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- Effect of Paracetamol on Blood Pressure: A Systematic Review
- Effects of Heated Tobacco Products compared to Conventional Cigarettes on Cardiovascular System: A Systematic Review
- Efficacy and Safety of Sodium-Glucose Cotransporter 2 Inhibitors (SGLT2i) in Cardiac Amyloidosis: A Systematic Review
- Cardiovascular risk and JAK inhibitor for the treatment of spondyloarthritis: A systematic review
- Long working hours and the risk of ischemic cardiac death: A systematic review and meta-analysis
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- The Effects of TNF-alpha Inhibitors on Subclinical Atherosclerosis and Endothelial Function in Patients with Psoriatic Arthritis: A Systematic Review

# Efficacy and Safety of Sodium-Glucose Cotransporter 2 Inhibitors (SGLT2i) in Cardiac Amyloidosis: A Systematic Review

## Efficacité et innocuité des inhibiteurs du cotransporteur sodium-glucose de type 2 (SGLT2i) dans l'amylose cardiaque: Revue systématique

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### ABSTRACT

**Introduction:** Cardiac amyloidosis is an underdiagnosed cause of heart failure characterized by extracellular deposition of misfolded proteins, most commonly transthyretin (ATTR) or immunoglobulin light chains (AL). Despite recent advances in disease-modifying therapies, prognosis remains poor. Sodium-glucose cotransporter 2 inhibitors (SGLT2i) have demonstrated cardiovascular and renal benefits. However, evidence regarding their safety and efficacy in cardiac amyloidosis remains limited.

**Aim:** This systematic review aimed to synthesize current evidence on the clinical outcomes and safety of SGLT2 inhibitors in patients with cardiac amyloidosis.

**Methods:** A comprehensive literature search was conducted in PubMed, Embase, Google Scholar, ScienceDirect, and Cochrane Library through June 2025, in accordance with PRISMA guidelines. Studies evaluating the use of SGLT2i in cardiac amyloidosis were included. Outcomes assessed were all-cause mortality, stroke, hospitalization for heart failure, and kidney failure. Data extraction and quality assessment were performed independently by two reviewers. Hazard ratios (HRs) and 95% confidence intervals (CIs) were pooled when appropriate.

**Results:** Five studies including a total of 17,416 patients met the inclusion criteria. The mean age was 76.8 years, and 78% of participants were male. The use of SGLT2 inhibitors was associated with a significant reduction in all-cause mortality (HR 0.64; 95% CI 0.57–0.71) and in stroke risk (HR 0.64; 95% CI 0.54–0.77). A trend toward reduced hospitalizations for heart failure was observed (HR 0.88; 95% CI 0.76–1.02), although this did not reach statistical significance. The risk of kidney failure was modestly decreased (HR 0.91; 95% CI 0.71–1.08). Overall, the methodological quality of the included studies was moderate.

**Conclusions:** SGLT2 inhibitors appear to represent a promising therapeutic option in cardiac amyloidosis, potentially improving survival and reducing cerebrovascular events while maintaining a favorable safety profile. However, the current body of evidence is limited by the observational nature and heterogeneity of the available studies. Well-designed randomized controlled trials are warranted to confirm these findings and to better inform clinical practice.

**Keywords:** Amyloidosis, SGLT2i, cardiac amyloidosis

### RÉSUMÉ

**Introduction:** L'amylose cardiaque est une cause sous-diagnostiquée d'insuffisance cardiaque caractérisée par un dépôt extracellulaire de protéines mal repliées, le plus souvent la transthyréine (ATTR) ou les chaînes légères d'immunoglobulines (AL). Les inhibiteurs du cotransporteur sodium-glucose de type 2 (SGLT2i) ont démontré des bénéfices cardiovasculaires et rénaux. Cependant, les preuves concernant leur sécurité et leur efficacité dans l'amylose cardiaque restent limitées. Cette revue systématique visait à synthétiser les preuves actuelles sur les résultats cliniques et la sécurité des inhibiteurs SGLT2 chez les patients atteints d'amylose cardiaque.

