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Review Article

Optimizing obesity management for women in an Indian obstetrics and gynecology setting: A consensus approach by the Indian Society of Assisted Reproduction (ISAR)

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ABSTRACT

Objective: Obesity has emerged as a pressing global and national concern, with a disproportionate impact on women's health. It is associated with a myriad of adverse outcomes including polycystic ovarian syndrome, infertility, gestational diabetes mellitus, miscarriages, birth defects, and so on. Despite its prevalence in clinical settings, the effective management of obesity remains a formidable challenge, emphasizing the urgent need for enhanced interventions tailored to Indian women.

Study Design: A set of 14 pivotal clinical inquiries was devised by conducting a literature search. The quality of evidence and consensus statements was evaluated with the help of the GRADE approach. The objective was to gather consensus from a pool of experts regarding the statements, utilizing the Delphi methodology.

Results: This consensus paper is an initiation by the Indian Society of Assisted Reproduction (ISAR), and it aims to provide evidence-based and pragmatic clinical insights to optimize obesity management, and an easy-to-use algorithm specifically tailored for Obstetricians and Gynecologists (O&G) in India.

Conclusion: The proposed algorithm could help individualize obesity management, ultimately improving health outcomes and quality of life for Indian women seeking gynecological care.

1. Introduction

Obesity [Body mass index (BMI) ≥30 kg/m^2] is experiencing a rapid and concerning surge, affecting

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approximately 100.7 crore adults (aged 20 years and over) globally.[1] Over the past three decades, there has been a significant rise in the prevalence of obesity, and notably, women are more susceptible to it than men across all age groups.[2,3] Globally, the age-standardized prevalence of obesity has surged from 4.6% in 1980 to 14.0% in 2019.[2]

Looking ahead, it is projected that under current conditions, approximately 23% of men and 27% of women (age ≥ 20 years) worldwide will be affected with obesity by the year 2035.[1]

The global epidemic of obesity, now recognized as a critical public health concern, brings with it a substantial risk of comorbidities, including diabetes, cardiovascular disease, obstructive sleep apnea, and cancer. In women, it is also intricately linked to conditions such as polycystic ovary syndrome (PCOS), hyperandrogenism, and infertility.[4]

Specifically, in the context of maternal health, obesity is associated with severe complications during pregnancy, including gestational diabetes mellitus (GDM), gestational hypertension, preeclampsia, and stroke. It also leads to intra-partum complications such as prolonged labor, shoulder dystocia, increased caesarean delivery rates, and anesthesia complications, as well as postpartum issues such as hemorrhage, puerperal pyrexia, wound infection, venous thromboembolism, longer hospital stays, and postpartum depression.[5] Furthermore, obesity poses risks to the fetus, including miscarriages, birth defects, macrosomia, unexplained stillbirths, neonatal intensive care unit admissions, and neonatal deaths.[5]

In the context of menopausal women, the menopausal transition is strongly associated with weight gain, marked by reduced estrogen levels and a shift of subcutaneous fat to visceral fat. Postmenopausal women with obesity face an elevated risk of cardiovascular diseases and metabolic syndrome.[6]

Obstetricians and gynecologists (O&Gs) play a pivotal role in the primary healthcare of women, and their effective diagnosis and treatment of obesity are imperative. This urgency arises from the escalating incidence of obesity-related complications in fertility, pregnancy, and gynecological health. Empowering women to achieve optimal weight holds the key to numerous advantages, including enhanced fertility, reduced androgen levels, lowered risk of gynecological cancers, prevention and management of polycystic ovarian syndrome (PCOS), improved ovulation, reduced stress incontinence, and decreased risk of dysmenorrhoea.[7]

Given the glaring lack of data on how obesity affects women's health and the need for a holistic approach to managing it within Indian O&G settings, there is a pressing demand for evidence-based clinical guidance. The Indian Society of Assisted Reproduction (ISAR) has initiated this consensus to furnish O&G with a thorough understanding of the link between obesity and various gynecological issues, diagnosing obesity, implementing lifestyle changes, choosing effective pharmacotherapy, and considering surgical interventions when managing obesity in Indian women.

2. Materials and Methods

2.1. Step I: Development of key clinical questions and consensus statements

Initially, we devised a set of 14 pivotal clinical inquiries by conducting a literature search. This search encompassed English articles published from 2018 to 2023 and involved keywords such as "obesity," "India," "women," and "anti-obesity medications (AOMs)." We deliberately excluded animal studies and articles in languages other than English. For each clinical query, we rigorously executed an independent literature search to procure top-tier evidence. Subsequently, we formulated 14 consensus statements based on the pertinent literature at our disposal.

2.2. Step II: Validation and grading of the statements

The quality of evidence and consensus statements was evaluated with the help of the GRADE approach.[8] The supporting evidence from a total of 75 articles was eventually included in this document. The grading of the research evidence was done as per the quality of the study design, execution, and the type of the study.

2.3. Step III: National steering committee meeting

A virtual national meeting convened with the participation of 12 renowned experts in the field of Obstetrics and Gynecology. The primary goal of this gathering was to extract practical, experience-based clinical insights pertaining to the consensus statements. The meeting entailed comprehensive discussions, delving into recent literature and real-world clinical perspectives associated with these statements.

2.4. Step IV: Regional meetings with experts

As a subsequent phase in a broader consultative process, traditional regional meetings convened, bringing together Obstetrics and Gynecology specialists from four major Indian cities: Bangalore, Mumbai, Delhi, and Patna. The objective was to gather consensus from a wider pool of experts regarding the statements, utilizing the Delphi methodology. The Delphi method hinges on the independent opinions of subject experts, drawing from their current experiences and knowledge while avoiding peer influence.

To initiate this process, voting was conducted for the consensus statements through the Mentimeter virtual platform. A consensus was considered achieved when a majority of 75% or more experts agreed with each statement. In cases where the threshold fell short of 75%

following content deliberation and evidence presentation, re-voting was carried out to seek a consensus majority of 75%. If there was limited or inconclusive evidence, the experts' opinion was considered essential in such cases.

3. Results

The following are the final consensus statements and algorithm for obesity management in women, which were developed through the aforementioned rigorous exercise:

3.1. Prevalence of obesity

3.1.1. Key clinical question

Have you observed a rising incidence of overweight/obesity among Indian women of reproductive age group (18–49 years), and is there evidence to suggest a similar trend of obesity in Asian women?

