

Efficacy and Tolerability of Belite in the Management of Obesity: A Multicentric Study

Research Article

Kanchan V, Patil CS, Danish MI, Bhatt Y, Sharma S, Pankaj Y, Jain N and Mohanty L*

Department of Clinical Research and PVG, Panacea Biotec Ltd., B-1 Extn. /G-3, Mohan Co-Op., Indl. Estate, Mathura Road, New Delhi, India

*Corresponding author: Dr. Lalitendu Mohanty, Department of Clinical Research and PVG, Panacea Biotec Ltd., B-1 Extn. /G-3, Mohan Co-Op., Indl. Estate, Mathura Road, New Delhi, India. E-mail Id: lalitendumohanty@panaceabiotec.com

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Abstract

The prevalence of obesity has increased dramatically in the past few years, the pathophysiology of which is complex, involving behavioral, environmental, and genetic factors. This study was aimed to evaluate the efficacy and tolerability of Belite, a herbal formulation of green tea extract, *Griffonia simplicifolia* extract, and *Saccharum officinarum* wax, in managing obesity among a cohort of 120 obese participants. Over a six-month period, participants were administered Belite, and the outcomes were meticulously assessed to determine its impact on various health parameters associated with obesity. The study design included rigorous monitoring of body weight, Body Mass Index (BMI), waist circumference, and lipid profiles, providing a comprehensive view of the formulation's effectiveness in managing obesity. Results indicated a significant reduction in body weight that was statistically meaningful. The decrease in BMI and waist circumference further underscored the potential of Belite as an effective intervention for obesity management. Additionally, improvements in lipid profiles were observed, suggesting that Belite not only aids in weight reduction but also contributes positively to cardiovascular health markers.

Keywords: Obesity; Belite; Green Tea Extract; Griffonia Simplicifolia Extract; Policosanol; Weight Loss; BMI; Lipid Profile.

Introduction

Obesity has become a global epidemic with serious health consequences. The prevalence of obesity has risen sharply in recent years, becoming a significant public health concern globally [1]. Obesity is defined as having a Body Mass Index (BMI) of 30 or higher, obesity is associated with a range of serious health risks, including diabetes, cardiovascular diseases, and certain cancers [1]. According to the World Health Organization (WHO), higher-than-optimal BMI was responsible for approximately 5 million deaths from non-communicable diseases (NCDs) worldwide in 2019 [2]. The same is true for countries in South-East Asian Region but good quality, nationally representative, secular trend data have either not been identified or are limited. However, few studies, e.g. a research

centre in Thailand, have highlighted diet-related reasons for chronic diseases, including obesity, which are on the increase in affluent urban populations [1].

The economic burden of obesity is projected to reach \$3 trillion annually by 2030 if current trends continue [3]. Individuals with obesity are about six times more likely to develop type 2 diabetes due to insulin resistance [4], and the condition significantly increases the risk of high blood pressure and cholesterol levels, leading to heart disease and stroke. Furthermore, there are strong associations between obesity and several types of cancer, including breast, colon, and endometrial cancers [5]. Beyond physical health, obesity can lead to mental health issues such as depression and low self-esteem, exacerbated by stigma and discrimination based on weight [4].

Addressing the obesity epidemic requires a comprehensive approach that includes individual lifestyle changes and broader societal interventions to create healthier environment [6]. Effective management strategies involve adopting a balanced diet rich in fruits, vegetables, whole grains, and healthy fats while reducing sugar and saturated fat intake [7]. Regular physical activity is essential; even modest weight loss (5-10% of body weight) can significantly reduce health risks associated with obesity [8]. While various treatments exist for the management of obesity, there is a need for effective and safe alternatives.

This study investigates the efficacy and tolerability of Belite, a novel herbal formulation, in managing obesity. Belite is a polyherbal product, which contains Green tea extract, *Griffonia simplicifolia* extract or 5-hydroxytryptophan (5-HTP), and purified *Saccharum officinarum* wax (Policosanol). The individual component i.e. Green tea extract is a known natural ingredient, which can be used for treating obesity. It exerts its activity by inducing thermogenesis and inhibition of gastric and pancreatic lipases [9-11]. Regular use of green tea extract helps in reducing body weight and waist circumference by inducing a feeling of satiety [12,13]. 5-HTP works as a serotonin (a neurotransmitter) precursor and can be used in treating compulsive or binge-eating syndrome often associated with obesity [14-16]. The other component of Belite i.e. purified *Saccharum officinarum* wax is sugarcane wax which contains Policosanol, a lipid-lowering agent, which can help in reducing and/or delaying the onset of obesity-related complications. Policosanol has been shown to be as effective as statins in the management of hypercholesterolemia [17-19].

