

Budget Impact Analysis of the Introduction of Real-Time Continuous Glucose Monitoring for the Treatment of Patients With T2 Diabetes on an Intensive Insulin Schedule From the Perspective of the Italian Healthcare Payer

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OBJECTIVES

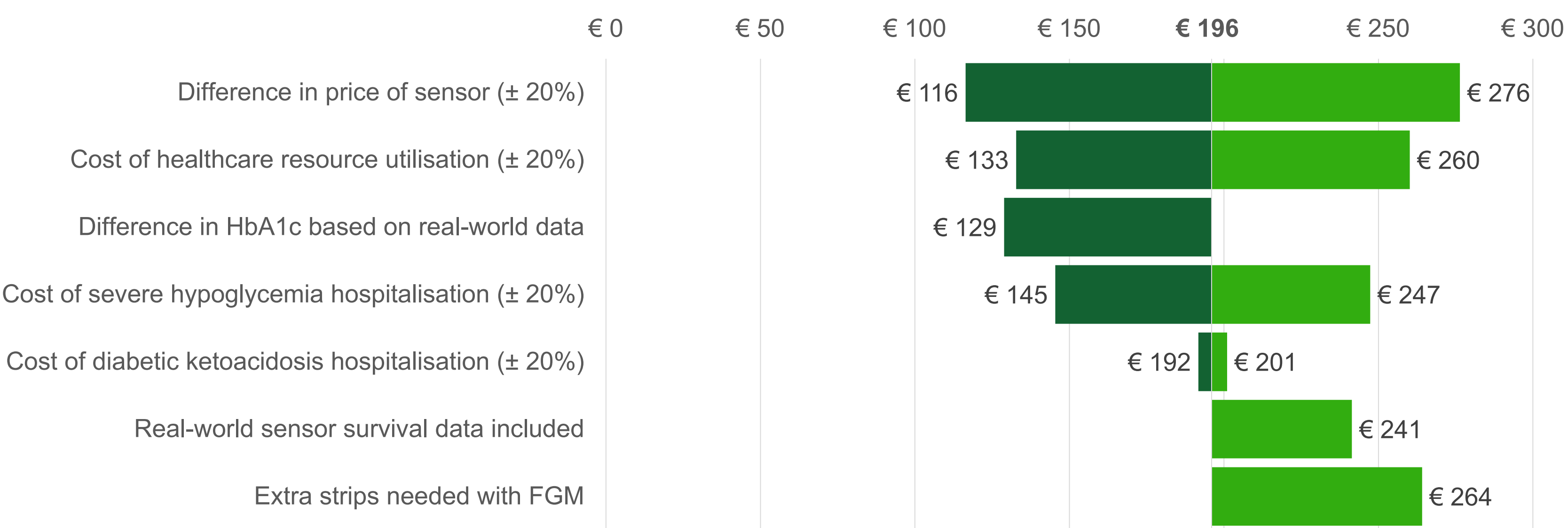
- Patients with T2 diabetes on an intensive insulin schedule require access to timely glucose readings to inform treatment decisions and to avoid acute events like severe hypoglycaemia and diabetic ketoacidosis.
- Real-time continuous glucose monitoring (rt-CGM) systems provide real-time glucose values and have the ability to set hypo- and hyperglycaemia alerts. Studies have shown that rt-CGM improves glycaemic outcomes and reduces severe hypoglycaemic events in patients with T2 diabetes, without the need for periodic scanning. [1] & [2]
- Studies have shown the value of continuous glucose monitoring (CGM) systems in the treatment of patients with T2 diabetes on insulin. However, no studies are available directly comparing rt-CGM with Flash glucose monitoring (FGM) systems.
- The objective of this research is to compare the net cost of the rt-CGM and FGM in the diabetes type 2 population on an intensive insulin schedule from the perspective of the Italian healthcare payer.

METHOD

- A budget impact model was developed to estimate the difference in net cost between rt-CGM and FGM.
- Clinical efficacy of rt-CGM versus FGM was assessed via indirect treatment comparison methods, using outcomes from two RCTs: DIAMOND T2 by Beck et al [2] for rt-CGM versus Self-Monitoring Blood Glucose (SMBG) and REPLACE by Haak te al [3] for FGM versus SMBG. Bucher’s adjusted indirect comparison method [4] was used to estimate the adjusted difference in HbA1c reduction to be -0.33 favouring rt-CGM.
- The baseline severe hypoglycaemic event rate was drawn from [5], and it was assumed that 16% of the events led to hospitalisation [6]. Reduction in hospitalisations was calculated from the study by Karter et al [2] for rt-CGM and from the REPLACE RCT by Haak et al [3] for FGM, resulting in an extra reduction in severe hypoglycaemic hospitalisations of +0.04 per patient favouring rt-CGM.
- The baseline diabetic ketoacidosis hospitalisation rate was sourced from Roussel et al [8], reduction in hospitalisation was calculated from the study by Karter et al [2] for rt-CGM and the study by Roussel et al [7] for FGM resulting in an extra reduction in hospitalisations for diabetic ketoacidosis of +0.004 per patient favouring rt-CGM.
- The costs associated with glucose monitoring (lancets, strips and sensors) and hospitalisations for severe hypoglycaemic events and diabetic ketoacidosis were estimated using Italian sources [8], while the costs of healthcare resource utilisation associated with a 1% reduction in HbA1c were transferred from international sources [9]. All cost were inflated to 2023 Italian Euros.
- The robustness of the results was examined by one-way sensitivity analysis by changing the main parameters by ± 20%, the reduction in HbA1c equal to -0.26 favouring rt-CGM, based on two real-world evidence studies [2] & [10], by including real-world sensor survival data [11] & [12], and by including extra test strips when using FGM [3].

RESULTS

- The results show that replacing FGM with rt-CGM potentially reduces the total costs of healthcare resources utilization and the cost of acute hospitalisations for severe hypoglycaemic events and diabetic ketoacidosis by €318, €255, and €23 respectively. The clinical performance of the rt-CGM makes it possible to offset costs for the management of diabetes and its complications of € 596 per patient/year.
- Replacing FGM systems with rt-CGM systems results in savings of €196 per patient per year.
- The one-way sensitivity analysis showed the robustness of the results in favour of rt-CGM.



- If an estimated 25,000 people with type 2 diabetes on intensive insulin therapy in Italy adopted continuous real-time blood glucose monitoring, then the savings would be EUR 4,900,000.

CONCLUSION

- In patients with T2 diabetes on an intensive insulin schedule, the use of rt-CGM was estimated to result in lower HbA1c values, along with a reduction in severe hypoglycaemic and diabetic ketoacidosis events compared to FGM.
- The use of rt-CGM is a potential cost saving strategy in the treatment of patients with T2 diabetes on an intensive insulin schedule in Italy.
- Sensitivity analysis in which we varied model parameters with ±20%, 2) reduction in HbA1c from real-world studies, 3) included extra strip use with FGM, and 4) including real-world sensor survival, showed the robustness of the results in favour of rt-CGM.
- Our findings can inform Italian payers about the economic value of different rt-CGM systems for patients with T2 diabetes on an intensive insulin schedule.

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