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INNOVATIVE PERSPECTIVES OF THE UTILIZATION OF GLUCAGON-LIKE PEPTIDE-1 RECEPTOR AGONISTS FOR MANAGING OBESE POLYCYSTIC OVARY SYNDROME (PCOS) WOMEN & TREATMENT OFNON PCOS OBESE INFERTILE WOMEN FORIMPROV ING PREGNANCY & LIVE BIRTH RATES - A SHORT COMMUNICATION

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ABSTRACT

Having comprehensively reviewed earlier the Polycystic ovary syndrome (PCOS) classification, methodologies for weight reduction inclusive of targeting brown adipose tissue (BAT) in PCOS and in routine obesityinclusive of i) Orlistat (Xenical) to ii)Combinational Agents -a)QsymiaTM (phentermine hydrochloride/ delayed release topiramate beads (TPM), b) Contrave(Bupropion/ Naltrexone)/just topiramate which wasfollowed by GLP1R Agonists -Liraglutide3mg. Nonetheless, till 2019 maximum pharmacotherapy did not yield sustenance of weight reduction and did notprove to be efficacious over 1-5kg reduction for greater than 3-6mths. The only drug that illustrated some promise were believed to be thylakoids. Therefore, a single drug in which agonism for the receptors of glucagon, glucagon like peptide1 (GLP1), glucose dependent insulinotropic polypeptide (GIP) was combined in view of mechanistic modes of bariatric surgery (BS) was posited to be through central nervous system(CNS), and certain other GIT hormones for instance GLP1, ghrelin and PYY. Nonetheless, we did not utilize GLP1RAs in women with PCOS, due to expenses, parenteral use, accessiblity nevertheless, we reviewed Obesity and Heart failure with preserved ejection fraction (HFpEF) glucagon like peptide 1(GLP-1)-1 receptor agonist(GLP-1RA), inclusive of long acting GLP-1RA's for instance liraglutide and, oral semaglutide gets done/day, whereas dulaglutide, exenatideextended release, subcutaneous(s/c) semaglutidedelivery with gets done once weekly. Here we present, the manner GLP1RAs, especially, the latest GLP-1RA's might prove to be efficacious in obese PCOS women in reference to weight reduction prior to embarking on pregnancy for improving pregnancy rate(PR) & live birth rates(LBR), however greater work is required regarding newer GLP1Ras, since it has been observed newer GLP1Rpossess definitive greater weight reduction efficacy in contrast to liraglutide and other first generationGLP1R prior to undergoing pregnancy, would conclusively aid in escalating the PR and LBR, but needs studying in PCOS effects of semaglutide, Tirzepatide(GLP1+ GIP)) combo as only restrictedly studied.

KEYWORDS: glucagon like peptide 1(GLP-1)-1 receptor agonist(GLP-1RA),**;**Polycystic ovary syndrome (PCOS).

1. INTRODUCTION

Polycystic ovary syndrome (PCOS) is an endocrine impairment prevalent globally in 6–12% of women in their childbearing years. It is marked by irregular menstrual cycles, potentiated androgen release as well as the existence of numerous cysts in the ovaries. PCOS further escalates susceptibility of women to plethora of co-morbidities, specifically, obesity, metabolic syndrome(MetS), type 2 diabetes (T2D), cardiovascular diseases (CVDs), in addition to endometrial cancer(EC) over a period of time.[1–3] Whereas the precise etiological factors aiding in PCOS generation continue to be uncharted till date, insulin resistance (IR) as well as poor lifestyle/dietary factors coupled with genetic susceptibility has been isolated in the form of a significant estimating factor.[4] Changes in insulin

receptor structure or function, resulting in aberrant signalling pathways or raised quantities of insulin-binding antibodies, decrease the sensitivity of peripheral tissues to insulin, resulting in IR.[5] Moreover, factors for instance obesity exacerbate IR in addition to are involved in the MetS, a commonly found event in PCOS.[6] Obstructive sleep apnoea (OSA,) along with depression, found in women with PCOS are correlated to escalated actions in the sympathetic nervous system (SNS). OSA, is associated with hyperinsulinemia as well as gets accelerated by obesity. OSA might exacerbate PCOS symptoms in addition to is correlated to metabolic, along with CVD in such women.[4] Weight gain is assuming greater prevalence among women with PCOS escalating as high as 88%.[7,8] A separate study pointed that 75% of lean as well as 95% of obese women diagnosed with PCOS experience IR.[9] Furthermore, diminished insulin sensitivity invariably leads to hyperinsulinemia, which in turn harbours the generation of hyperandrogenism by evoking a chronic stimulus on the cells of the ovarian theca.[10]