However, the combination of the two components has not been studied in the management of obesity. Thus, the current study was undertaken to assess the efficacy and tolerability of Belite (a combination of green tea extract 350 mg, *Griffonia simplicifolia* extract 100 mg, Purified *Saccharum officinarum* wax 20 mg) in obese participants.

This herbal remedy could be the breakthrough in the fight against obesity. The results could pave the way for a new, holistic approach to weight loss, offering hope to millions struggling with this condition.

Study Design and Methodology

This study used an open-label, non-comparative, multicentric study design, meaning both the participants and researchers were aware that the treatment was a herbal product named “Belite” (company brand name). The study involved 120 adults aged between 18-55 years with a BMI between 30-40 kg/m², who were in good health and had no major medical issues, and who agreed to participate. Belite, a herbal mix of green tea extract, *Griffonia simplicifolia* extract, and *Saccharum officinarum* wax, was to be taken by the study participants as two caplets (one morning caplet & one evening Caplet) daily for six months, divided into an initial phase and a maintenance phase. Data was collected on weight, BMI, waist circumference, lipid levels, blood glucose and quality of life using the ORWELL-97 questionnaire [8] at baseline (i.e. Day 0) and compared with the data collected at 3rd month and 6th month of the study. The tolerability of the product was assessed in terms of common adverse events including dry mouth, fatigue, constipation, headache and muscle pain. Analysis involved

basic statistics and a t-test to compare before and after values, with significance set at $p < 0.05$. Although the lack of a control group and the small sample size limit the study's findings, it provides a basic framework for assessing Belite's impact on obesity, though it lacks the diligence of a randomized controlled study.

This study was conducted in accordance with the Declaration of Helsinki and ICH-GCP guidelines. Regular monitoring was done to ensure compliance with the protocol and ICH-GCP guidelines.

Inclusion Criteria

1. Healthy (without any apparent disease) adult participants having a BMI in the range of 30-40
2. Participants of either sex of age between 18-55 years.
3. Participants not likely to become pregnant during the trial period (Monitored by measuring the β -HCG levels before the start of therapy and at the end of 3 months)
4. Participants willing to give informed consent

Exclusion criteria

The following individuals were excluded from the study:

1. Participants taking MAO inhibitors, tricyclic antidepressants, SSRI's, anti-Parkinsonian drugs, clozapine, risperidone, lithium, warfarin or theophylline
2. Known hypersensitivity to any of the drugs or ingredients of drugs used in the study
3. Pregnant or lactating women
4. Participants with significant cardiovascular disorders
5. Participants with uncontrolled type II diabetes mellitus
6. Participants with active renal disease or deranged renal function tests
7. Participants with hepatic disease or deranged liver function tests
8. Drug abuse and chronic alcoholics
9. Participants with asthma or carcinoid tumors (diagnosis on the basis of history and clinical examination)
10. Individuals taking any hormonal preparations e.g. oral contraceptive pills, growth hormones etc.
11. Individuals participating in new drug evaluation programme m proceeding 3months
12. Participants with apparent mental abnormalities

Results

A total of 120 participants with mean age 36 years (Table 1) were included in the study. The study population comprised of 42 males (35%) and 78 females (65%) who were obese with mean weight 87.5 kg (Table 1) and mean BMI of 34 kg/m² (Table 2) and (Figure 1). There were no drop outs in the study. However, the study had provisions to exclude participants from the analysis of the results pertaining to

Table 1: Demographic data

Sex	Min	Max	Mean	Median	Std Deviation
Age (years)	18	65	36.32	35.50	10.23
Weight (kg)	62	121	87.5	86.0	10.97
Height (m)	1.43	1.84	1.60	1.59	0.09

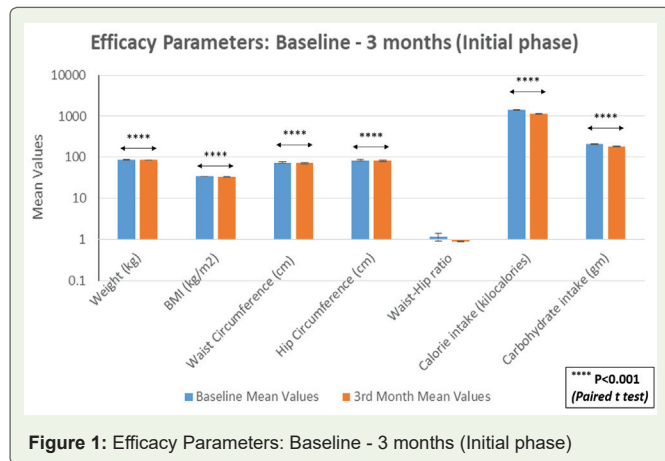


Figure 1: Efficacy Parameters: Baseline - 3 months (Initial phase)

