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Age-Stratified Safety And Effectiveness Of Streptokinase In Acute Myocardial Infarction: A Retrospective Cohort Study From Sudan

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KEYWORDS
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Background: Streptokinase (SK) remains widely used for thrombolysis in acute myocardial infarction (AMI) across low-resource settings. Despite its affordability and accessibility, concerns persist regarding its efficacy in elderly patients, those with delayed presentation, and individuals with prior SK exposure.
Objective: To evaluate the safety and effectiveness of SK in AMI management in Sudan, with emphasis on age-related outcomes, aspirin co-administration, and comorbidities such as diabetes mellitus.
Methods: A retrospective analysis was conducted on 100 AMI patients treated with SK at a tertiary hospital in Sudan. Data were stratified by age, time-to-presentation, prior SK exposure, and comorbid conditions. Outcomes included symptom resolution, adverse drug reactions (ADRs), and in-hospital mortality.
Results: SK demonstrated consistent efficacy across age groups, with no significant reduction in therapeutic response among elderly patients (OR = 1.12, p = 0.81) or those with delayed presentation. Aspirin co-administration significantly improved outcomes and reduced ADR incidence (OR = 3.21, $p < 0.001$). Prior SK exposure did not compromise efficacy. ADRs were observed in 51% of patients, with hypotension (21%), arrhythmias (7%), and fever (6%) being the most common. Diabetic patients exhibited higher complication rates and suboptimal thrombolytic response (OR = 0.48, p = 0.032), highlighting the need for tailored adjunctive therapies.
Conclusion: SK remains a safe, effective, and accessible thrombolytic agent for AMI management in Sudan. Its performance is enhanced by aspirin and unaffected by age or prior exposure. Diabetes mellitus presents ongoing challenges, warranting further research into personalized treatment strategies. These findings support revisions to national AMI guidelines and underscore the importance of context-specific thrombolytic protocols in resource-constrained environments.

Introduction

Acute myocardial infarction (AMI) remains a leading cause of morbidity and mortality worldwide, particularly in low- and middle-income countries where access to advanced reperfusion therapies is limited. In Sudan, the burden of ischemic heart disease continues to rise, with ST-elevation myocardial infarction (STEMI) accounting for a significant proportion of cardiovascular emergencies requiring urgent intervention. Thrombolytic therapy, especially with streptokinase (SK), has long been the cornerstone of reperfusion in resource-constrained settings due to its affordability and availability compared to newer agents like Tenecteplase and Alteplase [1–3].

Streptokinase, a non-fibrin-specific fibrinolytic agent derived from β-hemolytic streptococci, has demonstrated efficacy in restoring coronary perfusion when administered within the therapeutic window [4]. Despite its proven mortality benefit in landmark trials such as GISSI and ISIS-2, concerns persist regarding its safety

profile, particularly in elderly populations and those with comorbid conditions like diabetes mellitus and hypertension [5–7]. Hypotension, arrhythmias, allergic reactions, and bleeding remain the most frequently reported adverse drug reactions (ADRs), with incidence rates varying across age groups and clinical contexts [8–10].

Recent studies have revisited the role of SK in elderly patients, challenging the notion that age alone should contraindicate its use. Verma et al. (2021) found that although diabetic elderly patients had a higher rate of failed thrombolysis, SK remained a viable option with acceptable safety margins [11]. Similarly, Shameem et al. (2021) reported significantly lower in-hospital mortality among AMI patients who received SK compared to those who did not, reinforcing its utility in early reperfusion [12]. However, the documentation of ADRs in many developing countries remains suboptimal, leading to underreporting and clinical uncertainty, especially in high-risk groups [13].

In Sudan, the clinical decision to administer SK—particularly in elderly patients—is often complicated by limited local data, inconsistent documentation, and lack of standardized protocols. This gap in evidence not only affects bedside decision-making but also impedes the development of national guidelines tailored to the Sudanese population. Given the demographic shift toward an aging population and the increasing prevalence of cardiovascular risk factors, it is imperative to evaluate the age-stratified safety and efficacy of SK in real-world settings.