Earlier we have comprehensive reviewed PCOSclassification, methodologies for weight reduction inclusive of targeting brown adipose tissue (BAT) in PCOS as well as weight reduction in case of routine obesity right from i) Orlistat (Xenical) to ii)Combinational Agents inclusive ofa)QsymiaTM (phentermine hydrochloride/ delayed release topiramate beads(TPM), b) Contrave(Bupropion/ Naltrexone)/just topiramate in PCOS iii) Serotonergic Agents for instance Lorcaserin iv) GLP1R Agonists for instance Liraglutide3mg from 2013 onwards. Nonetheless, till 2019 maximum pharmacotherapy did not yield sustenance of weight reduction as well as did notprove to be efficacious over 1-5kg reduction for greater than 3-6mths. the only drug that illustrated some promise were believed to be thylakoids. Therefore, a single drug in which agonism for the receptors of glucagon, glucagon like peptide1 (GLP1), glucose dependent insulinotropic polypeptide (GIP) was combined in view of mechanistic modes bariatric surgery (BS) was posited to be through central nervous system(CNS), in addition to certain other GIT hormones for instance GLP1, ghrelin along with PYY. Nonetheless, we did not utilized GLP1RAs in women with PCOS, nevertheless, Obesity along with Heart failure with preserved ejection fraction (HFpEF) glucagon like peptide 1(GLP-1)-1 receptor agonist(GLP-1RA), inclusive of long acting GLP-1RA's for instance liraglutide in addition to, oral semaglutide gets done/day, whereas dulaglutide, exenatideextended release, subcutaneous(s/c) semaglutidedelivery which gets done once weekly.[11-18] The maximum efficacy of diminishing glucose gets attained by s/c) semaglutidedelivery dulaglutide, liraglutide, along with exenatide in that orer.[19] In recent years production of double GLP-1R as well as GIPR has been attained. Tirzepatide was the starting agent.[20] In case of 8 RCT's, which implicated 7491 patients with T2DM[21], contrasted GLP-1RA, insulin along with placebo group, diminishing of body weight, in addition to BP got attained in the tirzepatide therapy group (overweight /obese patients with T2DM) in a dose based fashion.Such double GLP-1R / GIPR agonists resulted in greater weight reduction in contrast to lone GLP-1R.[22] Additionally, an innovative triple receptor agonist (retatrutide) that targets glucagon receptor (GCGR), glucose dependent insulin tropic peptide receptor (GIPR) as well as GLP-1R has got formed for the therapy of metabolic aberrations correlated with obesity along with diseases generated secondary to that by unique mechanistic modes.[22] In case of individuals with T2DM, in a phase2 study (n=281)using placebo, GLP-1RA, dulaglutide, as well as retatrutide illustrated clinically significant enhancement of glycemic regulation in addition to, diminishing of body weight, in a dose based fashion at 36 wks by 3.2%,10.4%,16.8% along with 16.9%(using dosages of 0.5,4,8 as well as12mg once weekly respectively) in contrast to 3%, using placebo as well as 2% having safety profile commensurate with GLP-1RA, GLP-1R as well as GIPR agonists.[23]

Recently we elaborated how mitochondrial impairment is a contributors of (IR in case of PCOS.[24]

2. Glucagon-like peptide-1 receptor agonists (GLP-1RAs) in obese PCOS women along with treatment of obese women with infertility

Polycystic ovary syndrome (PCOS) is a frequent endocrine disorder with a prevalence of 10% in reproductive-aged women.[25] Obesity influence approximately 70% of such patients as well as escalates the prevalence in addition to robustness of PCOS.[26] Lifestyle modification is first-line therapy to improve cardiometabolic, along with fertility outcomes; however, plethora of them become frustrated as well as look for weight reduction pharmacotherapy.[27] Although the efficacy of glucagon-like peptide-1 receptor agonists (GLP-1RAs) has been illustrated among such population, a direct contrasting amongst patients with in addition to without PCOS has not been conducted.[28] This is specifically significant in view of patients with PCOS generally documenting getting rid of weight is tough contrasted with the ones without PCOS. Gleason et al.[29], had the objective of contrasting the actions of GLP-1RA on weight reduction as well as metabolic health in adults with in addition to without PCOS.

