RESEARCH PAPER

A Comparative Study of Drug-Coated and Plain Balloon Angioplasty for Malfunctioning or Delayed-Maturation Native Arm Arteriovenous Fistulas in Hemodialysis Patients

Elsayed A. Younes[1*], Mohsin Murshid[2], Najib A. Alaskary[3], Ahmed O. Korany[4], Reda A. Jamjoom[5], Usama A. Lotfi[6], Ali A. Elemam[7]

1. *Division of Vascular Surgery, Department of Surgery, Faculty of Medicine, Alexandria University, Alexandria, Egypt; Email: elsayedabdelfatah1975@gmail.com*
2. *Department of General Surgery, Hera General Hospital, Makkah, Saudi Arabia; Email: mohsin.murshid90@outlook.com*
3. *Division of Vascular Surgery, Department of Surgery, Faculty of Medicine, Alexandria University, Alexandria, Egypt; Email: Nagibabdo45@gmail.com*
4. *Division of Vascular Surgery, Department of Surgery, Faculty of Medicine, Alexandria University, Alexandria, Egypt; Email: Aokorany@hotmail.com*
5. *Division of Vascular Surgery, Department of Surgery, Faculty of Medicine, King Abdulaziz University Hospital, Jeddah, Saudi Arabia; Email: rjamjoom@kau.edu.sa*
6. *Division of Vascular Surgery, Department of Surgery, Faculty of Medicine, Cairo University, Cairo, Egypt; Email: usamalotfi@yahoo.com*
7. *Division of Vascular Surgery, Department of Surgery, Faculty of Medicine, Alexandria University, Alexandria, Egypt; Email: Alielemam69@gmail.com*

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ABSTRACT

Background: The global burden of end-stage renal disease (ESRD) continues to increase, leading to a growing demand for durable hemodialysis vascular access. Percutaneous transluminal angioplasty (PTA) remains the standard treatment for stenotic lesions within the dialysis access circuit; however, the comparative effectiveness of drug-coated balloon (DCB) angioplasty versus plain old balloon angioplasty (POBA) remains uncertain. This study aimed to compare the safety, clinical and radiological outcomes, and overall cost of DCB versus POBA in the management of malfunctioning or delayed-maturation native arteriovenous fistulas (AVFs) over a 12-month follow-up period.

Methods: This prospective comparative study included 40 hemodialysis patients with native arm AVFs. Twenty patients underwent DCB angioplasty, and 20 underwent POBA. Clinical outcomes, recurrence rates, thrombosis, primary patency, need for re-intervention, and total procedural costs were assessed over 12 months.

Results: Recurrence rates were 20% in the DCB group and 30% in the POBA group. Thrombosis occurred in 10% of patients in each group. Primary patency at 12 months was 90% in both groups. No re-interventions were required in either group during the follow-up period. Although recurrence was numerically lower in the DCB group, the difference was not statistically significant ($p = 0.465$). Total procedural cost was significantly higher in the DCB group compared with POBA ($p < 0.001$).

Conclusion: DCB angioplasty did not demonstrate a statistically significant clinical advantage over POBA in the treatment of malfunctioning or delayed-maturation native AVFs during the first 12 months of follow-up, while incurring substantially higher costs. These findings support the continued use of POBA as a cost-effective first-line endovascular treatment in this clinical setting. Larger studies with longer follow-up are required to validate these results.

Keywords: Hemodialysis access; arteriovenous fistula; delayed maturation; endovascular procedures; plain balloon angioplasty; drug-coated balloon angioplasty.

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INTRODUCTION

End-stage renal disease (ESRD) continues to rise globally, with an estimated prevalence of patients receiving kidney replacement therapy (KRT) of 900–1,100 per million population in 2023 [1,2]. Current treatment options include kidney transplantation (KT), hemodialysis (HD), and peritoneal dialysis (PD); however, HD remains the predominant modality worldwide, accounting for approximately 69% of patients, compared with 11% on PD and 20% with a functioning transplant [3]. In Egypt, the annual incidence of ESRD is approximately 74 per million population, with a dialysis prevalence of 264 per million population, and HD accounts for over 95% of dialysis treatments [2,4]. The financial burden is substantial, with dialysis costs estimated at USD 106.4 million in 2022—nearly 4% of the national health budget—and projected to reach USD 143.0 million by 2023 [5]. Vascular access for HD is achieved using native arteriovenous fistulas (AVFs), arteriovenous grafts, or central venous catheters [6]. Among

**Author for Correspondence: elsayedabdelfatah1975@gmail.com*

these, native AVFs are preferred due to lower infection rates, superior long-term patency, fewer required interventions, and better cost-effectiveness, forming the basis of the NKF-KDOQI "Fistula First" initiative [6–8].