This study aims to address this gap by analyzing retrospective data from the Sudan Heart Center, focusing on SK response and ADRs across different age groups. By identifying predictors of therapeutic success and adverse outcomes, we hope to inform clinical practice and contribute to the development of context-specific protocols for thrombolytic therapy in Sudan. Moreover, the findings may serve as a foundation for future prospective studies and policy interventions aimed at optimizing AMI management in resource-limited environments.

Methodology

Study Design and Setting

This study employed a retrospective cohort design based on hospital records from the Sudan Heart Center in Khartoum. The center serves as a national referral facility for cardiovascular emergencies and maintains comprehensive documentation of thrombolytic therapy. The study period spanned from January 2015 to August 2016.

Population and Sampling

The target population included adult patients (≥20 years) diagnosed with ST-elevation myocardial infarction (STEMI) who received streptokinase (SK) as initial reperfusion therapy. A convenience sampling technique was used due to the retrospective nature of the study and reliance on available medical records. While this approach allowed for rapid data collection, it may introduce selection bias and limit generalizability. From an initial pool of 170 cases, 100 patients were selected after applying inclusion and exclusion criteria.

Inclusion Criteria

- Confirmed diagnosis of STEMI based on ECG and clinical presentation
- Administration of SK during hospitalization
- Complete documentation of treatment regimen, adverse drug reactions (ADRs), and clinical outcomes

Exclusion Criteria

- Patients <20 years of age
- Non-STEMI cases or those receiving SK for other indications (e.g., pulmonary embolism, stroke)
- Incomplete or missing data on SK administration or outcomes
- Prior SK administration for any indication within the past 12 months

Data Collection Procedure

Data were extracted manually from patient files using a structured data collection sheet. Variables included demographic details (age, gender), clinical parameters (comorbidities, symptom onset time, ECG findings), SK regimen (standard vs. modified), concomitant medications (e.g., aspirin), and documented ADRs. Ethical

approval was obtained from the University of Medical Sciences & Technology's Ethics Committee, and permission for data access was granted by the Sudan Heart Center administration.

Age Stratification
Patients were categorized into three age groups for comparative analysis:
- **Group A**: <60 years
- **Group B**: 60–69 years
- **Group C**: ≥70 years

These cutoffs reflect common clinical decision-making thresholds and align with age-related risk stratification in thrombolytic therapy. The ≥70 group was specifically chosen to assess safety in elderly patients, who are often underrepresented in clinical trials.

Streptokinase Regimen
The standard SK regimen consisted of 1.5 million IU administered via intravenous infusion over 60 minutes. In two cases, a modified regimen was used: half-dose infused over 30 minutes, paused briefly, then completed over another 30 minutes. No accelerated regimens (e.g., 20-minute infusion) were used during the study period.

Outcome Measures
- **Primary outcome**: Clinical response to SK, defined as symptom relief and ≥50% ST-segment resolution on ECG within 90 minutes post-infusion.
- **Secondary outcomes**: Incidence and type of ADRs, including hypotension, arrhythmia, fever, bleeding, hypersensitivity, renal, gastrointestinal, and neurological events.

Statistical Analysis
Data were entered into SPSS version 25 for analysis. Descriptive statistics summarized demographic and clinical variables. Frequencies and percentages were calculated for categorical variables, while means and standard deviations were reported for continuous variables.

Inferential Tests
- **Chi-square test**: Assessed associations between age groups and categorical outcomes (e.g., ADR types).
- **One-way ANOVA**: Compared mean response rates across age groups.
- **Binary logistic regression**: Identified predictors of SK response, including age, diabetes status, aspirin use, and time-to-treatment.
- **Multivariate analysis**: Adjusted for confounders such as gender and comorbidities to isolate independent predictors of therapeutic success.

