THE USE OF GLYCATED ALBUMIN FOR GLYCAEMIC CONTROL IN DIABETIC PATIENTS WITH CHRONIC KIDNEY DISEASE: PRELIMINARY RESULTS FROM AN ITALIAN HTA

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Background

Glycated hemoglobin (HbA1C) is the reference test for long-term glucose monitoring (Goldstein *et al*., 2003)

Over the last few years, an innovative glycaemic marker (glycated albumin – GA) emerged in the clinical practice useful for monitoring the glycaemic status in settings where HbA1c is problematic: patients with altered red cell turnover or certain hemoglobinopathies, such as in patients with chronic kidney disease (CKD) (Selvin, 2021)

Literature declared that GA would better estimate the glycemic control in diabetic patients with CKD, since the evaluation of glycemic control with HbA1c may be problematic due to altered erythrocyte lifespan and use of iron and/or erythropoietin therapy (Inaba et al., 2007; Freedman et al., 2011; Murea et al., 2012)

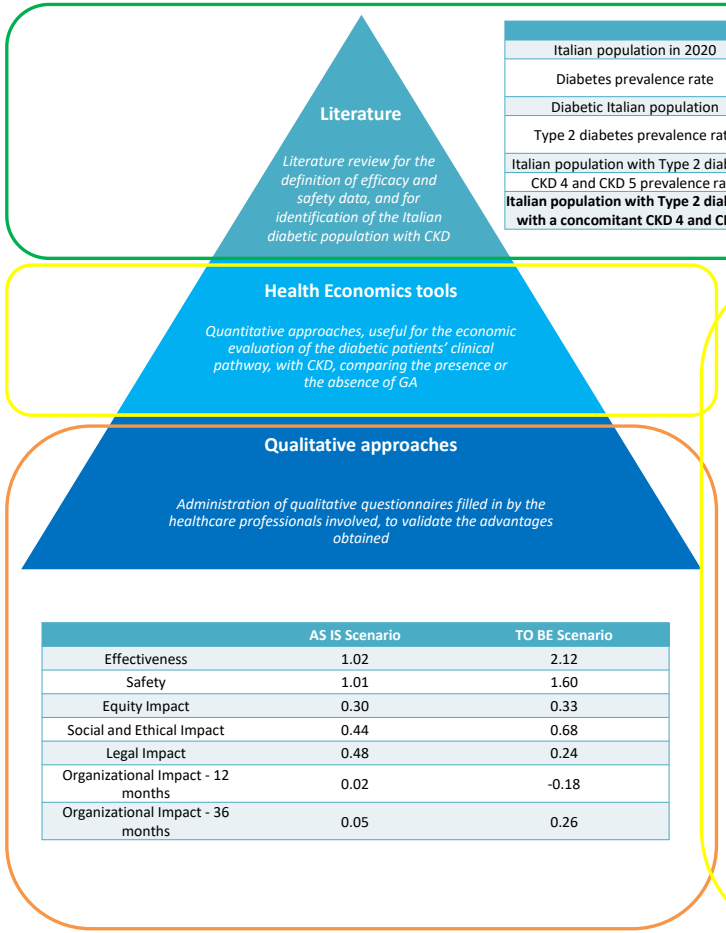
Objective

To investigate the implications of GA introduction, in the Italian clinical practice, as an innovative glycemic marker for monitoring type-2 diabetes mellitus (DM) in patients affected by chronic kidney disease (CKD) – level 4 and 5, in comparison to the gold standard glycated hemoglobin (HbA1c), thus supporting the Italian evidence-based decision-making process

Methods

A Health Technology Assessment was conducted, considering the Italian NHS perspective. The EUnetHTA Core Model dimensions were deployed by means of literature evidence, health economics tools and specific validated questionnaires, thus comparing the "AS IS" situation (use of only the traditional tests), with the "TO BE" scenario (introduction of the GA test in addition to the traditional panel of tests)

Results



	Population	Reference
Italian population in 2020	60,359,546	ISTAT, 2020
Diabetes prevalence rate	7.20%	Osservatorio Arno, 2019
Diabetic Italian population	4,345,887	
Type 2 diabetes prevalence rate	90%	Osservatorio Arno, 2019
Italian population with Type 2 diabetes	3,911,299	
CKD 4 and CKD 5 prevalence rate	2.30%	Koro et al., 2009
Italian population with Type 2 diabetes, with a concomitant CKD 4 and CKD 5	**89,960**	

Efficacy	HbA1c	GA
Capability to identify a worst glycemic control	19.2%	52%
Safety	HbA1c	GA
Cardiovascular events occurrence rate	45%	62%

	AS IS Scenario	TO BE Scenario
Effectiveness	1.02	2.12
Safety	1.01	1.60
Equity Impact	0.30	0.33
Social and Ethical Impact	0.44	0.68
Legal Impact	0.48	0.24
Organizational Impact - 12 months	0.02	-0.18
Organizational Impact - 36 months	0.05	0.26

Economic evaluation related to the management of single patient	AS IS Scenario	TO BE Scenario
Laboratory Exams	184.01 €	161.55 €
Specialist Visits	223.95 €	182.63 €
Diagnostic procedures	32.90 €	32.90 €
Drugs	1,236.84 €	1,236.84 €
Medical Devices	209.00 €	209.00 €
Total costs related to the clinical pathway	**1,886.70 €**	**1,822.92 €**
Dialysis	41,216.29 €	41,216.29 €
Total costs related to the clinical pathway + Dialysis	**43,102.99 €**	**43,039.21 €**
Hospitalization	973.70 €	737.23 €
Total costs related to the clinical pathway + Dialysis + hospitalization	**44,076.69 €**	**43,776.44 €**
Adverse Events	1,380.31 €	729.07 €
Total costs related to the clinical pathway + Dialysis + hospitalization + Adverse Events	**45,457.00 €**	**44,505.51 €**

Budget Impact analysis related to the management of the Italian eligible population	AS IS Scenario	TO BE Scenario	Difference (%)
Total costs related to the clinical pathway (drugs, specialists visit, laboratory and diagnostic procedures)	169,727,532.00 €	163,989,883.20 €	-3.38%
Dialysis	3,707,817,448.40 €	3,707,817,448.40 €	0.00%
Total costs + Dialysis	3,877,544,980.40 €	3,871,807,331.60 €	-0.15%
Hospitalization costs	87,594,052.00 €	66,321,210.80 €	-24.29%
Total costs + Dialysis + Hospitalization	3,965,139,032.40 €	3,938,128,542.40 €	-0.68%
Adverse events	124,172,687.60 €	65,587,137.20 €	-47.18%
Total costs + Dialysis + hospitalization + Adverse events	**4,089,311,720.00 €**	**4,003,715,679.60 €**	**-2.09%**

Conclusions

The integration of GA could better identify a worst glycemic control than HbA1c alone (52% *versus* 19.2%), with important advantages in the decrease of cardiovascular events occurrence rate (45% *versus* 62% - Freedman et al., 2011; Murea et al., 2012)

From an economic point of view, GA would lead to an overall economic saving equal to 2.09%, on annual basis, thus being the solution presenting a better trade-off between costs sustained and efficacy achieved (Cost-effectiveness Value: 6,325 *versus* 22,087)

An improvement in both patients and caregivers' quality of life emerged (2.00 *versus* 0.88)

From an organizational perspective, despite marginal investments would be required for training courses and equipment updates, GA would lead to an overall improvement in the patients' clinical pathway (2.25 *versus* 0.63)

Results demonstrated the strategic relevance of GA, in the optimization of glycemic monitoring in DM patient with CKD

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