AVF maturation is a complex, dynamic process of vascular remodeling driven by increased blood flow, shear stress, and circumferential wall tension [9]. The 2022 KDOQI guidelines emphasize physical examination as the primary assessment tool, complemented by radiologic criteria—including the "rule of sixes"—and hemodialysis machine parameters to evaluate maturation and function [8,10]. Despite standardized assessment, failure to mature (FTM) occurs in approximately 20–40% of newly created AVFs [11]. Diagnosis of established AVF dysfunction similarly relies on combined clinical and imaging criteria [12–14], with fistulography serving as the gold standard; luminal narrowing exceeding 50% is considered hemodynamically significant. The pathophysiology of FTM and AVF dysfunction is multifactorial, involving neointimal hyperplasia (NIH), inadequate outward remodeling, and insufficient arterial inflow (<500 mL/min) [12–14]. These processes are driven by localized hypoxia, inflammatory cytokine signaling (e.g., TGF-β, PDGF), and endothelial dysfunction, and are exacerbated in diabetes and uremia. Clinically, FTM prolongs dependence on central venous catheters, increasing the risk of infection, central venous stenosis, mortality, and healthcare costs due to repeated imaging and salvage interventions [15].

Percutaneous transluminal angioplasty (PTA) is the cornerstone treatment for delayed maturation and early AVF dysfunction, particularly within the first year after AVF creation. According to the 2022 KDOQI update, technical success is defined as <30% residual stenosis with restoration of adequate hemodynamic flow, and plain old balloon angioplasty (POBA) remains the guideline-recommended first-line therapy [8]. POBA achieves acute luminal enlargement through vessel overstretching but induces vascular injury that activates smooth muscle cell proliferation and growth factor release, leading to restenosis rates of 50–60% within the first year [16–19]. These limitations have driven interest in drug-coated balloons (DCBs), which deliver antiproliferative agents such as paclitaxel or sirolimus. Paclitaxel inhibits NIH formation and remains in the vessel wall for 28–60 days without significant systemic exposure, with randomized trials demonstrating no increase in early thrombosis compared with POBA [20,21]. Sirolimus offers a cytostatic alternative with encouraging early safety data, although long-term AVF-specific outcomes remain limited [22]. Comparative studies of DCB versus POBA have yielded inconsistent results, with some demonstrating superior patency with DCBs , others showing no significant difference, and no evidence supporting superiority of POBA over DCB [23–25].

Therefore, this study aimed to compare drug-coated balloon (DCB) angioplasty with plain old balloon angioplasty (POBA) in patients with delayed maturation or malfunctioning native arm arteriovenous fistulas, focusing on safety outcomes, Doppler-derived patency parameters, and overall procedural cost over a 12-month follow-up period.

MATERIALS AND METHODS

Study Design and Setting

This was a prospective comparative observational cohort study conducted at Alexandria University Hospital, Egypt, between December 2024 and December 2025. The study was not a randomized clinical trial; group allocation to DCB or POBA angioplasty was determined by operator preference and balloon availability at the time of each intervention. The study included 40 patients with end-stage renal disease (ESRD) receiving regular hemodialysis who presented with delayed maturation or malfunction of a native arm AVF caused by venous, anastomotic, or juxta-anastomotic stenosis. Patients underwent endovascular percutaneous transluminal angioplasty (PTA) and were allocated into two equal groups: 20 patients treated with DCB angioplasty and 20 treated with POBA. All patients were followed for a period of 12 months. The study flow diagram is shown in Figure 1.

