg/m^2)	27.8±3.7	26.1±3.4	1.80 (1.41 to 2.20)	0.001^{s}
Waist circumference (cm)	89.6±5.4	85.2±6.8	5.04 (3.61 to 6.46)	0.001^{s}

Continued.

Variable	Pretreatment (n=30) Mean±SD	Post treatment (n=25*) Mean±SD	Mean difference (95% confidence interval)	P value
Waist hip ratio	0.94±0.02	0.90±0.04	0.042 (0.028 to 0.057)	0.001[s]
Fasting glucose (mmol/l)	5.5±1.2	5.0±0.7	0.54 (0.04 to 0.94)	0.033[s]
Fasting insulin (µIU/ml)	16.2±7.1	10.1±3.2	6.58 (4.38 to 8.77)	0.001[s]
HOMA-IR	4.0±2.2	2.1±0.9	1.96 (1.24 to 2.67)	0.001[s]

*5 participants dropped out (4 pregnancies and 1 lost to follow up), p<0.05 is expressed as significant (s).

Table 4: Comparison between pretreatment and post treatment clinical and biochemical parameters in metformin group.

Variable	Pre-treatment (n=30) Mean±SD	Post treatment (n=26*) Mean±SD	Mean difference (95% confidence interval)	P value
Weight (kg)	63.2±4.6	61.0±4.0	2.92 (2.29 to 3.54)	0.001[s]
BMI (kg/m^2)	28.5±2.0	27.5±1.8	1.31 (1.01 to 1.62)	0.001[s]
Waist circumference (cm)	89.8±5.8	87.2±5.4	3.15 (2.37 to 3.93)	0.001[s]
Waist hip ratio	0.95±0.03	0.92±0.03	0.026 (0.017 to 0.036)	0.001[s]
Fasting glucose (mmol/l)	5.5±0.4	5.0±0.4	0.50 (0.33 to 0.66)	0.001[s]
Fasting insulin (µIU/ml)	17.6±4.9	11.6±3.3	6.56 (5.23 to 7.90)	0.001[s]
HOMA-IR	4.3±1.2	2.6±0.8	1.84 (1.48 to 2.21)	0.001[s]

*4 participants dropped out (2 pregnancies and 2 lost to follow up) , p<0.05 is expressed as significant (s).

Table 5: Post treatment clinical and biochemical parameters in two groups (n=51).

Variable	Acarbose (n=25) Mean±SD	Metformin (n=26) Mean±SD	Mean difference (95% confidence interval)	P value
Weight (kg)	58.8±7.4	61.0±4.0	-2.20 (-5.52 to 1.12)	0.189[ns]
BMI (kg/m^2)	26.1±3.4	27.5±1.8	-1.32 (-2.85 to 0.19)	0.087[ns]
Waist circumference (cm)	85.2±6.8	87.2±5.4	-1.95 (-5.41 to 1.50)	0.262[ns]
Waist hip ratio	0.90±0.04	0.92±0.03	-0.015 (-0.03 to 0.006)	0.163[ns]
Fasting glucose (mmol/l)	5.0±0.7	5.0±0.4	-0.03 (-0.33 to 0.26)	0.816[ns]
Fasting insulin (µIU/m)	10.1±3.2	11.6±3.3	-1.52 (-3.38 to 0.32)	0.104[ns]
HOMA-IR	2.1±0.9	2.6±0.8	-0.45 (-0.92 to 0.001)	0.051[ns]

ns=not significant.

Table 1 show that the socio-demographic characteristics of the two groups were comparable with no significant difference. Maximum patients in both groups were in 22-25 years of age. In both groups the prevalence of primary sub-fertility was higher than that of secondary sub-fertility. Table 2 shows that there is no significant difference in baseline clinical and biochemical parameters between the groups given acarbose and metformin. Table 3 show that weight, BMI, waist circumference and waist hip ratio were significantly decreased after 3 months of treatment with acarbose or metformin.

Table 5 shows that mean weight, BMI, waist circumference and waist hip ratio were lower after 3 months of treatment in acarbose group compared to the metformin group, but the difference was not statistically significant. Table 5 also shows that the mean fasting glucose, fasting insulin and HOMA-IR after 3 months of treatment were lower in acarbose group compared to metformin group, but the difference was not statistically significant. Regarding side effects, anorexia was found in 8.0% of participants in acarbose group and 19.2% of participants in metformin group. Diarrhoea and bloating/flatulence were found 11.5% and 11.5% of participants in metformin group respectively. The side effects were comparatively less in acarbose group.