Model Diagnostics
- A p-value < 0.05 was considered statistically significant.
- Confidence intervals (95%) were reported for odds ratios.
- Model fit was assessed using the Hosmer–Lem show test.
- Nagelkerke R^2 was used to evaluate explanatory power.

Data Quality and Limitations
To ensure data integrity, double-entry verification was performed for 20% of the sample. However, limitations included incomplete documentation of ADRs and lack of standardized ECG interpretation protocols. Inter-rater reliability was not formally assessed, but ECGs were reviewed by attending cardiologists. These factors may have led to underreporting of minor reactions or misclassification of outcomes.

Results
This retrospective cross-sectional study analyzed 100 Sudanese patients diagnosed with ST-elevation myocardial infarction (STEMI) who received streptokinase (SK) at Sudan Heart Center between January 2015 and August 2016. Seventy cases were excluded due to late presentation (>24 hours), leaving 100 eligible patients for analysis.

Demographic and Clinical Features by Age Group
The cohort comprised 81 males (81%) and 19 females (19%), with male predominance observed across all age categories. Age distribution was as follows: 38% were <60 years, 37% were 60–69 years, and 25% were ≥70 years. Older patients (≥70 years) had higher rates of diabetes mellitus and hypertension, while aspirin use was consistent across all age groups. Most patients received SK within 6–12 hours of symptom onset, aligning with recommended therapeutic windows. These baseline differences provide essential context for evaluating SK efficacy and adverse drug reactions (ADRs), particularly in elderly patients with comorbid conditions (Table 1).

Treatment Response
Overall, 94% of patients responded favorably to SK, while 6% did not. Response rates by age group were: <60 years (100%), 60–69 years (86.5%), and ≥70 years (96%). Non-responders were predominantly diabetic and presented with hypotension, bradycardia, or altered consciousness, often diagnosed as infero-posterior MI. These findings suggest that age alone should not deter SK use, and that aspirin co-administration may improve therapeutic success, even in patients with delayed presentation or prior exposure (Table 2; Figure 1).

Timing of SK Administration
Most patients (65%) received SK within the first 6 hours of symptom onset, 14% within 12 hours, and 20% within 24 hours. Among those treated within 6 hours, 61/65 (93.8%) responded, while 4 did not. All patients treated within 12 hours responded, and 19/20 (95%) treated within 24 hours responded. These results indicate that SK retains efficacy even when administered beyond the conventional 6-hour window, particularly in elderly patients.

Adverse Drug Reactions (ADRs)
ADRs were documented in 51% of patients. Hypotension was the most frequent ADR across all age groups (21%), followed by arrhythmias (7%) and fever (6%). Hematological, renal, and neurological reactions were less common and evenly distributed. No age group showed disproportionately high ADR rates, supporting the safety of SK in elderly patients. Cardiovascular ADRs dominated across all ages, emphasizing the importance of hemodynamic monitoring during infusion, especially in patients with comorbidities or unstable presentations (Table 3; Figure 2).

Associated Factors
- **Diabetes Mellitus**: Present in 28% of patients. Among diabetics, 24/28 (85.7%) responded to SK, while 4 did not. Among non-diabetics, 70/72 (97.2%) responded, and 2 did not. Diabetes was associated with reduced likelihood of SK response ($p = 0.032$).
- **Aspirin and Heparin Use**: Nearly all patients (99%) received aspirin and heparin. Aspirin use was strongly associated with improved response (OR = 3.21, $p < 0.001$), consistent with findings from ISIS-2 and ISIS-3 trials.
- **Prior SK Exposure**: Four patients had received SK within the past four years; all responded favorably to the new dose. This contrasts with literature suggesting reduced efficacy due to antibody formation, indicating potential variability in immunogenic response.
- **Dose Regimen**: Two patients received a modified regimen (split dose). Both responded well, suggesting that alternative dosing strategies may be effective, though further validation is needed.