Eligibility Criteria

Patients were eligible if they had delayed maturation of a native arm AVF or dysfunction of a mature native AVF. Exclusion criteria included thrombosed AVFs, prosthetic arteriovenous grafts, central venous stenosis, or known allergy to iodinated contrast media. Written informed consent was obtained from all participants prior to intervention. To minimize selection bias, consecutive eligible patients presenting during the study period were included. A formal sample size calculation was not performed because this study was designed as an exploratory prospective comparative study including all consecutive eligible patients presenting during the study period.

Pre-Procedural Assessment

All patients underwent standardized pre-procedural evaluation including clinical examination, assessment by the hemodialysis team, routine laboratory investigations (complete blood count and coagulation profile), and duplex Doppler ultrasound of the access circuit. Doppler assessment documented vein diameter, site and length of stenosis, degree of luminal narrowing, peak systolic velocity, flow volume, and evaluation of the anastomotic and adjacent arterial segments.

Procedural Technique

All interventions were performed under local anesthesia in an angiography suite. Vascular access was obtained via transvenous or trans-radial approach under ultrasound guidance, according to operator preference and anatomical considerations. Standard angioplasty technique was applied using either a drug-coated balloon or a plain balloon, depending on group allocation. Technical success was defined as less than 30% residual stenosis on angiography with restoration of adequate flow. Procedural duration, radiation exposure time, contrast volume, and number of balloons used were recorded for each case.

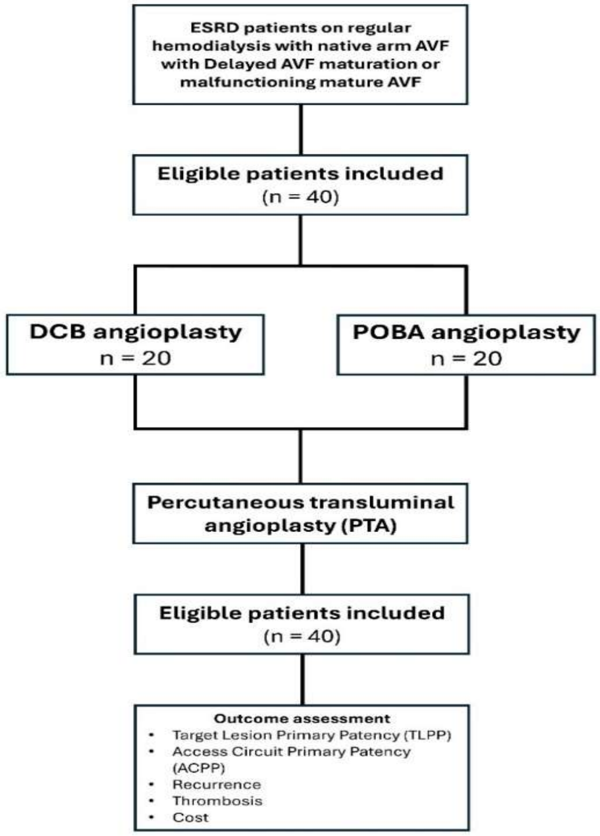

Figure 1. Flowchart of patient selection, intervention, and follow-up in the present study

Outcome Measures and Follow-Up

The primary safety endpoint was the occurrence of cardiac events or death at 30 days, 6 months, and 12 months. Secondary outcomes included target lesion primary patency, access circuit primary patency, late lumen loss due to thrombosis, recurrence of stenosis, need for re-intervention, and total procedural cost. Patients were followed clinically and with duplex Doppler ultrasound at 1, 3, 6, 9, and 12 months after the procedure to assess access function, patency, and complications.

Statistical Analysis

Statistical analysis was performed using IBM SPSS software version 20.0 (IBM Corp., Armonk, NY, USA). Categorical variables were expressed as frequencies and percentages and compared between groups using the Chi-square test; Fisher's exact test or Monte Carlo correction was applied when more than 20% of expected cell counts were <5. Continuous variables were assessed for normality using the Shapiro–Wilk test and are presented as range (minimum–maximum), mean ± standard deviation (SD), and median with interquartile range (IQR), as appropriate. Non-normally distributed continuous variables were compared between groups using the Mann–Whitney U test. All statistical tests were two-sided, and a p value ≤ 0.05 was considered statistically significant.