**Méthodes:** Une recherche bibliographique a été effectuée dans PubMed, Embase, Google Scholar, ScienceDirect et Cochrane Library jusqu'en juin 2025, conformément aux directives PRISMA. Les études évaluant l'utilisation des SGLT2i dans l'amylose cardiaque ont été incluses. Les résultats évalués étaient la mortalité toutes causes confondues, les accidents vasculaires cérébraux, les hospitalisations pour insuffisance cardiaque et l'insuffisance rénale.

**Résultats:** Cinq études incluant 17 416 patients répondaient aux critères d'inclusion. L'âge moyen était de 76,8 ans et 78 % des patients étaient des hommes. L'utilisation d'inhibiteurs du SGLT2 était associée à une réduction significative de la mortalité toutes causes confondues (HR 0,64 ; IC à 95 % 0,57-0,71) et du risque d'accident vasculaire cérébral (HR 0,64 ; IC à 95 % 0,54-0,77). En ce qui concerne les hospitalisations pour insuffisance cardiaque, une tendance à un bénéfice a été observée (HR 0,88 ; IC à 95 % 0,76-1,02), mais celle-ci n'a pas atteint le seuil de signification statistique. Le risque d'insuffisance rénale a été légèrement réduit (HR 0,91 ; IC à 95 % 0,71-1,08). La qualité globale de l'étude était modérée.

**Conclusions:** Les inhibiteurs du SGLT2 semblent être une option thérapeutique prometteuse dans l'amylose cardiaque, pouvant améliorer la survie et réduire les événements vasculaires tout en conservant un profil de sécurité favorable.

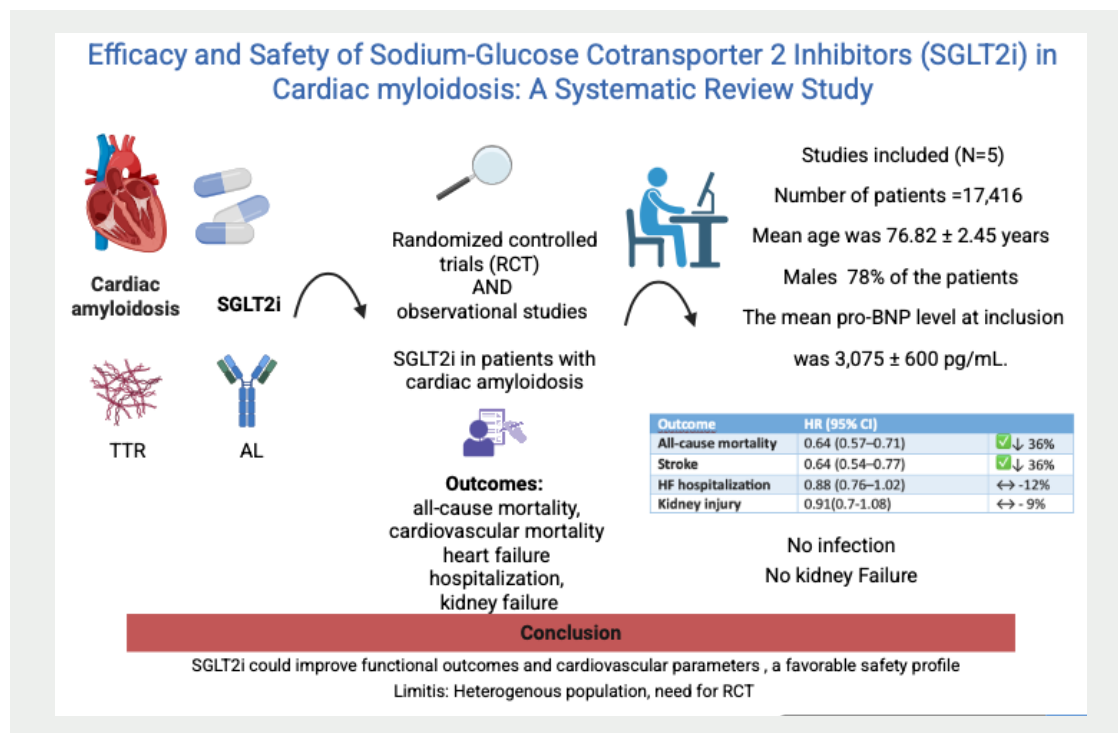
**Mots clés:** Amylose, SGLT2i, Amylose cardiaque