efficacy who had used less than 3/4th of the study medication. Waist circumference significantly reduced from a baseline mean of 73.81 to 66.27 cm along with decrease in hip circumference (Table 2-4) and (Figure 1-3). Caloric and carbohydrate craving reduced substantially during the initial and the maintenance phase (Table 2, 3) and (Figure 1,2). All the adverse events were mild and transient in nature, including dry mouth, constipation, headache, fatigue, and muscle pain indicating a good tolerability profile. An overall improvement in the quality of life and well-being of participants was indicated by a decrease in the score of the obesity related well-being questionnaire (ORWELL 97). Lipid profile showed favorable improvement with significant reduction in the LDL cholesterol from 131.29 mg/dl at baseline to 118.76 mg/dl (9.5% reduction) at the end of the 6th month along with statistically significant increase in the HDL levels (4.2%) (Table 6). There was also a statistically significant decrease in fasting (from 107.19 mg/dl to 97.84 mg/dl; 8.6%) and postprandial (from 157.95 mg/dl to 137.65 mg/dl; 12.85%) glucose levels post 6 months of treatment from baseline (Table 7). The weight reduction was gradual with minimal side effects in most study participants. Overall, the data suggests that Belite has a positive effect in reducing key metrics associated with obesity.

Discussion

Belite is a combination of green tea extract 350 mg, Griffonia simplicifolia extract 100 mg, Purified Saccharum officinarum wax 20 mg). Such a combination of the two listed constituents has not been assessed previously in the management of obesity. The study has yielded promising results, indicating its efficacy in reducing key metrics associated with obesity. The study demonstrated significant reductions in mean body weight, Body Mass Index (BMI), and waist circumference over a six-month period. These findings are particularly relevant given the global obesity epidemic and the urgent need for effective weight management strategies. The ability of Belite

Table 2: Efficacy Parameters: Baseline - 3 months (Initial phase)

Parameter	N	Baseline (Start of therapy)		End of month 3		P value
		Mean	SEM	Mean	SEM	
Weight (kg)	119	87.71	0.99	85.63	0.96	< 0.001
BMI (kg/m²)	119	34.11	0.28	33.15	0.28	< 0.001
Waist Circumferences (cm)	119	73.81	2.56	72.40	2.53	< 0.001
Hip Circumferences (cm)	119	83.94	3.29	82.46	3.27	< 0.001
Waist-hip ratio	119	1.16	0.26	0.90	0.01	0.317
Calorie intake (kilocalories)	119	1408.34	30.26	1126.93	23.42	< 0.001
Carbohydrate intake (gm)	119	209.71	4.44	185.10	3.55	< 0.001

Paired t test. Values are significant at P<0.05 (in bold)
SEM: Standard Error of Mean

Table 3: Efficacy Parameters: 3 months - 6 months (Maintenance phase)

Parameter	N	End of month 3		End of month 6		P value
		Mean	SEM	Mean	SEM	
Weight (kg)	119	85.87	1.03	82.41	0.99	< 0.001
BMI (kg/m²)	119	33.00	0.29	31.71	0.29	< 0.001
Waist Circumferences (cm)	119	69.79	2.61	66.27	2.67	< 0.001
Hip Circumferences (cm)	119	78.83	3.36	75.73	3.44	< 0.001
Waist-hip ratio	119	0.91	0.01	0.90	0.01	> 0.05
Calorie intake (kilocalories)	112	1121.10	24.59	1061.39	20.13	< 0.01
Carbohydrate intake (gm)	112	184.83	3.719	175.29	3.65	< 0.01

Paired t test. Values are significant at P<0.05 (in bold)
SEM: Standard Error of Mean

Table 4: Efficacy Parameters: Baseline-6 months

Parameter	Pre-treatment (Baseline) (N=109)		Post treatment (End of 6 month) (N=109)		P value
	Mean	SEM	Mean	SEM	
Weight (kg)	87.5	1.00	82.4	0.98	< 0.001
Waist Circumferences (cm)	73.8	2.53	66.3	2.67	< 0.001
Hip Circumferences (cm)	84.0	3.26	75.7	3.43	< 0.001
Waist-hip ratio	1.16	0.26	0.90	0.01	0.3
BMI (kg/m²)	34.08	0.28	31.71	0.29	< 0.001
ORWELL-97	72.87	1.23	51.9	1.09	< 0.001
Calorie intake (kilocalories)	1410.32	30.07	1066.95	20.41	< 0.001
Carbohydrate intake (gm)	210.01	4.41	176.64	3.65	< 0.001