RESULTS

A total of 40 patients meeting the inclusion criteria were enrolled in this study. All patients underwent percutaneous transluminal angioplasty for either delayed maturation or malfunction of a native arm arteriovenous fistula (AVF). Twenty patients were treated with drug-coated balloon (DCB) angioplasty and 20 with plain old balloon angioplasty (POBA). Patients were followed for 12 months after intervention. No missing clinical or follow-up data were recorded during the study period.

Baseline Demographic and Clinical Characteristics

Baseline demographic and clinical characteristics were comparable between the two groups, with no statistically significant differences identified (Table 1). In the DCB group, patient age ranged from 22 to 78 years, while in the POBA group it ranged from 20 to 62 years ($p = 0.094$). Male patients constituted 70% of each group ($p = 1.000$). The prevalence of diabetes mellitus and hypertension was identical in both groups (40% and 80%, respectively; $p = 1.000$ for each). Ischemic heart disease was present in 10% of patients in each group ($p = 1.000$). Systemic lupus erythematosus was observed only in the POBA group (20%), though this difference did not reach statistical significance ($p = 0.106$). Heart failure and dyslipidemia were reported exclusively in the DCB group (10% each; $p = 0.487$ for each). Viral markers for HIV and hepatitis C were negative in all patients.

*Author for Correspondence: elsayedabdelfatah1975@gmail.com

Table 1. Baseline Demographic and Clinical Characteristics. ***Fisher's exact test for all categorical variables; Mann–Whitney U for age.***

Variable	DCB (n = 20)	POBA (n = 20)	P value
Age, years (range)	22–78	20–62	0.094
Male sex, n (%)	14 (70%)	14 (70%)	1.000
Female sex, n (%)	6 (30%)	6 (30%)	1.000
Diabetes mellitus, n (%)	8 (40%)	8 (40%)	1.000
Hypertension, n (%)	16 (80%)	16 (80%)	1.000
Ischemic heart disease, n (%)	2 (10%)	2 (10%)	1.000
Heart failure, n (%)	2 (10%)	0	0.487
Dyslipidemia, n (%)	2 (10%)	0	0.487
Systemic lupus erythematosus, n (%)	0	4 (20%)	0.106

Access Characteristics and Stenosis Distribution

Most AVFs in both groups presented with delayed maturation rather than malfunction (90% vs 10%), and the majority were located in the left upper limb (Table 2); no statistically significant differences were identified between groups in any access characteristic. Cephalic vein and anastomotic stenosis predominated in both groups, accounting for 90% of cases in the DCB group and 70% in the POBA group (p = 0.235). Transposed basilic vein stenosis was more frequent in the POBA group (30%) compared with the DCB group (10%; p = 0.235). Anastomotic stenosis was observed in 10% of patients in each group (p = 1.000), while juxta-anastomotic stenosis was more common in the DCB group (30% vs 10%; p = 0.235). The side of AVF placement did not differ significantly between groups (left arm: 90% vs 100%; p = 0.487).

Table 2. Access Characteristics and Stenosis Distribution. ***Fisher's exact test for all variables.***

Variable	DCB (n = 20)	POBA (n = 20)	P value
Type of access dysfunction			
Delayed maturation, n (%)	18 (90%)	18 (90%)	1.000
Malfunctioning mature AVF, n (%)	2 (10%)	2 (10%)	1.000
Side of AVF			
Left arm, n (%)	18 (90%)	20 (100%)	0.487
Right arm, n (%)	2 (10%)	0	0.487
Site of stenosis			
Cephalic vein / anastomosis, n (%)	18 (90%)	14 (70%)	0.235
Transposed basilic vein, n (%)	2 (10%)	6 (30%)	0.235
Anastomotic stenosis, n (%)	2 (10%)	2 (10%)	1.000
Juxta-anastomotic stenosis, n (%)	6 (30%)	2 (10%)	0.235

Pre-procedural Doppler evaluation demonstrated comparable stenosis severity and hemodynamic parameters between groups (Table 3). Stenosis severity ranged from 60% to 85% in the DCB group and from 55% to 82% in the POBA group. Peak systolic velocity at the stenotic site ranged from 650 to 900 cm/s in both groups. Flow volume ranged from 180 to 560 mL/min in the DCB group and from 166 to 182 mL/min in the POBA group. No brachial artery stenosis was detected proximally or distal to the AVF in either group.