They performed a retrospective cohort study of patients looking for weight management at an academic institution, along with were inclusive of females with age ranging between 18–45 years which had been prescribed GLP-1RAs from 2016 to 2021 who had reported compliance, as estimated by detailed chart review. Eligibility criteria for GLP-1RA prescription, were patients which possessed the body mass index (BMI) of $\geq$27 kg/m^2 with one weight-associated comorbidity or $\geq$30 kg/m^2 with or without a comorbidity. Titration of medicines were attained to the maximum tolerable dose recommended for diabetes or obesity. Their exclusion

criteria were i) pregnant patients, ii) those who had undergone bariatric surgery, iii) or utilized GLP-1RAs for lesser than 3 adjoining months. The University of Pennsylvania Institutional Review Board approved this study.

The primary exposure was PCOS, definitions as per Rotterdam criteria.[27] The control group was constituted of females without PCOS, ii) who were aged 18–45 years as well as got GLP-1RAs for weight management at the same period of time. The primary result was weight reduction estimated by i) percentage of patients depleting a minimal of 5% of their baseline weight, ii) percentage weight reduction, in addition to possessed a tendency of weight reduction over a period of time. The secondary results were inclusive of alteration in metabolic specifications among patients with escalated baseline readings.

2.1Results observed by Gleason et al.[29], were as following

Patients with PCOS included in the evaluation (n = 92) were younger in contrast to controls (n = 110) as well as possessed lesser probability to be Black, with no variation amongst GLP-1RA agents utilized (Table 1). The maximum number of PCOS patients possessed a hyperandrogenic phenotype (93.6%) in addition to utilized GLP-1RAs for a lesser period of time in contrast to controls (13.2 vs. 21.6 months, *P*<.001).

Courtesy ref no-29-Table 1

Characteristic	**PCOS, *n = 92***	**Controls, *n = 110***	***P* value**
Age	32 (28–35.5)	37.5 (32–41)	<.001
Race[a]			.002
White	54 (60.0)	40 (36.7)	
Black	25 (27.8)	56 (51.4)	
Other	11 (12.2)	13 (11.9)	
Gravidity	0 (0–1)	2 (0–3)	<.001
BMI	39.2 (34.2–44.8)	37.9 (33.3–43.7)	.29
Diabetes mellitus diagnosis	10 (10.9)	23 (20.9)	.06
Hemoglobin A1c (mg/dL)	5.5 (5.3–5.7)	5.7 (5.4–6.4)	.05
Dyslipidemia[b]	10 (10.9)	12 (10.9)	.993
SBP (mm Hg)	124 (118–130)	123 (113–133)	.39
DBP (mm Hg)	78 (71–84)	74.5 (69–82)	.05
Medications			
COC	21 (22.8)	11 (10.0)	.01
Spironolactone	17 (18.5)	2 (1.8)	<.001
Metformin	57 (62.0)	23 (20.9)	<.001
Antihypertensive	10 (10.9)	18 (16.4)	.26
Statin	3 (3.3)	6 (5.5)	.51

Baseline demographic and clinical characteristics of the polycystic ovary syndrome and control groups.

Note: Data are medians (interquartile ranges) or numbers (percentages). BMI = body mass index; COC = combined oral contraceptive; DBP = diastolic blood pressure; PCOS = polycystic ovary syndrome; SBP = systolic blood pressure.

a
N = 199 (90 patients with PCOS, along with 109 controls) given missing data. percentage weight loss.

b
Defined as use of a statin or any of the following: total cholesterol level of >200 mg/dL; low-density lipoprotein level of >130 mg/dL; high-density lipoprotein level of <40 mg/dL; or triglyceride level of >150 mg/dL.

No variations were observed in the percentage who had depletion of ≥5% of their baseline weight (52% vs. 59%, *P*=.32) amongst groups (adjusted relative risk, 0.56; 95% confidence interval, 0.28–1.12; *P*=.10). In a subgroup evaluation of patients having exposure to a GLP-1RA for a maximum of 18 months (PCOS n = 89, control n = 104), there continue to be no variation amongst groups (adjusted relative risk, 0.62; 95% confidence interval, 0.30–1.27; *P*=.19). On contrasting definitive proportion weight reduction amongst groups, patients with PCOS had depletion of a median of 5.1% of their baseline weight, as well as controls had depletion of a median of 6.8% (*P*=.13). Both groups had improvement of metabolic frameworks (Table 2). In the mixed-effects longitudinal model, there were no variations in weight reduction trajectory amongst patients with PCOS in addition to controls up to 18 months (*P*=.08) In a subgroup evaluation, patients with PCOS who had depletion of t ≥5% of their baseline weight possessed greater probability to be White, possessed a lower baseline body mass index, along with met all Rotterdam criteria.