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## INTRODUCTION

Amyloidosis is a rare disease characterized by extracellular excessive protein deposition in organs such as the kidneys, heart, and digestive tract[1]. Amyloid cardiomyopathy is a rare etiology of heart failure with preserved left ventricular ejection fraction (LVEF) [2]. The two primary types of amyloidosis that are associated with amyloid cardiomyopathy are transthyretin (TTR) amyloidosis and AL amyloidosis (light chain amyloidosis)[2]. The accumulation of amyloid deposits in the myocardium is responsible for a deterioration in cardiac function. The treatment of ATTR has undergone a revolution, precipitated by the advent of fibril stabilizers, such as tafamidis and acoramedis [3], as well as RNA inhibitors [4] and CRISPR-based strategies [5]. The therapeutic approach for AL amyloidosis is predominantly focused on chemotherapy and novel biotherapy agents mainly daratumumab [6]. Sodium-glucose transport protein 2 inhibitor (SGLT2i) represents a revolutionary treatment in the management of heart failure and kidney dysfunction. Cardiac amyloidosis is novel cause of heart failure that remains underdiagnosed[7]. SGLT2i seems to be a promising treatment to improve cardiac function in ATTR and AL amyloidosis[8,9] [10]. Few retrospective studies about safety and efficacy of SGLT2i in cardiac amyloidosis have been published[11–17].

The objective of this study is to conduct a systematic review to assess clinical outcome and safety of SGLT2 inhibitors in cardiac amyloidosis, following the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines.

## METHODS

This study is a systematic review in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines[18]. The objective was to evaluate the efficacy and safety of sodium-glucose cotransporter 2 inhibitors (SGLT2i) in patients with cardiac amyloidosis. We established a detailed protocol prior to initiating the study [19]. The protocol was registered in PROSPERO under the number CRD42024584183 to ensure transparency and reproducibility and no amendments were made to the original protocol.

### Search strategy

A comprehensive search was conducted in electronic databases including Medline via PubMed, Embase, Google Scholar, ScienceDirect, and Cochrane Library, from inception June 2025.

Keywords that were included were: "cardiac amyloidosis", "Transthyretin Amyloid Cardiomyopathy", "amyloid light-chain cardiomyopathy", "SGLT2 inhibitors" or its subclasses such as "Canagliflozin", "Dapagliflozin", "Empagliflozin", "Ertugliflozin", and "Sotagliflozin", "efficacy", "safety", "clinical outcomes", and "Heart failure".

Reference lists of relevant articles will also be hand-searched for additional studies. There will be no restriction on publication year. No language restrictions will be applied; however, non-English studies will be translated when necessary.

### Search equation for PubMed

("cardiac amyloidosis" OR "ATTR cardiomyopathy" OR "AL cardiomyopathy") AND ("SGLT2 inhibitors" OR

"Canagliflozin" OR "Dapagliflozin" OR "Empagliflozin" OR "Ertugliflozin" OR "Sotagliflozin") AND ("efficacy" OR "safety" OR "clinical outcomes" OR "heart failure").

### Eligibility criteria

#### Inclusion Criteria:

Eligible studies included randomized controlled trials (RCTs) or observational studies examining the effects of SGLT2i in patients with cardiac amyloidosis.

#### Exclusion Criteria:

Studies that were excluded included case reports, case series, reviews, abstracts, clinical practice guidelines, protocols, and studies for which the full text could not be retrieved.

### Outcomes

The outcomes of the review included all-cause mortality, cardiovascular mortality, heart failure hospitalization, kidney failure, and the Pro-BNP rate (baseline and after SGLT2i), comparing SGLT2i users with nonusers.