3.1.2. Consensus statement

In recent trends, there has been a notable increase in the prevalence of obesity in Indian women and a similar trend has been observed in the South Asian women within the reproductive age group.

(Grade of Recommendation: A, Level of Evidence: 1a)

3.1.2.1. Evidence. A systematic review conducted by Ahirwar et al. in 2019 revealed that the prevalence of obesity in India varies significantly based on factors such as age, gender, geographic location, and socioeconomic status. Multiple studies have consistently shown that women are more susceptible to obesity than men. Furthermore, the urban population faced a higher risk of obesity compared to their rural counterparts.[9]

In a recent cross-sectional observational study conducted by Sangu et al. in 2022, it was found that obesity (defined as BMI ≥ 25) emerged as the most prevalent non-communicable disease, affecting a striking 52.4% of women. The majority of women with obesity fell within the age range of 18–30 years.[10]

Rai et al. conducted a prospective cohort study in rural Eastern India, enrolling 24,115 adults, of which 13,200 were women. The study revealed that the incidence of overweight among women was 27.2%, while for men, it was 19%.[11]

Another cross-sectional study by Das Gupta et al. in 2019 involved 644,006 Indian women of reproductive age. It reported that a significant proportion, namely 33.5% were either overweight or obese (defined as BMI ≥ 23.0 kg/m^2). Notably, the prevalence of obesity increased with age, with a significant p-value of <0.0001. Nearly, half (48.6%) of women aged 35–49 years fell into the overweight or obesity category.[12]

Kumar et al. conducted a study involving 454,517 married Indian women aged 15–49 years, revealing that approximately 25% of them were either overweight or obese.[1]

As per the National Family Health Survey (NFHS)-5 (2019–2021) data, the prevalence of obesity in India (defined as BMI ≥ 25.0 kg/m^2) is indicated to be 33.2% among urban women and 19.7% among rural women in India.[3]

Concerning the South Asian context, a recent meta-analysis by Ferdausi et al. demonstrated an overall prevalence of overweight/obesity of 36.3% among reproductive-aged women in four countries, namely Bangladesh, Maldives, Nepal, and Pakistan.[13] In a study involving women of reproductive age with iron deficiency, the prevalence of overweight and obesity was 29.9% and 13.1%, respectively.[14] As per evidence, the most frequently seen maternal comorbidity is obesity (24.2%).[15]

3.2. Impact of obesity on women

3.2.1. Key clinical question

Does obesity have adverse effects on reproductive function and maternal outcomes?

3.2.2. Consensus statement

The impact of obesity, in the realm of women's health, extends from the onset of menarche to the transitional phase of menopause and it is associated with diabetes in pregnancy, macrosomia, increased risk of caesarean delivery, and a negative impact on offspring health.

(Grade of Recommendation: A, Level of Evidence: 1a)

3.2.2.1. Evidence. Obesity poses distinct health risks for women from the initiation of menarche to menopause.[14] Gaining weight between pregnancies elevates the chances of developing complications such as gestational diabetes mellitus (GDM), an increased likelihood of undergoing a caesarean section, and an elevated risk of delivering large-for-gestational-age babies.[16] Moreover, a higher maternal body mass index (BMI) during mid-pregnancy and excessive gestational weight gain (GWG) have adverse effects on the health of the offspring, including greater abdominal adiposity and an unfavorable lipid profile in children born to mothers with excessive GWG.[17] Obesity is also associated with an increased risk of macrosomia.[18] Recent findings from a prospective cohort study highlight that the most prevalent adverse pregnancy outcomes linked to obesity is the need for a C-section, with GDM affecting 23.1% of women with obesity.[19]

In women, the impact of obesity also encompasses conditions such as uterine fibroids and urinary incontinence (UI).[20–24] In overweight women, UI was observed in 60% of cases, while in obese women it was reported in 81.4% of cases. The risk of developing UI was 1.86 times higher in overweight women and 5.45 times higher in obese women compared to those with a BMI <25 kg/m^2. Moreover, when compared to patients with a BMI less than

25, overweight/obese women displayed significantly higher urinary incontinence across all categories of UI severity.[23] Fibroids are 2-3 times more common in obese women, especially those with central obesity and a BMI of 35 kg/m^2 or higher.[24]

3.2.3. Key clinical question

How does obesity impact fertility in women?

3.2.4. Consensus statement

Obesity is associated with adverse effects on cycle regularity, time to conception, chances of live births, and risk of miscarriages.

(Grade of Recommendation: A, Level of Evidence: 1a)

3.2.4.1. Evidence. Obesity in women has been associated with a statistically significant lower live birth rate following Assisted Reproductive Technology (ART) when compared to women with normal BMI. Women with a BMI ≥30 kg/m^2 experience a higher rate of miscarriages.[20]

Obesity has a detrimental impact on endometrial implantation and various other reproductive functions, leading to complications such as delayed PCOS, conception and diminished success rates in assisted conception treatments.[21] It is associated with a longer time to conceive, reduced fertility rates, an increased need for gonadotropins, menstrual irregularities, poor oocyte quality, decreased live birth rates, and a higher incidence of cycle cancellations.[22]

3.3. Beneficial impacts of weight loss on women's health

3.3.1. Key clinical question

How does weight loss aid in improving women's health and restoring the fertility rate?

3.3.2. Consensus statement

Weight loss restores cycle regularity, increases the natural conception rate, reduces the time to pregnancy, and increases the chances of live birth.

(Grade of Recommendation: A, Level of Evidence: 1a)

3.3.2.1. Evidence. Weight loss yields enduring benefits, including the prevention or amelioration of obesity-related complications, reduced healthcare costs, and an enhanced quality of life.[8] Non-pharmacological interventions have demonstrated notable increases in both pregnancy rates and natural conception rates.[25] Similarly, following a lifestyle intervention, shedding excess weight enhances the prospects of pregnancy and live births.[26] Furthermore, weight loss can positively impact the chances of unassisted conception.[27]

In the realm of anti-obesity pharmacotherapy, a short-term preconception intervention involving low-dose liraglutide in conjunction with metformin has proven superior to metformin alone. This combination significantly boosts pregnancy rates per embryo transfer and cumulative pregnancy rates among infertile women with PCOS and obesity (85.7% versus 28.6%; P=0.03).[28]

Weight loss achieved through bariatric surgery also has been shown to lead to a substantial reduction in infertility and menstrual cycle irregularities.[29]

3.3.3. Consensus statement

Weight loss has been associated with multiple health benefits in women such as improved incontinence symptoms and overall quality of life.