Vascular access was achieved predominantly via a transvenous approach, with transradial access used in 10% of patients in each group. Ultrasound-guided access was successful on the first attempt in all DCB cases and in 90% of POBA cases. The number of balloons used per procedure ranged from one to three in both groups, with a total of 26 balloons used in the DCB group and 28 in the POBA group. Technical success, defined as <30% residual stenosis with restoration of adequate flow, was achieved in 100% of cases. Procedure duration ranged from 1 to 2 hours, radiation exposure time ranged from 5 to 15 minutes, and contrast volume ranged from 15 to 100 mL in both groups. No acute procedure-related complications were observed in either group. Post-procedural Doppler surveillance demonstrated no cases of radial artery thrombosis. Hospital stay was similar in both groups, with a median duration of three days.

**Author for Correspondence: elsayedabdelfatah1975@gmail.com*

Table 3. Procedural and Doppler Characteristics

Parameter	DCB	POBA	P value
Stenosis severity, % (range)	60–85	55–82	0.678
Peak systolic velocity, cm/s (range)	650–900	650–900	0.164
Flow volume, mL/min (range)	180–560	166–182	— †
Balloon(s) per procedure (range)	1–3	1–3	1.000
Balloon total number	26	28	—
Technical success rate	100%	100%	1.000
Procedure time	1–2 h	1–2 h	—
Radiation time, min (range)	5–15	5–15	—
Contrast volume, mL (range)	15–100	15–100	—

Clinical Outcomes and Cost Analysis

At 12-month follow-up, access circuit primary patency was maintained in 90% of patients in both groups (Table 4). Target lesion primary patency was 70% in each group. Recurrence at the treated lesion occurred in 20% of patients in the DCB group and 30% in the POBA group, a difference that did not reach statistical significance ($p = 0.465$). Thrombosis resulting in late lumen loss occurred in 10% of patients in each group. No deaths were recorded during the follow-up period. The total balloon-related procedural cost was significantly higher in the DCB group compared with the POBA group (USD 26,598 vs USD 4,900; $p < 0.001$).

Table 4. Twelve-Month Outcomes and Cost Comparison

Outcome	DCB (n = 20)	POBA (n = 20)	*P* value
Target lesion primary patency, n (%)	14 (70%)	14 (70%)	1.000
Recurrence at treated site, n (%)	4 (20%)	6 (30%)	0.465
Access circuit primary patency, n (%)	18 (90%)	18 (90%)	1.000
Thrombosis (LLL), n (%)	2 (10%)	2 (10%)	1.000
Deaths, n (%)	0	0	—
Total balloon cost (USD)	**26,598**	**4,900**	**<0.001**

DISCUSSION

The global prevalence of end-stage renal disease (ESRD) continues to increase, with hemodialysis (HD) remaining the predominant kidney replacement therapy worldwide [1,2]. Native arteriovenous fistulas (AVFs) are widely accepted as the optimal vascular access for HD due to superior patency, lower infection rates, and reduced long-term costs compared with grafts and central venous catheters [6–9]. However, failure of maturation (FTM) occurs in approximately 20–40% of newly created AVFs, resulting in a substantial need for endovascular intervention to achieve or maintain access usability [6–9,19]. Percutaneous transluminal angioplasty (PTA) therefore remains the cornerstone treatment for delayed maturation and early AVF dysfunction, with plain old balloon angioplasty (POBA) continuing to serve as the guideline-recommended first-line therapy [6–9,19].

Despite its widespread use, POBA is associated with significant restenosis rates, reported to reach 50–60% within the first year, primarily due to barotrauma-induced neointimal hyperplasia (NIH) [19]. This limitation has driven interest in drug-coated balloons (DCBs), which deliver antiproliferative agents—most commonly paclitaxel or sirolimus—to inhibit NIH and potentially improve patency. While several studies have suggested superior outcomes with DCBs, others have demonstrated no significant difference compared with POBA, and no published data support the superiority of POBA over DCB [23–25]. Consequently, the clinical role of DCBs in AVF angioplasty remains debated.