### Study Selection

In the initial phase, two authors independently screened all titles and abstracts from the research strategy records. Any disagreements were resolved through consensus. The screening process was performed using the Covidence tool.

### Data Extraction

A data extraction form was developed. Data extraction was conducted independently in duplicate. For each study, we extracted information on sample size and clinical and demographic characteristics.

### Quality Assessment

The methodological quality of the included studies was independently evaluated by two reviewers using the Newcastle-Ottawa Scale (NOS) for observational studies [20]. This tool assesses studies based on three domains: Selection, Comparability, and Exposure. Each study can receive a maximum score of 9 stars, with higher scores reflecting better quality. As an alternative validated tool for non-randomized studies, the MINORS scale was also considered and is discussed as a complementary approach[21].

### Data Analysis

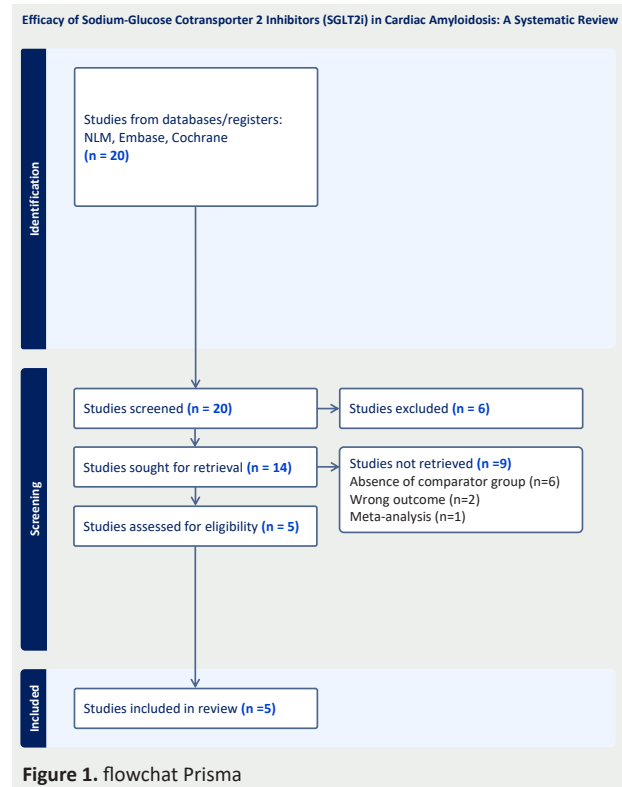
All analyses were performed using Easymed Stat. Categorical variables are reported as frequencies and percentages. Continuous variables are reported as means with standard deviations (SDs). To estimate the relative effects between the intervention and control groups, effect estimates and their confidence intervals were used. Pooled Hazard ratios( HRs) with their 95% confidence

intervals were calculated using the inverse -variance method.For each study, the natural logarithm of the HR (LnHR) was computed and weights were assigned as the inverse of the variance (22).

## RESULTS

### Study Selection and Characteristics

The PRISMA diagram detailing the database search and study selection process is provided in Figure 1. After removing duplicate records, an initial set of 20 studies was screened by title and abstract; 15 of these studies were excluded. Five studies involving 17,416 patients were analyzed after a full-text evaluation[22–26]. Four of these studies used propensity score matching. The mean age was  $76.82 \pm 2.45$  years, and 78% of the patients were male. The mean pro-BNP level at inclusion was  $3,075 \pm 600$  pg/mL. The baseline characteristics of the included studies are presented in Table 1. The risk of bias is presented in Table 2.



### All-Cause Mortality (table 3)

Five studies evaluated all-cause mortality in patients with AL-CA and ATTR-CA, and the use of SGLT2i was significantly associated with a lower mortality risk compared to patients with cardiac amyloidosis who were not under SGLT2i treatment (HR: 0.64; 95% CI: 0.57–0.71).

### Stroke

Three studies assessed the effect of SGLT2i on stroke. The SGLT2i group had a lower risk of stroke than nonusers (3,747 patients; HR, 0.64; 95% CI, 0.54–0.77).