(Grade of Recommendation: A, Level of Evidence: 1a)

In a cross-sectional study of 1,351 consecutive patients, severity, and different types of UI in overweight and obese women were studied. Weight reduction was advocated as a first-line treatment in the management and improvement of incontinence symptoms.[24] Losing 5-10% of body weight is linked to betterment in various accompanying ailments like depression, sexual dysfunction, urinary stress incontinence, and mobility and improves the overall quality of life.[30]

3.4. Clinical assessment

3.4.1. Key clinical question

In the context of Indian gynecological practice, should additional assessment modalities be considered alongside BMI and waist circumference for women with obesity?

3.4.2. Consensus statement

In a clinical setting, anthropometric measurements including height, weight, body mass index, waist circumference, and waist-to-hip ratio are essential, while laboratory assessments (elaborated in the evidence below) may be offered to women with obesity.

(Grade of Recommendation: A, Level of Evidence: 1a)

3.4.2.1. Evidence. In South Asia, BMI is commonly employed as a measure to classify obesity, while waist circumference (WC) receives comparatively less attention from clinicians. There is a growing imperative to assess obesity in South Asians using ethnicity-specific guidelines.[31] The comprehensive evaluation of obesity encompasses several components, including a thorough medical history, physical examination (including vital signs and anthropometric measurements), laboratory assessments, and adipose-related blood tests. The medical history should encompass a detailed body weight history, baseline medical information, medication history, review of systems, family history, social context, socioeconomic and cultural factors, nutritional habits, behavioral patterns, physical activity levels, and routine preventive care considerations.[32]

The physical examination encompasses a thorough assessment of vital signs and various anthropometric measurements, including height, weight, body mass index (BMI), waist circumference, blood pressure, pulse rate,

neck circumference, and waist-to-hip ratio.[32,33] Notably, the routine inclusion of waist circumference measurement in clinical practice holds the potential to enhance patient care significantly.[34] Special attention may also be directed towards specific areas known to carry elevated risks associated with obesity, such as the nose, throat, neck, abdomen, and overall body shape.[32]

Laboratory assessment involves a range of evaluations, including general laboratory tests (such as complete blood count and urinalysis) and adipose-related blood tests (covering parameters like fasting blood glucose, fasting lipid levels, glycated hemoglobin, liver enzyme levels, electrolyte balance, renal function tests, urine analysis for protein and/or microalbumin to creatinine ratio, uric acid levels, thyroid-stimulating hormone levels, and 25-hydroxyvitamin levels). Additionally, assessments of body composition may be conducted using methods such as bioelectrical impedance, dual-energy X-ray absorptiometry, and whole-body air displacement plethysmography.[32]

3.5. Lifestyle interventions

3.5.1. Key clinical question

Do you consider lifestyle interventions effective as the first-line approach for the management of obesity?

3.5.2. Consensus statement

Lifestyle modification should be the first-line approach for the management of obesity.

(Grade of Recommendation: D Level of Evidence: 5)

3.5.2.1. Evidence. Emphasizing a reduction in excess calorie intake from carbohydrates and fats, coupled with the inclusion of high-quality proteins, is crucial. In the context of obesity prevention and management, it is essential to intensify dietary and exercise interventions, particularly within the Asian Indian population.[31]

A meta-analysis conducted by Taghavi et al. comprising ten randomized trials involving 1490 women with obesity and subfertility demonstrated the effectiveness of lifestyle interventions encompassing diet and exercise programs in reducing BMI. However, the available evidence is insufficient to ascertain whether such lifestyle changes impact clinical pregnancy or live births.[35]

Examining the immediate effects of a mindfulness-based program (MBP) which involves a meditation practice that cultivates present-moment awareness based on focused attention and open monitoring, on lifestyle-related weight loss in infertile women with obesity, notable reductions in body weight were observed [1.8 kg (2.1%) with MBP (p=0.001) versus 1.7 kg (1.9%) with control (p=0.035)]. Moreover, a decrease in waist circumference was evident.[36]

In peri-menopausal women with obesity, following a lower-fat (20% kcal) or moderate-fat (35% kcal) diet with energy restriction for a year resulted in weight loss, reductions in total and low-density lipoprotein cholesterol, and an increase in HDL cholesterol.[37] In postmenopausal women with overweight or obesity (BMI ≥25 kg/m^2), a combination of dietary modifications aimed at weight loss and exercise yielded substantial weight reduction.[38]

3.5.3. Key clinical question

Would you recommend a consistent daily calorie restriction as an effective approach for weight reduction in women with obesity?

3.5.4. Consensus statement

Daily calorie restriction enables weight reduction in women with obesity.

(Grade of Recommendation: D Level of Evidence: 5)

3.5.4.1. Evidence. Portion control, including the incorporation of meal replacement (MR) plans, constitutes a valuable component of weight reduction strategies. Notably, the effectiveness of a low-energy diet (LED) based on meal replacements has demonstrated superiority over traditional food-based LED approaches, However, practical challenges in sustaining LED approaches, such as adherence, managing hunger, social situations, and long-term sustainability, need to be addressed for successful implementation.[39]

Research has shown that intermittent fasting can lead to more substantial weight loss and body fat reduction compared to calorie restriction alone.[40] However, the results of a randomized controlled trial (RCT) suggest that intermittent calorie restriction (ICR) and continuous calorie restriction (CCR) yield similar modest weight loss outcomes over two years.[41]

Time-restricted eating (TRE) represents an evolving dietary approach focused on leveraging the metabolic benefits of nightly fasting and ketosis. Typical TRE regimens involve daily fasting periods lasting 12 to 18 hours, often initiated in the evening or night-time. Individuals with obesity who adhered to daily 14-hour metabolic fast TRE regimen for 8 weeks in conjunction with a commercial weight loss program experienced clinically significant weight loss.[42] In a recent RCT, participants in the time restriction group achieved a mean weight loss of -8.0 kg from baseline at 12 months, surpassing the -6.3 kg achieved by those in the daily calorie-restriction group.[43]

3.6. Behavioral therapy

3.6.1. Key clinical question

Do you recommend cognitive behavioral therapy for all women with obesity?