DISCUSSION

PCOS (polycystic ovarian syndrome) is one of the most prevalent endocrine conditions among women of reproductive age. Overweight women with PCOS experience more severe endocrine and metabolic abnormalities compared to those who are not overweight.[16] Waist-to-height ratio (WHtR), a measure of central adiposity, is elevated in PCOS patients compared to the non-PCOS controls. Women with polycystic ovarian syndrome who have a greater waist-hip ratio are more likely to be insulin resistant.[16]

Abdominal obesity appears to be a more accurate indicator of PCOS-related insulin resistance and other metabolic issues. South Asian women exhibit higher levels of insulin resistance compared to Caucasian women with similar BMI.[17] As a result, different BMI and waist circumference cutoff points have been proposed for women from Asia by WHO Asia Pacific BMI Classification.[14] This study was performed to see the effect of acarbose compared to metformin on reducing central obesity. Both acarbose and metformin treatment for 3 months have shown significant reduction in waist circumference, waist hip ratio, fasting insulin and HOMA-IR. The magnitude of reduction in waist circumference, waist hip ratio in terms of mean difference was higher in the women given acarbose compared to the women given metformin, though the difference was not statistically significant.

There are few studies with central obesity as outcome. There was a substantial decrease in WC and WHR from baseline to post-treatment observations when acarbose 100 mg three times daily after meals was given for three months.[20] Others assessed the effects on BMI. There was statistically significant decrease in BMI following a similar course of acarbose medication for three-months.[11,12] Similar results was achieved when 150 mg of acarbose per day was given for six months.[21] Hanjalic-Beck et al used the same dosage and duration of acarbose, but did not observe a statistically significant decrease in BMI.[9] There was significant decrease in body weight and BMI following treatment with metformin.[9,22-24]

Few studies, however, resulted in different findings. Rezai et al did not observe a statistically significant reduction in BMI despite administering metformin at the same dose and duration. Sonmez et al gave 1700 mg of metformin per day for three months and there was no statistically significant change in the weight or BMI. This may be explained by the characteristics of their study participants who were Caucasian women with much higher baseline BMI.[12]

Our study observed that fasting glucose, fasting insulin and HOMA-IR were significantly decreased post treatment in women given acarbose or metformin. These results corroborate with other studies as well as systematic review and metanalysis.[11,12,21,25]

However, Hanjalic-Beck et al and Afrin et al showed a contrary conclusion, finding no statistically significant difference in fasting insulin and fasting glucose/insulin ratio after treatment in the acarbose group.[9] Rezai et al and Guan et al have demonstrated contradicting results with no significant difference in fasting insulin fasting blood glucose following metformin administration.[16] Hanja lick-Beck et al found a statistically significant decrease in fasting insulin but there was no significant drop in the fasting glucose/insulin ratio.[9,11]

In our study the post treatment mean weight, BMI, waist circumference and waist hip ratio were lower in participants given acarbose when compared to those given metformin, but the difference was not significant. The findings are similar to that of other studies.[9,11] Sonmez et al found statistically significant reduction of post treatment weight and BMI in acarbose group compared to metformin group.[12] Other anthropometric parameters were not studied by them. Our study observed that the post treatment fasting insulin and HOMA-IR were lower in women having acarbose compared to those having metformin but the difference was not statistically significant. This finding is supported by other studies.[9-11]

More participants having metformin experienced gastrointestinal adverse effects than those having acarbose. Other studies as well as a systematic review and meta-analysis revealed that gastrointestinal adverse effects of acarbose were less than that of metformin. Pregnancy was not the end point of this study. Four participants starting on acarbose and 2 starting on metformin conceived during study period.

Rezai et al showed that the frequency of ovulation was considerably higher in the acarbose group compared to metformin group when ovulation induction was done with 100 mg of clomiphene. According to Hanjalick-Beck et al both the metformin and acarbose groups are able to attain comparable high rates of regular menstrual cycles and ovulation.[9,11,12]

Although most of the studies are in support of the findings of our study, there are some studies with dissimilar findings. These dissimilarities may be explained by the difference in sample size and duration of studies, geographical variation, environmental factors and different eating habits. Acarbose appears to be a safe and effective drug for reducing central obesity and insulin resistance in PCOS women. Acarbose represents a potential alternative for treatment of insulin resistant overweight PCOS women, particularly those who are intolerant to metformin. In our study there was no fixed diet or exercise program. This is representative of a true clinical setting rather than a controlled environment. The study has some limitations. Conducted over a short period of time, the study has a small sample size limiting the power of statistical analysis. The participants and investigators were not blinded to the treatment after randomization.

The participants were recruited from one location of a single hospital, so the findings may not be generalized and represent the whole community with genetic, racial and geographical variations. Large scale multi-centre clinical studies with well-structured double- blind design and longer follow-up are recommended to assess the comparative long-term efficacy and safety of acarbose and metformin in PCOS women.

CONCLUSION

There is significant reduction in waist circumference and waist hip ratio, fasting insulin and HOMA-IR in infertile

PCOS women given acarbose or metformin over three months. However, there is no statistically significant difference between the two groups. Acarbose has less gastrointestinal side effects, so can be a suitable alternative in those who are intolerant to metformin.

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