**Table 1.** Baseline characteristics

Study, year, number of patients	Follow up (years)	Amyloidosis type	Mean age		LVEF(%)		NT-Pro BNP (pg/ml)		Tafamidis (%)		GFR ml/min.1.73m2	
			I	C	I	C	I	C	I	C	I	C
Byer et al 2025, 1246	5	TTR	77.9+/-7.6	78.3+/-8.5	51.3	50.2	3757	5293.7	NR	NR	NR	NR
Jaiswal et al 2024, 4306	3	TTR	74.2+/-10.8	74.4+/-14.1	50.5	51.5	NR	NR	13%	11 %	NR	NR
Schwegel et al 2024, 116	2.6	TTR	80 (76-82)	80(77-83)	49	54	3224	2717	16%	14%	58	59
Procari et al 2024, 440	2.3	TTR	76.7+/-7.7	77.2 +/-7.5	46	45.8	2815	2625	46	48	56	55
Augusto et al 2025, 11224	5	TTR and AL	74.5+/-11	74.8+/-13.4	50.5	55.2	NR	NR	NR	NR	57.5	53.5

LVEF: left ventricular ejection fraction, GFR: glomerular filtration rate, TTR: Transthyretin, AL: amyloidosis light chain, NR not reported, I: intervention group receiving SGLT2i, C: control group

**Table 2.** Risk of Bias Assessment Using the Newcastle-Ottawa Scale (NOS)

Study	Selection (0–4)	Comparability (0–2)	Exposure (0–3)	Total (0–9)
Procari et al	3	2	1	6
Jaiswal et al	4	2	2	8
Schwegel	3	1	1	5
Beyer et al	3	2	2	7
Augusto et al	4	2	2	8

The Newcastle-Ottawa Scale (NOS) evaluates observational studies across three domains: Selection (0–4 stars), Comparability (0–2 stars), and Exposure (0–3 stars). The total score ranges from 0 to 9, with higher scores indicating better methodological quality. Interpretation: 7–9 = high quality, 5–6 = moderate quality, <5 = low quality.

### Heart Failure Hospitalization

All studies investigated the risk of heart failure hospitalization. The SGLT2i group presented a lower risk of hospitalization for heart failure compared to the control group: HR 0.88, 95% CI (0.76–1.02).

### Risk of kidney injury

Two studies examined the effect of SGLT2i on kidney failure and found that SGLT2i users had a lower risk of kidney failure than non-users (12,470 patients; HR: 0.91, 0.71–1.08).

**Table 3.** Comparative Hazard Ratios of SGLT2 Inhibitors Across Major Outcomes in Cardiac Amyloidosis Studies

	HR All cause of mortality	HR stroke	HR Heart failure	HR MACE	HR kidney failure
Byer et al 2025	0.82 (0.632-1.08)	NR	0.743(0.57,0.956)	NR	0.662(0.52-0.843)
Jaiswal et al,2024	0.50 (0.43,0.58)	0.51 (0.37,0.69)	0.91(0.68,1.22)	0.64(0.51,0.81)	NR
Schwegel et al 2024	0.457 (0.227–0.922)	NR	1.17 (0.88,3.43)	1.23(0.65,2.34)	NR
Procari et al 2024	0.57 ( 0.37-0.89)	NR	0.57(0.36,0.91)	0.41 (0.24,0.7)	NR
Augusto et al, TTR cohort	0.64 (0.52- 0.79)	0.72(0.57,0.91)	1.35(0.95,1.92)	0.87(0.59,1.29)	1.18(0.86,1.62)
Augusto et al, AL cohort	0.72 (0.57- 0.91)	0.74(0.41,1.31)	0.88(0.58,1.33)	1.25(0.76,2.05)	1.36(0.93,1.98)

### Safety

In all studies, no side effect was reported: neither infection nor acute renal failure.

### Risk of bias

The studies were evaluated using the Newcastle-Ottawa Scale. Overall, the risk of bias was moderate (Table 2).