3.6.2. Consensus statement

Cognitive behavioral therapy is beneficial in women with obesity trying to lose weight.

(Grade of Recommendation: A Level of Evidence: 1b)

3.6.2.1. Evidence. Obesity and depression often coexist, and while effective treatments targeting each condition separately exist, integrated approaches are still needed. A collaborative care intervention, which combines behavioral weight loss treatment, problem-solving therapy, and as-needed antidepressant medications, has demonstrated significant improvements in both weight loss and depressive symptoms after one year compared to conventional care.[44]

In the case of women with PCOS seeking to conceive and having a BMI >25 kg/m^2, a comprehensive one-year lifestyle intervention incorporating cognitive behavioral therapy resulted in more substantial weight loss when compared to a year of standard care (CAU) that encouraged weight loss through publicly available services.[45]

Furthermore, a study by Kim M et al. underscored the effectiveness of digital cognitive behavioral therapy, showing a significantly higher mean weight loss at 8 weeks when compared to the control group (-3.1% versus -0.7%, P = .04). This study validated the impact of an innovative cognitive behavioral therapy approach, facilitated by a multidisciplinary team and leveraged through digital technologies, rather than relying solely on technology-based interventions.[46]

3.7. Pharmacotherapy for weight loss

3.7.1. Key clinical question

When should you consider use of anti-obesity medications for women with obesity in your practice? What would be the preferred medications for this purpose?

3.7.2. Consensus statement

Pharmacotherapy is effective as second-line management in women with BMI ≥ 27 kg/m^2 along with lifestyle modifications.

(Grade of Recommendation: A Level of Evidence: 1b)

3.7.2.1. Evidence. Pharmacotherapy can complement lifestyle modifications to facilitate weight loss.[31]Table 1 provides an overview of the available evidence pertaining to various anti-obesity medications (AOMs), including liraglutide, semaglutide, orlistat, phentermine/topiramate, and naltrexone/bupropion, and their respective outcomes in terms of weight loss.

3.7.3. Key clinical question

3.7.4. Consensus statement

GLP-1 RAs are effective anti-obesity medications for the management of obesity in women.

(Grade of Recommendation: A Level of Evidence: 1b)

3.7.4.1. Evidence. Sustained weight loss of 5–15% could improve many conditions associated with obesity, with adjunctive pharmacotherapy suggested for achieving this goal.[47] Semaglutide and liraglutide are modified, long-acting analogues of native GLP-1.[48] In the network meta-analysis of 23 trials with a total of 941 women, weight loss varied significantly between liraglutide, orlistat, and metformin. Liraglutide was superior to metformin and orlistat in reducing weight and waist circumference.[49] In another study, women with PCOS were randomly assigned to receive liraglutide 3 mg (n = 55) or placebo (n = 27) once daily for 32 weeks, along with lifestyle interventions. Liraglutide 3 mg once daily was greater than placebo in decreasing body weight and androgenicity as well as enhancing cardiometabolic parameters in women with obesity and PCOS. Liraglutide considerably lowered the free androgen index compared to placebo. Liraglutide 3 mg had a significant effect on weight reduction, changes in body composition, and improvements in hormonal and metabolic parameters in women with obesity and PCOS. Administering Liraglutide 3 mg once a day for 32 weeks leads to weight loss, alleviates hyperandrogenism, and restores regular menstrual cycles in non-diabetic women who have both obesity and polycystic ovary syndrome (PCOS).[49]

Robust mean weight loss in the range of 13-18% was reported in STEP trials (Semaglutide Treatment Effect in People with Obesity) with injectable semaglutide 2.4 mg. The STEP 4 Randomized Clinical Trial inspected the impact of current weekly subcutaneous Semaglutide versus placebo on the maintenance of weight loss in adults with obesity. The study aimed to determine whether Semaglutide could help sustain weight loss in this population. The STEP-4 trial, a total of 902 individuals received once-weekly subcutaneous semaglutide. After 20 weeks (16 weeks of dose escalation; 4 weeks of maintenance dose), 803 participants (89.0%) who had reached the 2.4-mg/week semaglutide maintenance dose were randomised (2:1) to 48 weeks of continued subcutaneous semaglutide (n = 535) or placebo (n = 268), with lifestyle intervention in both groups. STEP-4 trial established that among adults with obesity, subcutaneous semaglutide (2.4 mg) once weekly enabled continued weight loss over 48 weeks.[47] Similarly, the STEP-8 trial reported that among adults with obesity without diabetes, once-weekly subcutaneous semaglutide 2.4 mg along with counselling for diet and physical activity enabled substantially greater weight loss at 68 weeks compared to once-daily subcutaneous liraglutide 3 mg.[48] Weight loss due to semaglutide seems to be due to improved appetite control, and subsequent decreased energy intake, through effects in the hypothalamus and area postrema of the brain.[47]A few RCTs showed similar significant weight loss outcomes with semaglutide.[50,51]