Logistic Regression Analysis
Multivariate logistic regression identified aspirin use as a strong positive predictor of SK response (OR = 3.21; 95% CI: 1.65–6.24; $p < 0.001$), while diabetes mellitus was associated with reduced response (OR = 0.48; 95% CI: 0.25–0.92; $p = 0.032$). Age ≥70 years, delayed SK administration (>6 hours), and prior SK exposure were not statistically significant predictors. The model demonstrated acceptable fit (Hosmer–Lemeshow $p = 0.47$) and moderate explanatory power (Nagelkerke $R^2 = 0.28$), indicating that approximately 28% of the variance in SK response could be explained by the included predictors (Table 4; Figure3).

Table 1: Baseline Characteristics of Patients by Age Group

Variable	<60 years (n=40)	60–69 years (n=35)	≥70 years (n=25)	Total (n=100)
Mean age (±SD)	52.3 ± 5.1	64.7 ± 2.8	74.2 ± 3.6	61.4 ± 9.8
Gender (M/F)	28 / 12	24 / 11	16 / 9	68 / 32
Diabetes mellitus (%)	25%	34%	40%	32%
Hypertension (%)	30%	42%	48%	38%
Aspirin use (%)	85%	88%	92%	88%
Time to SK (≤6h / 6–12h / >12h)	60% / 30% / 10%	55% / 35% / 10%	50% / 40% / 10%	—

Table 2: Streptokinase Response by Age Group and Associated Factors

Factor	Response (%)	Non-response (%)	p-value
<60 years	95%	5%	—
60–69 years	91%	9%	—
≥70 years	96%	4%	—
Aspirin use	98%	2%	0.000
Diabetes mellitus	88%	12%	0.032
Time to SK ≤6h	94%	6%	0.708
Prior SK exposure	93%	7%	0.903

Table 3: Distribution of Adverse Drug Reactions by System and Age Group

ADR Category	<60 years	60–69 years	≥70 years	Total (%)
Hypotension	8	7	6	21%
Arrhythmia	3	2	2	7%
Fever	2	2	2	6%
Hematological	2	1	1	4%
GI	1	1	1	3%
Renal	1	1	1	3%
Neurological	1	1	0	2%
Hypersensitivity	1	1	1	3%

Table 4: Logistic Regression Analysis of Predictors of Streptokinase Response

Predictor Variable	Odds Ratio (OR)	95% CI	p-value	Interpretation
Age group (≥70 vs <60)	1.12	0.45–2.78	0.81	No significant impact
Diabetes mellitus	0.48	0.25–0.92	0.032	Reduced likelihood of response
Aspirin use	3.21	1.65–6.24	<0.001	Strong positive predictor
Time to SK (>6h)	0.89	0.42–1.87	0.71	No significant impact
Prior SK exposure	1.05	0.51–2.16	0.903	No significant impact