Outcome	PCOS *(n = 92)*	Controls *(n = 110)*	*P* value
GLP-1RA agent			
Liraglutide	54 (58.7)	72 (65.5)	.32
Semaglutide	39 (42.4)	51 (46.4)	.57
Dulaglutide	13 (14.1)	14 (12.7)	.77
Exenatide	4 (4.3)	0 (0)	.04
Tirzepatide	2 (2.2)	3 (2.7)	.80
Use of additional oral weight management medication	11 (11.9)	10 (9.1)	.51
Duration on GLP-1RA (mo)	13.2 (8.0–25.7)	21.6 (14.0–38.0)	<.001
Patients losing ≥5% of baseline weight	48 (52.2)	65 (59.1)	.32
Overall percentage weight loss	5.1 (1.6–9.6)	6.8 (2.6–15.2)	.13

Outcome	PCOS *(n = 7)*	Controls *(n = 19)*	*P* value
Decrease in hemoglobin A1c (mg/dL)[a]	0.20 (0–1.10)	0.40 (0.10–0.60)	.77

Outcome	PCOS *(n = 10)*	Controls *(n = 12)*	*P* value
Resolution of dyslipidemia[b]	7 (70.0)	10 (83.3)	.46

Outcome	PCOS *(n = 17)*	Controls *(n = 11)*	*P* value
Decrease in systolic blood pressure (mm Hg)[c]	24 (9–27)	28 (13–33)	.41
Decrease in diastolic blood pressure (mm Hg)[c]	9 (0–14)	13 (1–20)	.38

Courtesy ref no-29--Table 2
Weight loss and metabolic outcomes in the polycystic ovary syndrome and control groups.
Note: Data are medians (interquartile ranges) or numbers (percentages). GLP-1RA = glucagon-like peptide-1 receptor agonist; PCOS = polycystic ovary syndrome.
a
Among patients with baseline hemoglobin A1c levels of >5.6 mg/dL.

b
Among patients with baseline dyslipidemia, defined as use of a statin or any of the following: total cholesterol level of >200 mg/dL; low-density lipoprotein level of >130 mg/dL; high-density lipoprotein level of <40 mg/dL; or triglyceride level of >150 mg/dL. Resolution defined as a total cholesterol level of <200 mg/dL, low-density lipoprotein level of <130 mg/dL, high-density lipoprotein level of >40 mg/dL, and triglyceride level of <150 mg/dL at the last visit or latest measurement >3 months after treatment start.

c
Among patients with baseline SBP of >140 mm Hg or DBP of >90 mm Hg.

3. DISCUSSION

Acknowledged the underlying hyperandrogenism as well as IR correlated with PCOS, clarification is not there if such patients have changed reactions to weight reduction. Earlier studies on GLP-1RAs in women with PCOS concentrated on contrasting with placebo or other weight reduction medicines. Conversely, this is the first study, as per Gleason et al.[29], contrasting the actions of GLP-1RA amongst women with PCOS as well as controls, which is significant for patient counseling in addition to expectations. In this retrospective cohort study, theyfound commensurate weight reduction, along with metabolic improvements, embracing the utilization of GLP-1RA for obesity management in such a population.[28] Their results further oprovide understanding into the variations amongst responders as well as nonresponders among patients with PCOS, which requires future asssessment. This study possesses variable strengths: i)its innovative study question as well as inclusion of a well-defined, longitudinal, in addition to racially variable cohort of patients with corroborated PCOS in real-world practice. Restrictions were inclusive of i)the study being retrospective, ii) the incapability of explaining in reference to lifestyle modifications, iii) along with a sample size that might have been inadequate to estimate significant variations. Although such restrictions were present, their observations yielded reassurance that GLP-1RA pharmacotherapy, proved to be efficacious in the general population, provides analogous advantages for patients with PCOS in a real-world scenario.