Table 1: Summary of clinical trials on anti-obesity medications

Study/Author	No of patients	Patient population	AOMs and treatment duration	Outcomes
Meta-analysis by Wang FF et al. (2018)[52]	941 (23 trials)	Women with PCOS and overweight/obesity (BMI ≥ 28-30 kg/m2)	Liraglutide, orlistat and metformin (12-26 weeks)	-Amount of weight lost differed significantly: Liraglutide, orlistat, and metformin (-5.18, -3.23, and -1.37) -Liraglutide alone, liraglutide/metformin, and metformin alone significantly reduced WC (-5.69, -4.68, and -2.68) -No change in WC with orlistat
RCT by Elkind-Hirsch KE et al. (2022)[49]	82	Women with PCOS and obesity (BMI >30 kg/m2)	Liraglutide 3 mg (n=55) and placebo (n=27) once daily	-Greater reduction in body weight (−5.7% versus -1.4%), mean WC, WHR, FAI, total body, trunk, and upper body fat, and android/gynoid fat ratio -More women on liraglutide achieved at least 5% weight reduction
RCT by Rubino D et al. [STEP-4 trial] (2021)[47]	902 (79% women)	Adults with overweight or obesity (BMI ≥30 kg/m2 or ≥27 kg/m2 with ≥1 weight-related comorbidity)	20-week run-in of weekly subcutaneous 2.4 mg semaglutide; randomized to continued treatment with semaglutide versus placebo (additional 48 weeks)	-From week 20 to week 68: Mean weight change was −7.9% with continued semaglutide versus +6.9% with placebo
RCT by Rubino D et al. [STEP-8 trial] (2022)[48]	338 (78.4% women)	Adults with BMI ≥30 kg/m2 or ≥27 kg/m2 with 1 or more weight-related comorbidities, without diabetes	Once-weekly semaglutide, 2.4 mg, versus once-daily subcutaneous liraglutide, 3.0 mg (+ diet and physical activity) [68 weeks]	-Mean body weight change from baseline to 68 weeks: –15.8% with semaglutide versus –6.4% with liraglutide -Treatment discontinuations: Liraglutide (27.6%), placebo (17.6%), and semaglutide (13.5%)
RCT by Wadden TA et al. (2021)[50]	611 (81% women)	Adults with BMI ≥27 kg/m2 with at least 1 weight-related comorbidity or BMI ≥30 kg/m2	Once-weekly subcutaneous semaglutide 2.4 mg versus placebo (intensive behavioral therapy + initial low-calorie diet)	-Estimated mean body weight change from baseline was –16.0% for semaglutide versus –5.7% for placebo (P< .001)
RCT by Ghusn W et al. (2022)[51]	408 (75.4% women)	Adults with BMI ≥27 kg/m2	Weekly 1.7-mg or 2.4-mg semaglutide subcutaneous injections (3-6 months)	-Mean weight loss from baseline: After 3 months: 5.9% (P < 0.001) After 6 months: 10.9% (P < 0.001)

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Table 1 continued

RCT by Wang Z et al. (2021)[53]	877	Infertile women scheduled for IVF (BMI ≥25 Kg/m2)	Orlistat or placebo [4 to 12 weeks]	Mean change in body weight: −2.49 kg with orlistat versus −1.22 kg with placebo (P = .005)
RCT by Kujawska-Luczak M et al. (2018)[54]	120	Women with obesity [BMI ≥ 30 kg/m2]	Low-calorie diet or isocaloric diet and 500 mg metformin twice daily (IM) or isocaloric diet with 120 mg orlistat three times daily (12 weeks)	Change in weight: –4.0 ± 5.9 (Low-calorie diet), –2.1 ± 4.3 (Metformin) and –5.5 ± 8.8 (Orlistat)
Meta-analysis by Khera R et al. (2018)[55]	29,018	Adults with BMI≥30kg/m2 or 25–29.9kg/m2	Phentermine-topiramate, naltrexone-bupropion, and placebo	Decrease in waist circumference with phentermine-topiramate and naltrexone-bupropion: By 7 cm (95% CI −8.4, −5.6; SMD −0.49) and 3.5 cm (95% CI, −4.4, −2.6; SMD, −0.37) respectively
Meta-Analysis by Lie XG et al (2021)[56]	Sample size varied from 45 to 2,487	Adults with overweight (BMI ≥ 25 kg/m2) or obesity (BMI ≥ 30 kg/m2)	Phentermine/ topiramate versus placebo	Average weight loss by phentermine/topiramate versus placebo: 7.73 kg (95% CI: 6.60–8.85)
RCT by Elkind-Hirsch KE et al. (2022)[49]	119	Non-diabetic women (BMI >30 kg/m2) and PCOS	Phentermine topiramate extended release and Exenatide/Dapagliflozin	Significant decrease in absolute body weight and BMI (P < .0001) with both regimens
Meta-analysis by Sposito AC et al. (2021)[57]	19,176	Adults with BMI 32 ± 5 kg/m2 (55% females)	Naltrexone-Bupropion	Reduction of −3.14 cm in WC and loss of 5.0 kg
RCT by Grilo CM et al. (2021)[58]	136	Patients with binge-eating disorder (81.6% women; mean BMI, 37.1 kg/m2)	Placebo, naltrexone-bupropion, BWL-placebo, and BWL-naltrexone-bupropion	Rates of participants attaining 5% weight loss: 11.8% with placebo, 18.8% with naltrexone-bupropion, 31.4% with BWL-placebo, and 38.2% with BWL-naltrexone-bupropion
RCT by Grilo CM et al. (2022)[58]	22	Patients with binge-eating disorder and obesity (86.4% women)	Naltrexone-bupropion	Patients attaining 3% weight loss was significantly greater with naltrexone-bupropion versus placebo (45.5% versus 0%)
by Tronieri JS et al. (2019)[59]	45	Adults with obesity (75.6% female, BMI= 34.3±4.7 kg/m2)	Liraglutide 3.0 mg plus phentermine 15.0 mg (12 weeks)	Mean weight loss with liraglutide-phentermine: 1.6±0.6%

Disclaimer: Orlistat and Semaglutide 2.4 mg are currently the only approved anti-obesity medications in India. Semaglutide 2.4 mg is not yet available in the Indian market

Abbreviations: WC: Waist circumference, WHR: Waist-hip ratio, FAI: Free androgen index; TRG: Triglyceride, TRG/HDL: Triglyceride to high-density lipoprotein cholesterol, STEP: Semaglutide treatment effect in people with obesity, IVF: In vitro fertilization, CI: Confidence interval, SMD: Standardized mean difference, BWL: Behavioral weight loss

The major side effects seen with semaglutide were gastrointestinal tract disorders. However, most gastrointestinal events were transient and mild-to-moderate in severity, and most patients recovered without treatment discontinuation.[47]

3.7.5. Key clinical question

Apart from weight loss, are anti-obesity medications associated with other beneficial effects?

3.7.6. Consensus statement

Anti-obesity medications may be associated with other beneficial effects related to women's health beyond weight loss.