## DISCUSSION

This systematic review presents new evidence regarding SGLT2 inhibitors (SGLT2i) in patients with cardiac amyloidosis, a population that is severely underrepresented in current therapeutic trials. Although the pathophysiology of amyloid cardiomyopathy differs markedly from that of other forms of heart failure, our pooled analysis suggests that SGLT2i may provide cardiovascular and renal benefits in this unique clinical

setting as well.

The pooled hazard ratio for all-cause mortality across five observational studies was 0.64 (95% confidence interval [CI]: 0.54–0.77), indicating a 36% relative reduction in the risk of death among SGLT2i users. This finding is clinically meaningful given the high mortality rate in patients with cardiac amyloidosis, especially those with the AL subtype. This reduction in mortality establishes the benefits of SGLT2i in heart failure populations, including those with heart failure with preserved ejection fraction (HFpEF), as evidenced in large randomized trials such as EMPEROR-Preserved and DELIVER [25, 26].

Our analysis also showed a favorable trend toward a reduction in stroke risk, with a combined hazard ratio (HR) of 0.64 (95% confidence interval [CI]: 0.54–0.77). Although stroke is a less commonly studied outcome in amyloidosis cohorts, this result is noteworthy, especially considering the elevated thromboembolic risk observed in ATTR-CA, which often occurs independently of atrial fibrillation [27].

Potential mechanisms for reducing stroke may include improved volume status, endothelial function, and vascular compliance associated with SGLT2 inhibition [28]. Regarding hospitalization for heart failure (HHF), the pooled hazard ratio (HR) was 0.88 (95% confidence interval [CI]: 0.76–1.02), suggesting a 12% relative risk reduction, though not statistically significant. Importantly, the direction of the effect was consistent across all studies, supporting the hypothesis that SGLT2i may improve hemodynamics and reduce congestion in amyloid-related HF.

Although renal outcomes were reported less consistently, preliminary data from two studies suggested a slower decline in estimated glomerular filtration rate (eGFR) and fewer renal events among patients receiving SGLT2i. Given the frequency of renal involvement in AL amyloidosis, SGLT2i therapy seems promising. However, a recent comparative analysis of the effects of SGLT2i in patients with AL amyloidosis showed no difference in eGFR or proteinuria [29].

According to the Oxford Centre for Evidence-Based Medicine (OCEBM) classification, the studies included in this review provide Level 3b–4 evidence, as they are primarily retrospective observational cohorts and case-control studies. Consequently, the strength of recommendation is Grade C, acknowledging the limitations inherent to non-randomized designs. These findings should therefore be interpreted with caution, while highlighting the need for well-designed randomized controlled trials to confirm the observed associations.

Despite these encouraging results, the evidence base remains limited by several factors. First, all of the included studies were observational and were susceptible to selection bias, confounding by indication, and misclassification. Although some authors employed propensity score matching or multivariable adjustment, residual confounding cannot be excluded. Second, heterogeneity in patient populations, amyloid subtypes (AL vs. ATTR), comorbidities, and concurrent therapies may limit external validity. Additionally, SGLT2i molecules varied across studies (e.g., empagliflozin, dapagliflozin, and canagliflozin), and dose information was often lacking. Furthermore, the relatively short follow-up periods reported in most studies limit our understanding of long-term efficacy and safety.

To date, no randomized controlled trials (RCTs) have evaluated SGLT2i specifically in cardiac amyloidosis. Nevertheless, our findings support the rationale for such studies, especially given SGLT2i's acceptable safety profile.

## CONCLUSION

This systematic review highlights the potential efficacy and safety of SGLT2 inhibitors (SGLT2i) in managing cardiac amyloidosis, a condition with significant unmet therapeutic needs. The findings suggest that SGLT2i could improve functional outcomes and cardiovascular

parameters in this patient population while maintaining a favorable safety profile. However, the current evidence is limited by study heterogeneity. This emphasizes the need for well-designed, randomized controlled trials to confirm these results and define SGLT2i's precise role in cardiac amyloidosis. Until then, clinicians should consider these results alongside individual patient profiles and existing treatment protocols. This study lays the groundwork for future research and emphasizes the importance of exploring innovative therapeutic approaches to improve outcomes in patients with cardiac amyloidosis.

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