Paired t test. Values are significant at P<0.05 (in bold)
SEM: Standard Error of Mean

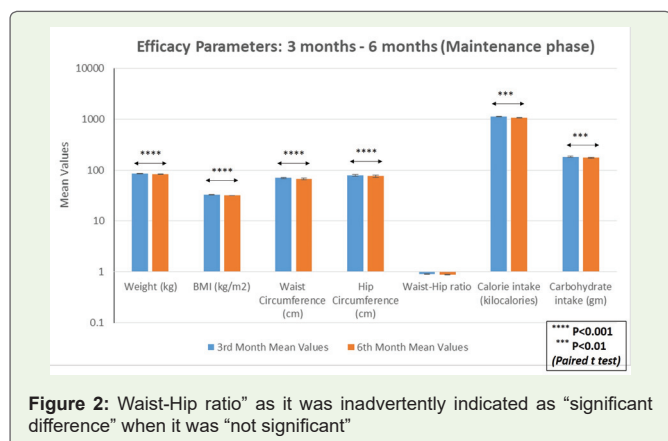


Figure 2: Waist-Hip ratio as it was inadvertently indicated as “significant difference” when it was “not significant”

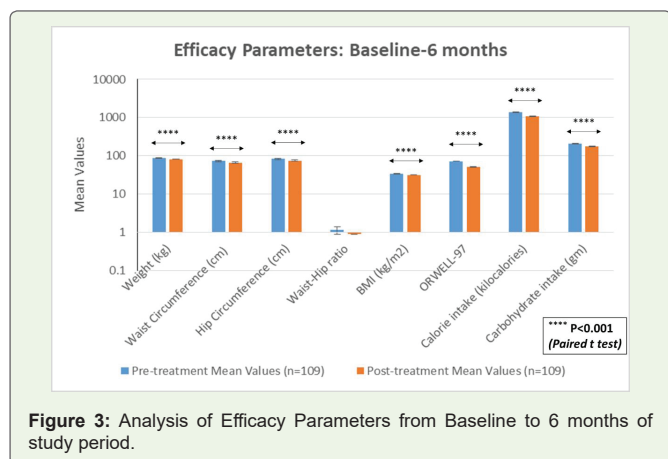


Figure 3: Analysis of Efficacy Parameters from Baseline to 6 months of study period.

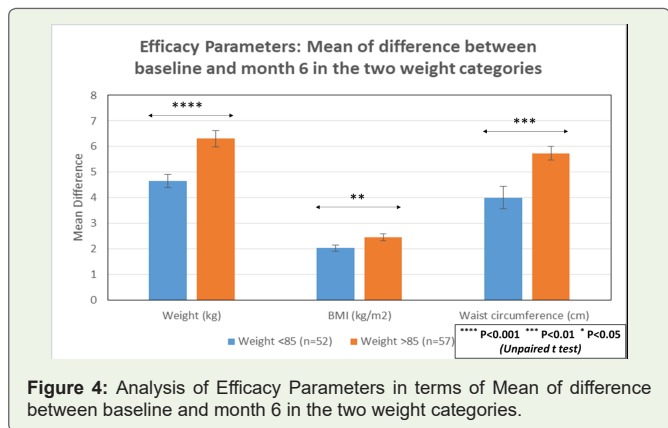


Figure 4: Analysis of Efficacy Parameters in terms of Mean of difference between baseline and month 6 in the two weight categories.

Table 5: Efficacy Parameters: Mean of difference between baseline and month 6 in the two weight categories (<85 Kg and >85 Kg)

Parameters	Weight	N	Mean difference	SEM	P value
Weight (kg)	<85	52	4.6538	0.26	< 0.001
	>85	57	6.3035	0.32	
BMI (kg/m ²)	<85	52	2.0396	0.12	< 0.05
	>85	57	2.4600	0.13	
Waist Circumferences (cm)	<85	52	4.0000	0.44	< 0.01
	>85	57	5.7368	0.27	

Unpaired t test used; Values are significant at P<0.05 (in bold) SEM: Standard Error of Mean

Table 6: Lipid Parameters: Baseline vs. Month 6

Parameter	N	Baseline		End of month 6		P value
		Mean	SEM	Mean	SEM	
Serum Cholesterol (mg/dl)	112	198.97	2.77	189.66	5.57	0.104
LDL(mg/dl)	112	131.29	2.01	118.76	1.49	< 0.001
HDL(mg/dl)	112	45.51	0.85	47.41	1.19	< 0.05
Triglycerides (mg/dl)	111	150.4054	3.84	150.48	3.29	0.984