(Grade of Recommendation: A Level of Evidence: 1b)

3.7.6.1. Evidence. According to findings from clinical trials, liraglutide improved whole-body insulin sensitivity and significantly reduced triglyceride concentrations and triglyceride to high-density lipoprotein cholesterol ratios in comparison to placebo. Also, it brought back menstrual cyclicity within a month. Excess testosterone in women causes the risk of obesity and high blood sugar levels. A modest weight reduction has been associated with a positive impact on hormone levels, it improves ovulation and leads to more regular menstrual cycles. Treatment with liraglutide 3 mg was associated with a marked reduction in serum levels of testosterone in comparison to placebo ($P < 0.006$). Liraglutide has also been used in the treatment of obesity in overweight PCOS patients.[49]

In a meta-analysis summarizing the STEP trials, injectable semaglutide (2.4 mg) demonstrated improvements in various metabolic parameters, such as reduced HbA1c levels, improved insulin sensitivity, UI, and decreased cardiovascular risk factors and long-term weight management contributing to overall health benefits beyond weight loss.[47,48,50,51] As per the STEP-4 trial, blood pressure reduced significantly with semaglutide versus placebo ($P < 0.001$). Moreover, additional reductions in HbA1c and fasting plasma glucose and improvements in lipid profile ($P < 0.001$) were observed.[47] The STEP-8 trial demonstrated that the LDL cholesterol level, triglyceride level, HbA1c level, and C-reactive protein level were significantly greater with semaglutide as compared to liraglutide (all $P < .001$).[48]

In a large cardiovascular outcome trial (SELECT), patients with overweight and /or obesity without T2D, injectable Semaglutide 2.4 mg had a significant 20% reduction in the major adverse cardiovascular events, compared to the placebo arm, on top of standard of care. These benefits were evident soon after initiation, suggesting an effect of semaglutide 2.4 mg beyond weight loss alone.[60]

A subset analysis from the STEP 1 trial comprising 96 women with PCOS reported a significant reduction in insulin resistance with Semaglutide 2.4 mg versus placebo in addition to the robust reduction in weight and waist circumference.

In a post-hoc analysis of STEP 1 trial, the participants with frequent UI episodes (≥1/day) at baseline and evaluable data at week 68,35.6% (58/163) reported a decrease in episodes to ≤1/week at week 68. Greater weight loss was associated with a higher proportion of participants who reported a decrease in UI episodes.

An RCT reported that before in vitro fertilization and embryo transfer in women with obesity, orlistat resulted in a significant increase in singleton birth weight.[53]

3.8. Bariatric surgery

3.8.1. Key clinical question

When should you refer your patient to a bariatric surgeon for obesity management?

3.8.2. Consensus statement

Indian women with BMI ≥ 35 kg/m^2 with/without presence of any obesity related co-morbidity may be referred to a bariatric surgeon for evaluation and management.

(Grade of Recommendation: A Level of Evidence: 1b)

3.8.2.1. Evidence. As per the Obesity and Metabolic Surgery Society of India, Indian Women with BMI ≥ 35 kg/m^2 with/without the presence of any obesity-related co-morbidity may be referred to a bariatric surgeon for evaluation and management. The standard surgical procedures include adjustable gastric banding, sleeve gastrectomy, Roux-en-y gastric bypass, biliopancreatic diversion with duodenal switch, and one anastomosis gastric bypass/mini gastric bypass.[54,58,59,61–67] Laparoscopic sleeve gastrectomy continues to be the most popular procedure in the country.[68]

A systematic review that assessed the effects of bariatric surgery on maternal and infant outcomes of pregnancy reported a post-surgery mean BMI of 30.9±6.4 versus a pre-surgery mean BMI of 47.1±8.3. Surgery did not increase the risk of adverse outcomes such as miscarriage and/or stillbirth, preterm birth, or infant complications.[69] Significant and rapid weight loss was seen in premenopausal women with obesity (BMI of 40.7–56.7 kg/m^2) after bariatric surgery. A significantly lower incidence of abnormal menstruation (relative risk: 0.40, $P = 0.008$) and decreased serum insulin levels, triglycerides, and total testosterone were also achieved.[70] An RCT involving 66 women reported that Roux-en-Y gastric bypass surgery was the most common and successful weight loss method compared to gastric banding, gastric sleeve, and dietary intervention. It enabled a decrease of −34.9 kg from baseline at 12 months ($p < 0.001$).[71] Lastly, the percentage of excess weight loss at ten years was found to be greater after laparoscopic Roux-en-Y-gastric bypass versus laparoscopic sleeve gastrectomy. However, both procedures resulted in

good and sustainable weight loss.[72]

3.9. Weight management in pregnancy

3.9.1. Key clinical question

What are the preferred approaches or modalities for managing obesity during pregnancy?

3.9.2. Consensus statement

Lifestyle interventions stand as the primary and recommended approach for preventing excessive weight gain in pregnant women with obesity.

(Grade of Recommendation: A Level of Evidence: 1b)

3.9.2.1. Evidence. The use of anti-obesity medications during pregnancy and assisted reproductive techniques (ART) raises complex considerations due to potential risks to both maternal and fetal health. Limited research exists on the safety and efficacy of such medications during pregnancy, and caution is advised. Some studies suggest possible adverse outcomes, including congenital malformations and developmental issues.[73] Weight loss with exercise is universally considered an approach for staying healthy and decreasing pregnancy complications and adverse birth outcomes. A meta-analysis reported that exercise in pregnancies with obesity could reduce GWG by 0.21 kg and lower the risk of gestational hypertension by 47%. As compared with usual care, lifestyle interventions such as improved weight, diet, physical activity, and stress management resulted in a reduced weekly rate of GWG. Telehealth lifestyle interventions could improve healthy behaviors and markers of insulin resistance among pregnant women with obesity.

4. Discussion

The consensus statements provide practical guidance based on robust evidence and consensus from experts in the field of Obstetrics & Gynecology for the optimal management of obesity in women. A large proportion of women have abnormal BMI, which is concerning and can raise the risk of acquiring non-communicable diseases.[1] Weight loss enables various benefits such as improvement of obesity-related complications and increased quality of life. It increases the chances of pregnancy and live births, as well as enables a significant reduction in infertility and menstrual cycle irregularities. Lifestyle modification should be the initial preferred approach for the management of obesity. Cognitive behavioral therapy also shows benefits in women with obesity. Multidisciplinary programs are helpful for relevant and long-term weight loss in PCOS women.[45] Pharmacotherapy is effective as second-line management. AOMs like GLP-1 RAs can be added to lifestyle modifications to aid the process of weight loss. Sustained weight loss of 5–15% could enhance obesity-related complications with adjunctive pharmacotherapy suggested for accomplishing this goal. Women with BMI $\geq$ 35 kg/m^2 without comorbidities or BMI $\geq$ 30 kg/m^2 with comorbidities might be referred to a bariatric surgeon for effective weight loss. The effective implementation of the current clinical guidance will help tackle the increasing burden of obesity in women.

