

# Efficacy and safety of injection Liraglutide in Indian Adolescents with obesity

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## INTRODUCTION

- Childhood obesity is known to be associated with many non-communicable diseases in adulthood.
- In India, analysis of data after 2010 estimates a combined prevalence of 19.3 per cent of childhood overweight and obesity, which was a significant increase from the earlier prevalence of 16.3 per cent, reported in 2001-2005.
- Interventions available for pediatric obesity are very limited. Three major intervening modes are – Lifestyle interventions, pharmacotherapy and bariatric surgery.
- One large study reports a success rate of only 20% with life style interventions in extremely obese adolescent. These findings indicate the unmet need for pharmacological interventions required in adolescents with obesity
- The only approved pharmacotherapy for adolescents with obesity is Orlistat, despite the fact it has a significant effect on weight loss, a large number of patients remain to have non-significant effect on weight loss.
- Another medication, which has been used widely for treatment of type 2 diabetes and unofficially used for obesity with insulin resistance as well, is “metformin”. Various study reports beneficial effect in terms of weight loss with metformin.
- Despite the various studies in this population showing the effect of above mentioned two medicines, there are a great number of adolescents with obesity who remain to struggle with obtaining a significant weight loss which leads to a clinician to look forward to the anti-obesity medication approved for adult population; such a medicine which has been recently tested for adolescent population as well on a pilot basis is liraglutide. It is a GLP-1 analogue which has a possible weight loss by multiple mechanisms, one of it being by upregulation of adenylate cyclase 3.
- Keeping the above facts in mind our institute developed an institutional guideline to help adolescents with obesity, where we decided to give option of liraglutide to our adolescent patients with obesity, who didn't respond to lifestyle interventions and orlistat and metformin, each for minimum period of 12 weeks. After taking written informed consent from these patients they were started on injection liraglutide. This study retrospectively evaluates the efficacy and safety of injection liraglutide in adolescents with obesity.

## METHODS

- 36-week, non-randomized, open-label study involving retrospective data collection from 356 Adolescents (age 12-18 years) with obesity (>27 adult equivalent as per age and sex specific Indian Academy of Pediatrics (IAP) growth chart/ IOTF Asian guidelines) with Tanner Staging 2-5.
- The study enrolled all adolescents with obesity who were diagnosed as simple/nutritional obesity.
- Injection liraglutide was started as 0.6mg subcutaneously one hour before dinner which was increased 0.3mg every week to a maximum dose of 1.8 mg.
- Patients with gastro-intestinal effects were advised tab pantoprazole and tab ondansetron. All the patients were evaluated and investigated again after 12 weeks of treatment.
- The study was initiated after taking an approval from institutional ethics committee and was conducted in accordance with principals of the Declaration of Helsinki and ICH Good Clinical Practice.

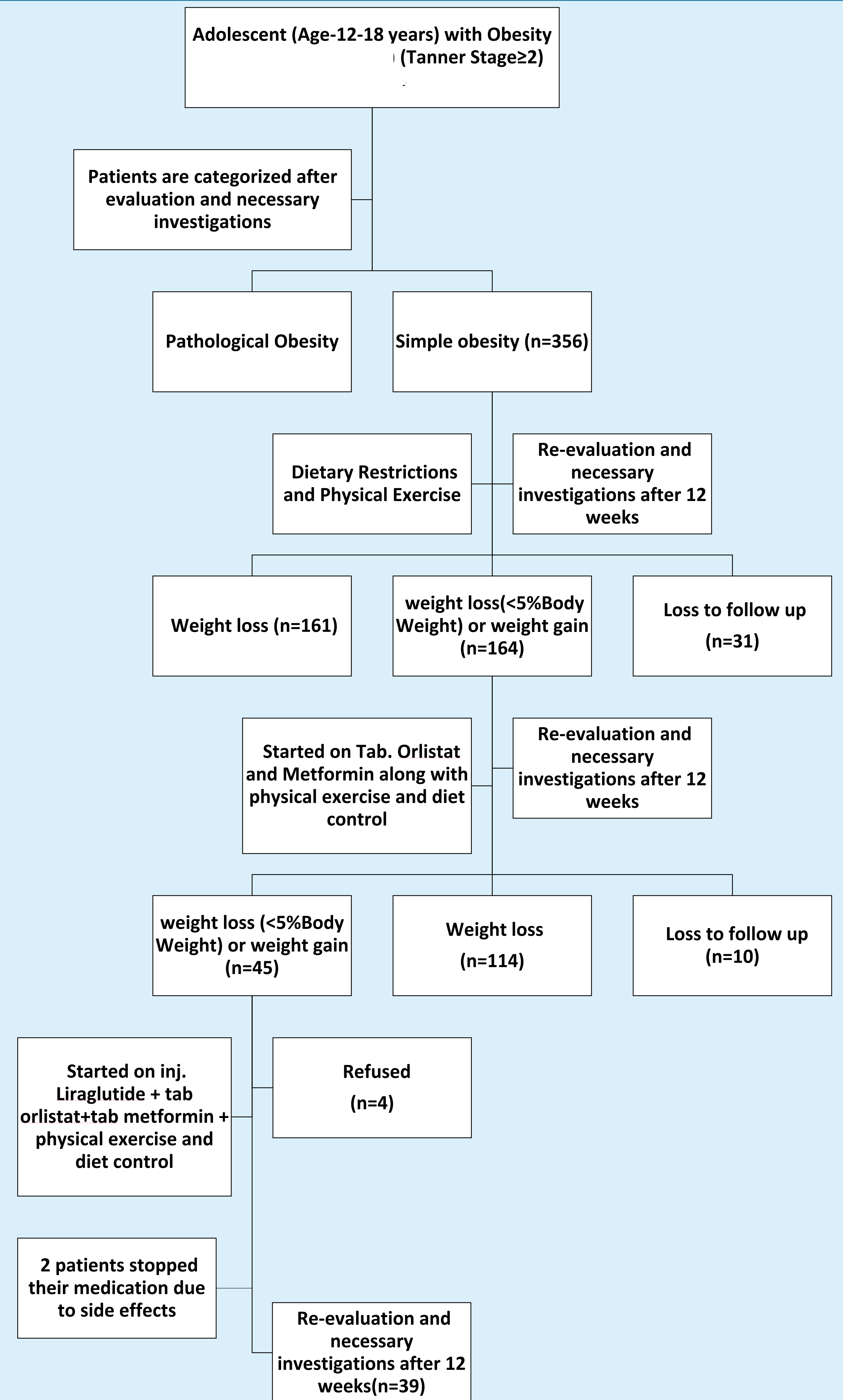
### Inclusion Criteria:

- Informed consent obtained before child was started on Tab metformin/ Injection Liraglutide.
- Male or female, age 12 to less than 18 years at the time of signing informed consent and completion of treatment.
- BMI corresponding to equal to or above 27 kg/m<sup>2</sup> adult equivalent by Indian Academy of Pediatrics guideline (Same as IOTF guideline for Asian population) for definition of obesity
- History of failing to lose sufficient weight with lifestyle modification as judged by the investigator and documented in subject's medical record

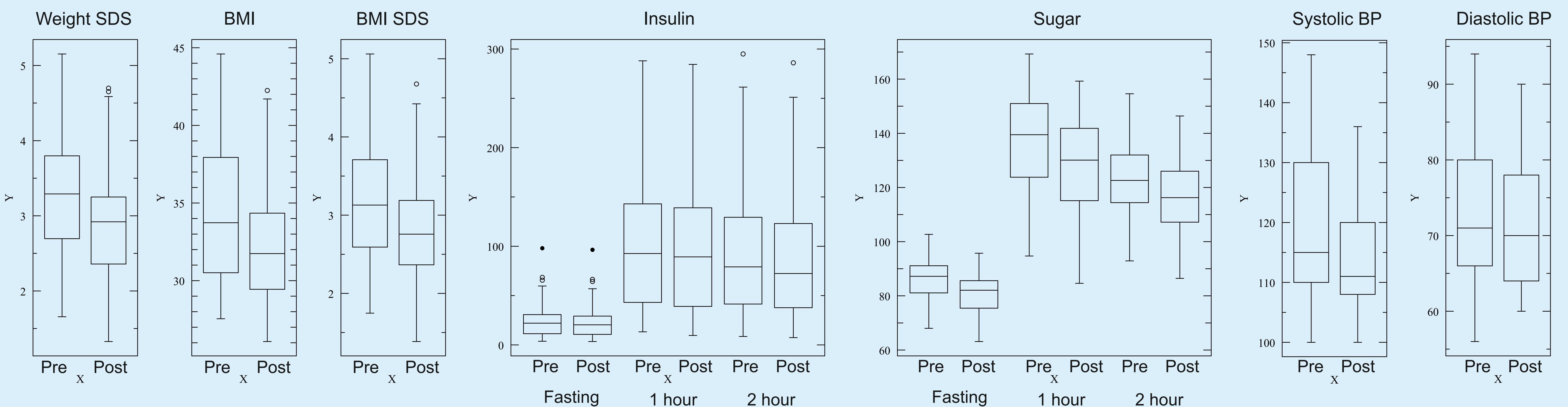
### Exclusion Criteria:

- Pre-pubertal subjects (Tanner stage 1) at screening
- Type 1 diabetes mellitus (T1DM)
- Family or personal history of multiple endocrine neoplasia type 2 (MEN2) Medullary thyroid carcinoma (MTC)
- History of pancreatitis (acute or chronic)
- Subjects with secondary causes of obesity (i.e., hypothalamic, Drug-induced, genetic or endocrine causes)

## STUDY DESIGN



## RESULTS



Adverse Event	Percent (No.)
1 Hypoglycemia	None
2 GI disorders	92.3%(32)
a Nausea	71.7%(28)
b Abdominal pain	15.3%(6)
c Vomiting	41.0%(16)
d Diarrhea	20.5%(8)
3 Decrease in Appetite	69.2% (27)
4 Injection site pain or pruritis	5.1%(2)
5 Skin and subcutaneous tissue disorders	0
6 Headache	0

## CONCLUSION

- Treatment with liraglutide in adolescents with obesity offers an efficacious and safe alternative to patients who are not responding to other available modalities rather putting these patients through surgical modalities for treating obesity.

## CONFLICT OF INTEREST

- The authors declare that there is no conflict of interest and disclosures associated with this manuscript.