Paired t test. Values are significant at P<0.05 (in bold) SEM: Standard Error of Mean

Table 7: Other Laboratory Parameters: Baseline vs. Month 6

Parameter	N	Baseline		End of month 6		P value
		Mean	SEM	Mean	SEM	
Fasting Blood Sugar (mg/dl)	32	107.19	3.48	97.84	4.12	< 0.001
Postprandial blood Sugar (mg/dl)	20	157.95	3.44	137.65	3.21	< 0.001
Random blood Sugar (mg/dl)	79	109.76	2.19	107.21	1.75	0.150
Serum bilirubin Sugar (mg/dl)	112	.94	0.18	0.69	0.02	0.186
SGOT (U/l)	112	25.17	0.49	22.97	0.45	< 0.001
SGPT (U/l)	112	24.21	0.60	21.77	0.57	< 0.001
Alkaline phosphatase (U/L)	112	60.33	5.29	62.74	5.35	0.102
Serum creatinine (mg/dl)	112	0.96	0.06	0.66	0.04	< 0.001
BUN	112	13.53	0.32	12.38	0.11	< 0.001
Hb %	112	12.43	0.12	12.76	0.13	< 0.001

Paired t test. Values are significant at P<0.05 (in bold) SEM: Standard Error of Mean

to facilitate such reductions suggests that it may serve as a viable adjunct or alternative to traditional pharmacological interventions. The substantial weight loss observed in participants aligns with findings from other studies investigating herbal formulations for obesity management [9,11]. Research has shown that various herbal products can enhance metabolic processes, suppress appetite, and promote fat oxidation [10,13]. For instance, studies on other herbal blends have reported significant reductions in body weight and waist circumference similar to those seen with Belite [20]. This positions Belite within a broader context of emerging herbal therapies that target obesity, offering a potential solution for individuals seeking natural alternatives to conventional weight loss medications.

In addition to weight loss, the study reported improvements in lipid profiles among participants using Belite. Specifically, reductions in LDL cholesterol and increases in HDL cholesterol were noted similar to previously reported studies [17,18]. These changes are critical as dyslipidemia is often associated with obesity and significantly increases cardiovascular risk. Previous studies have highlighted the role of herbal formulations in improving lipid metabolism, suggesting that Belite may contribute not only to weight management but also to cardiovascular health [19]. Additionally, significant decreases in both fasting and postprandial blood sugar levels were noted among participants using Belite. This effect is particularly relevant given the strong association between obesity and type 2 diabetes [1].

The study also found significant reductions in caloric intake and carbohydrate cravings among participants using Belite. This finding is noteworthy because controlling dietary intake is essential for successful weight management [7,13,16]. Herbal formulations have been shown to influence appetite-regulating hormones, thereby aiding individuals in adhering to dietary restrictions necessary for weight loss [21]. By reducing cravings, Belite may enhance dietary compliance, making it easier for users to achieve their weight management goals. Improvements in quality of life, as measured by the ORWELL-97 questionnaire, further highlight the holistic benefits of using Belite for obesity management [8]. This finding aligns with other research indicating that effective weight management positively impacts overall well-being [6].

The good tolerability of Belite, with minimal side effects reported during the study, is another significant advantage [22,23]. Common adverse events such as dry mouth, constipation, headache, fatigue, and muscle pain were mild and transient, and less severe than those associated with many conventional obesity medications. The favorable safety profile of Belite enhances its appeal as a treatment option for individuals seeking alternatives to traditional pharmacotherapy, which often comes with a higher risk of adverse effects.

Despite these promising results, the study emphasizes the need for further long-term research to explore the potential benefits of Belite for related comorbid conditions such as dyslipidemia and diabetes mellitus. As obesity is frequently accompanied by metabolic disorders, understanding how Belite influences these conditions over extended periods will be crucial for establishing its role in comprehensive obesity management strategies [6]. Future studies should aim to include diverse populations and longer follow-up durations to fully assess the long-term efficacy and safety of Belite [24]. As healthcare continues to evolve towards more integrative approaches, products like Belite may play an essential role in addressing the complexities of obesity management while minimizing adverse effects commonly associated with conventional therapies.

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Conflict of interest

The authors declare that they are full-time employees of Panacea Biotec Ltd, New Delhi, which has developed the candidate herbal anti-obesity formulation, Belite. This multicentric efficacy & tolerability study pertaining to Belite, has been funded by Panacea Biotec Ltd.

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