The consensus statements which are based on evidence and the deliberation of experts have been tabulated in Table 2. A management algorithm for obesity in women encompassing essential diagnostic and treatment approaches is depicted in Figure 1. Management of obesity in women with comorbidities such as PCOS, pre-conceptional weight management, and post-partum weight loss can be guided as per the target weight loss.

Weight loss plays a vital role in enhancing fertility, reducing androgen levels, and positively impacting the ovulatory cycle, ultimately leading to an enhanced quality of life. Notably, anti-obesity drugs, including GLP-1 RAs, have demonstrated significant benefits in terms of promoting weight loss, augmenting ovulation rates, enhancing markers of ovarian function and lipid profiles, regularizing menstrual cycles, and increasing the likelihood of successful pregnancies in women.[47,49,52] This consensus highlights the importance of a well-defined therapeutic approach to address obesity and its substantial implications for women's health management. However, the availability of stronger evidence is essential for further implementation of the statement 5.2.

4.1. Algorithm to optimize obesity management for women in India visiting obstetrics and gynecology setting

A management algorithm for obesity in women encompassing essential diagnostic and treatment approaches is depicted in Figure 1.

4.1.1. Step 1: Anthropometric assessment and evaluation of obesity-related comorbidities depending on chief complaints, history, signs and symptoms

During the initial visit of the patient, mandatory anthropometric assessments such as Body Mass Index (BMI) and waist circumference and optional anthropometric assessments such as waist-to-hip ratio (WHR) must be performed. The mentioned assessments should be coupled with an evaluation of PCOS, hypertension, diabetes, infertility, uterine fibroids, endometrial cancers, urinary in continence, dyslipidemia, MAFLD, OSA, and CVD.

4.1.2. Step 2: Risk stratification

After initial assessment, the risk for obesity should be stratified based on parameters such as BMI and waist circumference in women. If the BMI is <23 kg/m^2 and

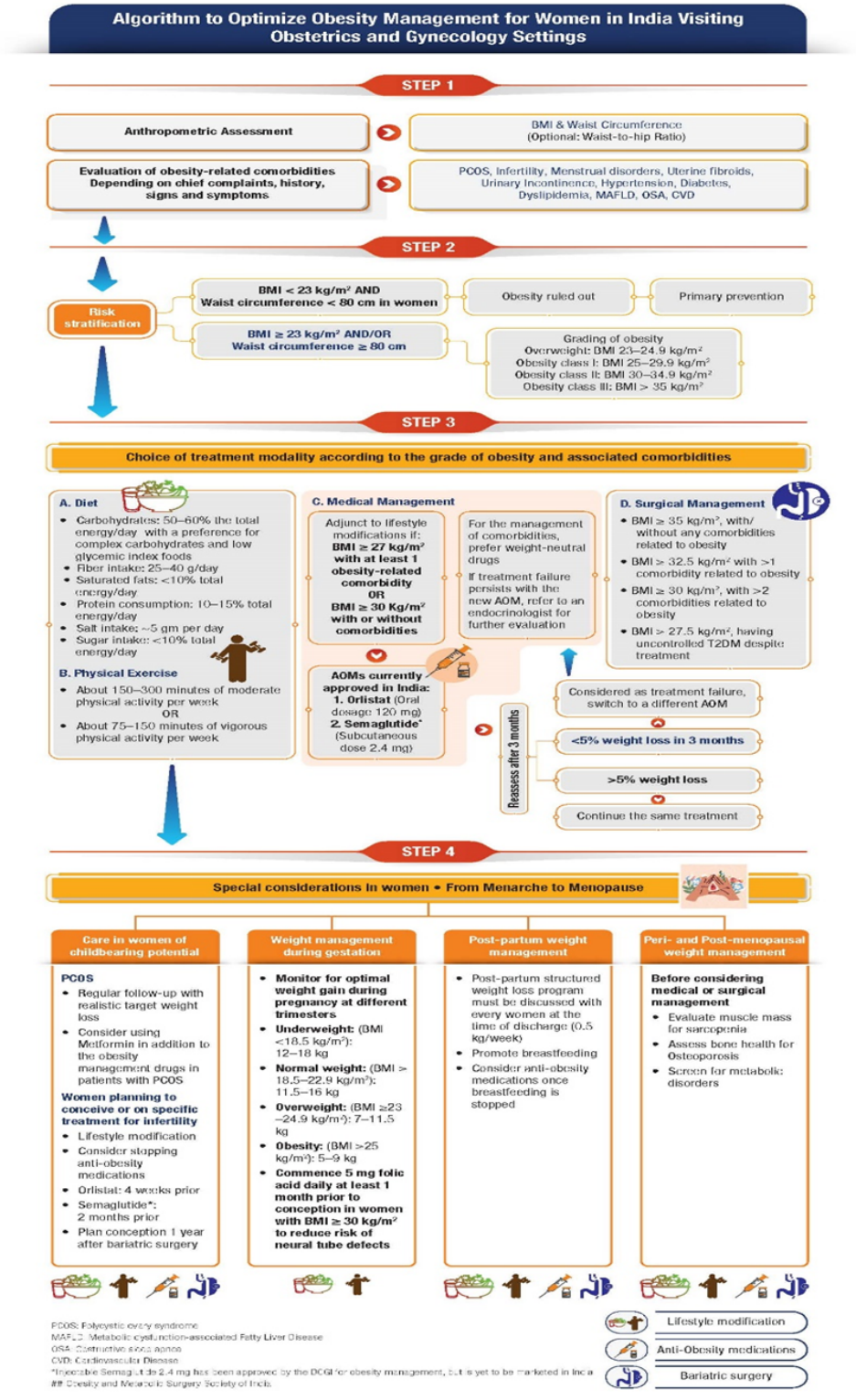

Figure 1: Management algorithm for obesity in women (Attached)