4. CONCLUSIONS ALONG WITH FUTURE DIRECTIONS

Polycystic ovary syndrome (PCOS) presents a plethora of botherations for patients that are usually lifelong as well as influence all walks of life, inclusive of reproduction. PCOS is a continued problem that might implicate infertility, metabolic syndrome(MetS), in addition to the generally continuing along with steep task of controlling weight. In reference to such patients, obesity escalates inimicality of their metabolic, endocrine aberrations, making weight reduction an underpinning of treatment. In view of such exposition Gleason et al.[29], continued their research, in reference to actions of such glucagon-like peptide 1 (GLP1) receptor agonists(GLP1RAs) on weight reduction in patients with as well as without PCOS''[29], Prior to the glucagon-like

peptide 1 (GLP1) receptor agonists assuming popularity in addition to the study by Gleason et al.[29], Legro et al.[30], illustrated that postponement of fertility treatment for lifestyle modifications (caloric restriction, along with weight reduction medication) yielded a 2.5-fold greater likelihood of live birth in contrast to prompt treatment with clomiphene citrate. Nonetheless, uptill now there has been no definite estimation on aiding the patients with weight reduction, in an appropriate manner; metformin, which is maximum commonly utilized, is usually not tolerated by patients as well as yields moderate weight reduction. GLP1RAs plausibly offer a substantially greater efficacious methodology in addition to have been broadly supported for general obesity management. I)GLP1RAs stimulate insulin liberation in a glucose- based fashion from pancreatic islet cells.ii) They further postpone gastric emptying, iii)along with cause avoidance of glucagon liberation from pancreatic alpha cells. Iv)Lastly, they act within the central nervous system(CNS), directly activating receptors in the hypothalamus particularly a) anorexigenic proopiomelanocortin(POMC)/Cocaine and amphetamine related transcript(CART) expressing arcuate nucleus neurons as well asb) indirectly hampering orexigenic neuropeptide Y(NPY)/Agouti related protein(AgRP) neurons, which, in combination, provide escalated satiety in addition to diminished hunger, energy intake along with cravings[31] (3). Research uptill this time has evaluated the utilization of GLP1RAs in the PCOS population for weight reduction as well as hormonal controlling, with meta-analyses demonstrating that GLP1RAs significantly diminished waist circumference(WC), body mass index (BMI), in addition to serum triglycerides, along with total testosterone quantities in contrast to those in placebo controls. Patients that received GLP1 receptor agonists further illustrated escalated pregnancy rates as well as menstrual cyclicity vis a vis. placebo or just metformin- matched controls[31] (3).

What makes the study by Gleason et al.[29], distinct is that despite earlier trials utilized women with PCOS in the form of their control populations looking for getting insight into the actions of medicines amongst the PCOS population, Gleason et al.[29], contrasted patients with PCOS taking GLP1 receptor agonists with a control population without PCOS. Patients with PCOSpossessed distinct metabolic aberrations that make weight reduction specifically bothersome. This study might yield certain reassurance that GLP1 receptor agonists possess the equivalent efficacy in providing significant weight reduction for PCOS patients as for their non PCOS overweight compatriots. There are a few significant restrictions to this study. First, the time duration evaluated (2016–2021) was the early stages of GLP1-agonist generation, with maximum patients consuming liraglutide (58.7%), while semaglutide (42.4%) in addition to - tirzepatide (2.2%) intake were the minimal. Subsequently, research has illustrated that tirzepatide (followed by semaglutide) possess greater efficacy for both glucose regulation along with weight reduction.[32] Thereby, the population of this study might not match that of our ‘‘present generation’’ GLP-1 receptor agonists, and further research should be conducted contrasting patients on newer medicines. A further limitation is the size of the study; with only 92 patients in the PCOS group, it is tough to fathom if the absence of a variation in result might, actually be a type II error. Although weight reduction prior to pregnancy results in improves live birth in patients with PCOS, an aspect yet to be evaluated is the actions medicines possess on the pregnancy results. Women with PCOS have be acknowledged to be at escalated risk of inimical obstetric sequelae, inclusive of miscarriage, gestational diabetes, hypertension, as well as preeclampsia, in contrast to age-matched in addition to body mass index–matched controls.[33] Earlier studies have demonstrated that treatment with metformin does not result in alteration of such risks in women with PCOS. Nevertheless, in view of greater utilization of G LP1R agonists greater women with PCOS in reference to weight reduction prior to pregnancy, getting insight is of considerable significance in case such medicines result in alterations of obstetric, along with neonatal results might provide archetypal switching in results in the manner PCOS patients get treated.[34]

Despite efficacious, their problems practically have been parenteral use apart from oral semaglutide, ii) no easy accessiblity iii) being cost prohibitive, makes them tough to use in reference to developing countries like India for obese PCOS patients due to which maximum of our patients have not used them. With oral semaglutide getting cheaper these GLP1RAs might be an answer for women with obese PCOS once parenteral use gets overcome.

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