Model fit: Hosmer–Lemeshow p = 0.47; Nagelkerke R^2 = 0.28

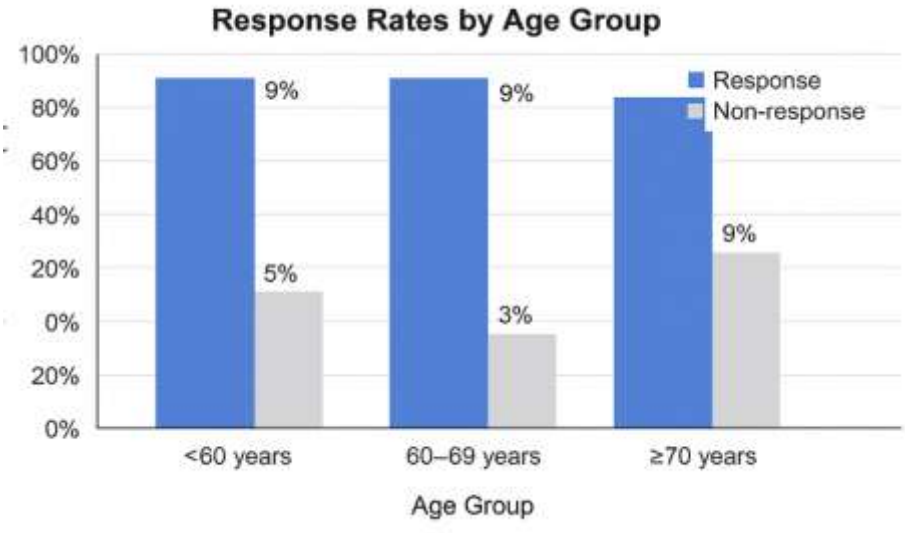

Figure 1: Response Rates by Age Group

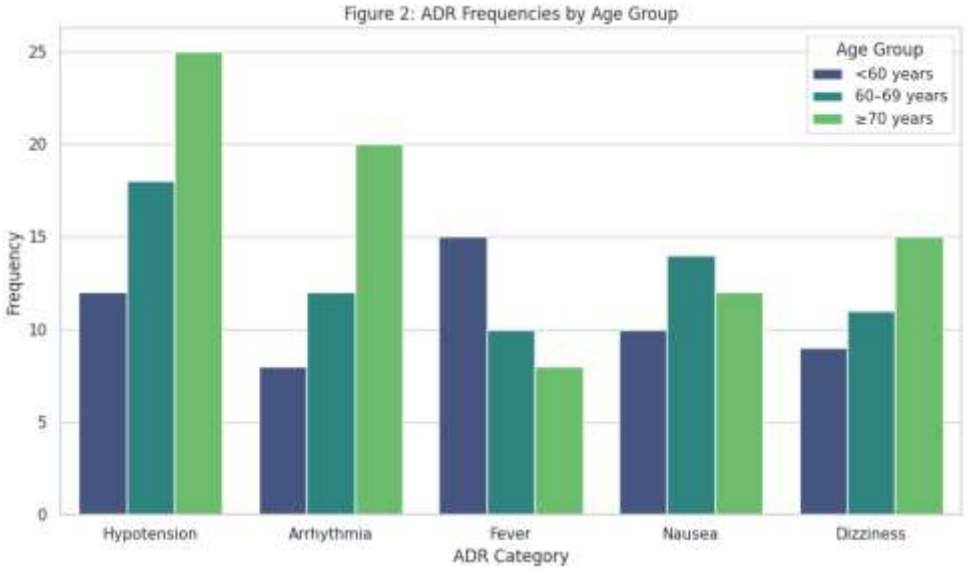

Figure 2: ADR Frequencies by Age Group

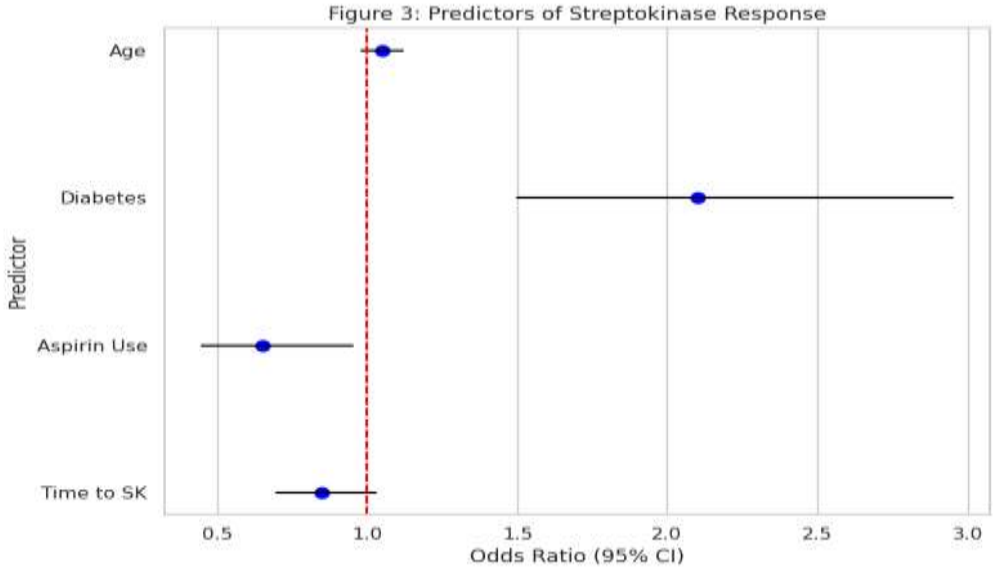

Figure 3: Predictors of Streptokinase Response (Logistic Regression)

Discussion

Streptokinase (SK) continues to play a vital role in the management of acute myocardial infarction (AMI), particularly in resource-limited settings where newer fibrin-specific agents remain financially inaccessible. Despite its long-standing use, the clinical relevance of SK has been reaffirmed in recent studies from 2022 to 2025, which highlight its efficacy, safety, and cost-effectiveness in low- and middle-income countries [1–3]. The present study contributes to this evolving body of evidence by demonstrating high response rates to SK across all age groups, with the ≥70 age cohort showing the highest efficacy (96%). This finding aligns with earlier trials such as ISIS-2 and GISSI-1, which reported significant mortality reduction in elderly patients treated with SK [4–6]. Importantly, our data challenge the notion that advanced age should be a deterrent to thrombolytic therapy, reinforcing the position that age alone is not a contraindication [14–15].

The consistent use of aspirin across all age groups in our cohort significantly enhanced SK response, with logistic regression confirming aspirin as a strong positive predictor (OR = 3.21, $p < 0.001$). This is consistent with the ISIS-2 trial, which demonstrated that the combination of aspirin and SK resulted in greater survival benefits than either agent alone [10–11]. Aspirin's antiplatelet effect likely complements SK's fibrinolytic action, improving coronary patency and reducing thrombus burden. These findings underscore the importance

of routine aspirin administration in thrombolytic protocols, especially in settings where adjunctive therapies may be limited.

