

Pilot study: Potency drug reduces long-term blood sugar in type 2 diabetes

May 4 2023



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A small group of patients with type 2 diabetes significantly improved their long-term blood sugar levels when treated with high-dose tadalafil, a medication used to treat erectile dysfunction. The result from the

University of Gothenburg pilot study is striking, but repetition in a larger study and over a longer period is needed.

Tadalafil is one of the active pharmaceutical substances known as PDE5 (phosphodiesterase type 5) inhibitors, a group that also includes the well-known drug Viagra. PDE5 inhibitors are used to treat impotence or erectile dysfunction (ED).

"Self-medication with PDE5 inhibitors must never take place because, at worst, it can be life-threatening in combination with certain other drugs. These medicines are available on prescription only, and must always be prescribed by the attending physician," says Per-Anders Jansson, professor at Sahlgrenska Academy, University of Gothenburg.

Unlike the other three PDE5 inhibitors that are approved in Sweden, tadalafil is long-acting and can be prescribed as a daily dose.

Insulin sensitivity unaffected

The study comprised 18 participants, 12 men and 6 postmenopausal women. In this randomized, double-blind placebo-controlled study, they were all first assigned by [random selection](#) to receive either a high daily dose (20 mg) of the active substance tadalafil or a placebo for six weeks. After an eight-week break, they were then given the other option for six weeks.

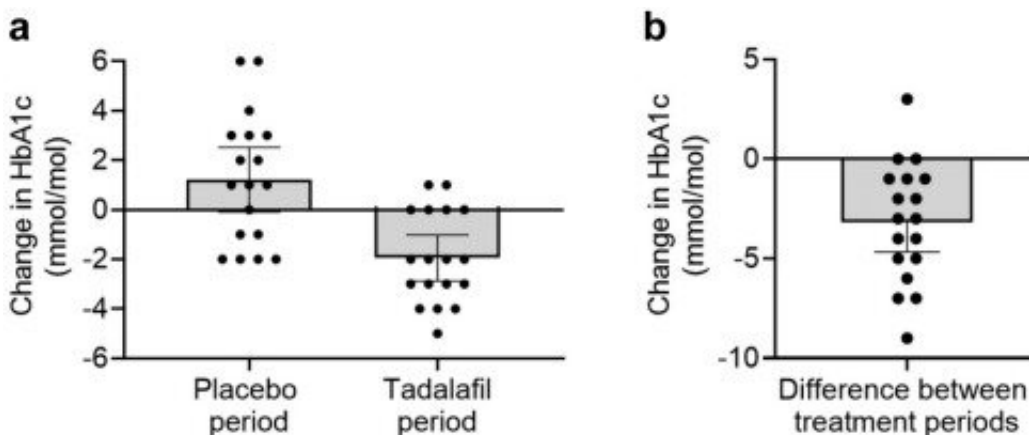
The study participants thus served as their own controls. Since tadalafil has a number of known side effects (including headache, heartburn, diarrhea, muscle and back pain, [low blood pressure](#), nasal congestion, tinnitus, and blurred vision), they were closely monitored.

The results of the study, which was conducted in collaboration with Sahlgrenska University Hospital, are published in the journal

eClinicalMedicine. The primary aim was to investigate whether tadalafil might enhance the patients' insulin sensitivity. In this respect, however, there was no discernible difference compared with the placebo. On the other hand, tadalafil caused a clear improvement in metabolic control, based on measurements of hemoglobin A1c (HbA1c) in [blood](#) samples. On average, the level of HbA1c fell by 2.50 mmol/mol.

"That's a very distinct improvement in the long-term sugar levels, which we couldn't have dreamed of after only six weeks of supplementary treatment in patients with well-controlled type 2 [diabetes](#). This improvement in [blood sugar](#) is on par with what we've seen with new drug candidates that are now the fourth treatment option for type 2 diabetes," says Jansson, who led the research.

"The HbA1c level is precisely monitored in [blood samples](#) from patients who are undergoing treatment for type 2 diabetes. The higher the HbA1c value, the greater the risk of complications, including microvascular damage to the eyes, kidneys and nerves," Jansson says.



Tadalafil treatment (20 mg orally once daily for 6 weeks) significantly reduces Hemoglobin A1c (HbA1c) compared to placebo treatment. (a) Change in HbA1c over respective treatment period (n = 18, full analysis set (FAS) population). (b) Difference in HbA1c-change between periods, comparing placebo and tadalafil

treatment for every individual (n = 18, FAS population). Data are presented as mean (95% confidence interval (CI)). Credit: *eClinicalMedicine* (2023). DOI: 10.1016/j.eclinm.2023.101985

Better blood flow and metabolism

Tadalafil has potential as a supplement to the treatment currently given for type 2 diabetes, especially for men who also have ED. More than 70% of men with obesity and type 2 diabetes develop ED. However, the results from the [pilot study](#) need to be repeated in a larger study where more patients are treated for a longer period of time, which the University of Gothenburg research group is now considering. The current primary treatment for type 2 diabetes combines lifestyle changes with the drug metformin. In the past 10 to 20 years, several other new drugs have also been developed.

Tadalafil increases blood flow in skeletal muscle, heart and adipose tissue. This present study also shows increased blood flow and a favorable effect in the liver, where an established marker of fatty liver decreased during the drug treatment, compared with the placebo. In addition, the researchers saw an increase in [glucose uptake](#) with the tadalafil treatment compared with the placebo.

More information: Emanuel Fryk et al, Feasibility of high-dose tadalafil and effects on insulin resistance in well-controlled patients with type 2 diabetes (MAKROTAD): a single-centre, double-blind, randomised, placebo-controlled, cross-over phase 2 trial, *eClinicalMedicine* (2023). [DOI: 10.1016/j.eclinm.2023.101985](https://doi.org/10.1016/j.eclinm.2023.101985)

Provided by Sahlgrenska Academy

Citation: Pilot study: Potency drug reduces long-term blood sugar in type 2 diabetes (2023, May 4) retrieved 20 May 2024 from <https://medicalxpress.com/news/2023-05-potency-drug-long-term-blood-sugar.html>

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