Table 2: Consensus statements on obesity in women's health

Key area	Consensus statement	Grade of Recommendation	Level of evidence
Prevalence	Statement 1: 1. In recent trends, there has been a notable increase in the prevalence of obesity in Indian women and a similar trend has been observed in the South Asian women within the reproductive age group.	A	1a
Impact of obesity on women	Statement 2: 1. The impact of obesity, in the realm of women's health, extends from the onset of menarche to the transitional phase of menopause and it is associated with diabetes in pregnancy, macrosomia, increased risk of caesarean delivery, and a negative impact on offspring health.	A	1a
	2. Obesity is associated with adverse effects on cycle regularity, time to conception, chances of live births, and risk of miscarriages.	A	1a
Benefits of weight loss in infertility management	Statement 3: 1. Weight loss restores cycle regularity, increases natural conception rate, reduces time to pregnancy, and increases chances of live birth.	A	1a
	2. Weight loss has been associated with multiple health benefits in women such as improved incontinence symptoms and overall quality of life.		
Clinical assessment	Statement 4: 1. In a clinical setting, anthropometric measurements including height, weight, body mass index, waist circumference, and waist-to-hip ratio are essential, while laboratory assessments may be offered to women with obesity.	A	1a
Lifestyle interventions	Statement 5: 1. Lifestyle modification should be the first-line approach for management of obesity.	A	1b
	2. Daily calorie restriction enables weight reduction in women with obesity.	D	5
Behavioral therapy	Statement 6: Cognitive behavioral therapy is beneficial in women with obesity trying to lose weight	A	1b
Pharmacotherapy	Statement 7: 1. Pharmacotherapy is effective as second-line management in women with BMI ≥ 25 kg/m2 along with lifestyle modifications.	A	1b
	2. GLP-1 RAs are effective anti-obesity medications for the management of obesity in women.	A	1b
	3. Anti-obesity medications may be associated with other beneficial effects related to women's health beyond weight loss.	A	1b
Bariatric surgery	Statement 8: 1. Indian Women with BMI ≥35 kg/m 2 with/without presence of any obesity related co-morbidity may be referred to a bariatric surgeon for evaluation and management.	A	1b
Weight management in pregnancy	Statement 9: 1. Lifestyle interventions stand as the primary and recommended approach for preventing excessive weight gain in pregnant women with obesity.	A	1b

waist circumference is <80 cm, possibility of women having obesity is ruled out and such women should follow primary prevention methods for managing obesity. If the BMI is ≥ 23 kg/m^2 and the waist circumference is ≥80 cm the women are categorized under obesity. Such women are further graded as overweight (BMI 23-24.9kg/m^2), obesity class I (BMI 25-29.9 kg/m^2), obesity class II (BMI 30-34.9 Kg/m^2) and obesity class III (BMI > 35kg/m^2).

4.1.3. Step 3: Choice of treatment modality according to the grade of obesity and associated comorbidities

Based on the grading of obesity and initial assessments, the choice of available treatment options needs to be made. Lifestyle modifications include dietary modifications along with physical exercises. Dietary modifications involve the intake of carbohydrates accounting for 50-60% of total energy per day with a special preference for complex carbohydrates and foods with low glycemic index. Fiber intakes of 25-40 g/day should be maintained; saturated fats and sugar should individually account for >10% of total energy per day. Total of 10–15% energy per day should be owed to protein consumption. Salt intake should

be restricted to 5 grams per day.[1] Physical exercise should involve 150–300 minutes of moderate or 75–150 minutes of vigorous physical activity per week. When the BMI is ≥27 kg/m^2 along with at least one obesity-related comorbidity or when the BMI is ≥30 kg/m^2 with or without comorbidities, anti-obesity medications can be used as a treatment modality. Currently, Orlistat and Semaglutide SC 2.4 mg are the only approved AOMs in India. Semaglutide SC 2.4 mg has been approved by the Drugs Controller General India (DCGI) for obesity management but is yet to be marketed in India. Orlistat 120 mg is administered orally and Semaglutide 2.4 mg is administered subcutaneously. Weight-neutral drugs should be preferred for the management of comorbidities. As per Obesity and Metabolic Surgery Society of India, women can undergo bariatric surgery if their BMI is greater than or equal to 35 kg/m^2 with or without any comorbidity related to obesity; if BMI is greater than or equal to 32.5 kg/m^2 with more than 1 comorbidity related to obesity; if BMI is greater than or equal to 30 kg/m^2 with more than 2 comorbidities related to obesity and if BMI is greater than or equal to 27.5 kg/m^2 having uncontrolled T2DM despite treatment.[68]

4.1.4. Step 4: Special considerations in women

For women with obesity, who are planning to conceive, lifestyle modification is the only recommended option as anti-obesity medications like orlistat and semaglutide should be stopped 4 weeks and 2 months respectively prior to conception. Conception should be planned only 12 months later in those who undergo any bariatric surgery.

For women with PCOS, consider regular follow-up with realistic target weight loss of 5–10%.[2] Metformin should be used along with obesity management drugs.

During pregnancy, weight gain should be monitored at different trimesters. If BMI is <18.5 kg/m^2, gain around 12-18 kg of weight. For a BMI of 18.5–22.9 kg/m^2, gain 11.5–16 kg, and 23–24.9 kg/m^2, gain 7–11.5 kg for a BMI > 25 kg/m^2, gain 5–9 kg.

For postpartum weight management, discuss a structured weight loss program with a healthcare provider and aim for a weight loss of 0.5 kg/week. Breastfeeding should be promoted. Anti-obesity medications should be considered only after breastfeeding has stopped.

In peri-menopause and post-menopause women, before considering medical or surgical management, muscle mass should be evaluated for sarcopenia, bone health to be assessed for osteoporosis, and screening for metabolic disorders should be done for weight management.

5. Conclusion

Obesity is a major public health concern in India, particularly among women. Current consensus statements provide evidence-based guidelines and recommendations that may aid gynecologists in effectively managing obesity in women. The proposed algorithm could help individualize obesity management, ultimately improving health outcomes and quality of life for Indian women seeking gynecological care.

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7. Conflict of Interest

None.

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