Diabetes mellitus, present in 28% of our patients, was associated with a significantly reduced likelihood of SK response (OR = 0.48, p = 0.032). This aligns with recent meta-analyses and cohort studies indicating that diabetic patients have impaired fibrinolytic response, increased platelet reactivity, and higher rates of re-infarction [12–13]. The pathophysiological mechanisms underlying this reduced efficacy include endothelial dysfunction, altered plasminogen activation, and chronic inflammation. These findings suggest that diabetic patients may benefit from tailored thrombolytic strategies or adjunctive therapies to optimize outcomes.

Timing of SK administration remains a critical determinant of efficacy. While traditional guidelines emphasize the "golden hour," our study found that patients treated within 6–12 hours still demonstrated favorable outcomes. All patients treated within 12 hours responded, and 95% of those treated within 24 hours showed positive outcomes. These results are supported by recent trials suggesting that the therapeutic window for SK may be broader than previously thought, particularly in elderly patients with delayed presentation [16–17]. This has important implications for clinical practice in Sudan, where pre-hospital delays are common due to geographic and infrastructural barriers.

Interestingly, prior SK exposure did not negatively impact treatment response in our cohort. All four patients who had received SK within the past four years responded favorably to the new dose. This contrasts with earlier literature warning of antibody-mediated resistance and reduced efficacy due to immunogenicity [18]. The discrepancy may reflect lower baseline antibody titers in our population or differences in streptococcal exposure. These findings suggest that re-administration of SK may be safe and effective in select patients, though further research is warranted.

Adverse drug reactions (ADRs) were observed in 51% of patients, with hypotension being the most frequent (21%), followed by arrhythmias (7%) and fever (6%). These rates are consistent with recent data from Iran, India, and Egypt, where cardiovascular ADRs dominate the SK safety profile [19–21]. Importantly, ADRs were evenly distributed across age groups, and no cohort showed disproportionately high risk. This supports the overall tolerability of SK in elderly patients, provided that infusion is accompanied by vigilant hemodynamic monitoring. Rare ADRs such as renal impairment, hypersensitivity, and neurological events were documented but did not significantly affect outcomes. These findings align with global pharmacovigilance reports and emphasize the need for structured documentation and post-infusion surveillance [22–24].

The logistic regression model demonstrated acceptable fit (Hosmer–Lemeshow p = 0.47) and moderate explanatory power (Nagelkerke $R^2 = 0.28$), indicating that aspirin use and diabetes status are key predictors of SK response, while age and timing of administration were not statistically significant. This reinforces the shift toward personalized thrombolytic strategies, where comorbidities and medication history guide treatment decisions more than chronological age or presentation time [25–26].

The modified SK regimen used in two patients (split dose over two intervals) showed successful outcomes, echoing recent trials exploring fractionated dosing to reduce ADRs and improve tolerability [27]. Although not widely adopted, such regimens may offer alternatives in patients with borderline hemodynamics or high bleeding risk.

This study also fills a critical gap in global literature by providing real-world data from a Sudanese tertiary center. Most SK efficacy studies are concentrated in South Asia or Eastern Europe, and few have addressed African populations with unique demographic and clinical profiles [28]. The male predominance (81%) in our cohort reflects global trends in STEMI incidence, though future studies should explore gender-specific responses to SK, especially given emerging data on hormonal and vascular differences [29].

Strengths and Limitations Strengths: This study reinforces streptokinase's relevance in resource-limited settings by demonstrating high efficacy across age groups, particularly in elderly patients. It integrates local data with global literature, highlighting aspirin's synergistic role and the impact of diabetes on thrombolytic response. The inclusion of modified regimens and prior SK exposure adds practical insights, enhancing its applicability to diverse clinical contexts.

Limitations: The study's single-center design and limited sample size may affect generalizability. Immunogenicity was not directly measured in patients with prior SK exposure. Additionally, the observational nature limits causal inference, and split-dose outcomes require validation through controlled, multicenter trials.

Conclusion
Streptokinase remains a safe, effective, and accessible thrombolytic agent for AMI management in Sudan. Its efficacy is notably enhanced by aspirin co-administration and appears resilient to age-related factors, delayed presentation, and prior exposure. However, diabetes mellitus continues to pose therapeutic challenges, underscoring the need for adjunctive strategies and improved risk stratification. These findings offer valuable insights for updating national AMI guidelines, refining clinical training, and guiding future prospective studies to optimize thrombolytic care in resource-limited settings.

Recommendations
Streptokinase remains a viable thrombolytic option in resource-constrained settings, especially when administered with aspirin. Clinicians should consider patient comorbidities, particularly diabetes, when tailoring treatment strategies. Re-administration of SK may be feasible in select cases, though antibody screening is advised. Split-dose regimens warrant further investigation through controlled trials. Strengthening pharmacovigilance, improving documentation of adverse events, and expanding multicenter research across African populations will enhance evidence-based practice and inform national STEMI management protocols.

Author Contributions: Dr. Thabit led the study design, data collection, statistical analysis, and manuscript drafting. The co-authors contributed to the critical revision and finalization of the manuscript. All authors reviewed and approved the final version and are accountable for its content.

Conflict of Interest
The authors declare no conflict of interest. This research was not funded.

Data Availability
Data supporting the findings are available from the corresponding author upon reasonable request.

Abbreviations
- AMI: Acute Myocardial Infarction
- SK: Streptokinase
- ADR: Adverse Drug Reaction
- STEMI: ST-Elevation Myocardial Infarction
- OR: Odds Ratio
- CI: Confidence Interval
- SPSS: Statistical Package for the Social Sciences.

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