In the present prospective comparative study, most interventions were performed for delayed AVF maturation rather than malfunction, consistent with previous reports highlighting delayed maturation as the predominant cause of early AVF failure [26]. The predominance of left-sided AVFs observed in this cohort aligns with KDOQI recommendations favoring initial access creation in the non-dominant upper limb [26]. The demographic distribution, including male predominance and the prevalence of diabetes and hypertension, mirrors national and international renal registry data , supporting the representativeness of the study population [2,27,28].

Anatomically, cephalic vein and anastomotic stenosis constituted the majority of lesions in both groups, with fewer cases involving transposed basilic veins. This distribution is expected given the preferential use of cephalic veins for AVF creation, as recommended by KDOQI guidelines [8]. Juxta-anastomotic stenosis was more frequent in the DCB group; however, the overall incidence of anastomotic and juxta-anastomotic lesions in this cohort was lower than that reported in earlier studies, where rates of 30–60% have been described [29]. Pre-procedural Doppler findings, including stenosis severity, peak systolic velocity, and flow volume, were consistent with established diagnostic criteria for AVF dysfunction and the “rule of sixes” [8].

From a technical standpoint, venous access was used in the majority of cases, reflecting current practice patterns reported in the literature [30,31]. Transradial access was employed in a minority of patients without subsequent radial artery thrombosis, consistent with recent evidence demonstrating declining thrombosis rates with improved technique and ultrasound guidance [32]. Procedural parameters, including radiation exposure time and contrast volume, were comparable to published benchmarks for AVF angioplasty [33]. Technical success was achieved in all cases, consistent with reported success rates exceeding 90% in systematic reviews and meta-analyses [34].

At 12-month follow-up, access circuit primary patency (ACPP) was high and identical in both groups (90%), while target lesion primary patency (TLPP) was 70% in each group. Although recurrence was numerically lower in the DCB group (20% vs 30%), this difference did not reach statistical significance, aligning with meta-analyses of randomized trials showing a trend favoring DCB without definitive statistical superiority [23]. Importantly, recurrence in most cases did not meet clinical or radiologic criteria for re-intervention within the study period. Thrombosis rates were low and identical between groups, corroborating evidence that DCB use does not increase thrombotic risk in AVF angioplasty [35]. No deaths or major adverse events were observed, consistent with prior randomized data showing no increase in mortality or acute complications with DCB use [35].

The most notable finding of this study was the significantly higher procedural cost associated with DCB angioplasty compared with POBA. While some economic analyses have suggested that DCBs may be cost-saving by reducing re-intervention rates within the first year [36], this was not observed in the present cohort, likely reflecting the absence of a statistically significant patency advantage with DCB during the 12-month follow-up period. In healthcare systems with constrained resources, this cost difference may be clinically relevant and supports continued use of POBA as a cost-effective first-line strategy.

Limitations of the Study

This study has several limitations. The sample size was relatively small, limiting statistical power to detect modest differences between groups. Follow-up was limited to 12 months, precluding assessment of longer-term patency and cost-effectiveness. In addition, the study was conducted at a single center, which may limit generalizability. Larger multicenter studies with extended follow-up are required to further clarify the role of DCBs in AVF angioplasty.

CONCLUSION

In this prospective comparative study, recurrence after angioplasty was numerically lower with drug-coated balloons (DCB) than with plain old balloon angioplasty (POBA); however, this difference did not reach statistical significance. No clinically or radiologically significant restenosis requiring re-intervention was observed in either group during the 12-month follow-up period. Target lesion primary patency was comparable between groups, and the use of DCB was not associated with increased thrombosis or mortality. In contrast, POBA was associated with a significantly lower procedural cost compared with DCB. Taken together, these findings support POBA as a safe, effective, and more cost-efficient first-line endovascular treatment for delayed maturation or malfunctioning native arteriovenous fistulas during the first year after intervention. Although the prospective and comparative design represents a strength of this study, the relatively small sample size and limited follow-up duration warrant caution. Larger, multicenter studies with longer follow-up are needed to better define the long-term clinical and economic role of DCB angioplasty in this setting.

Ethics approval and consent to participate

This study (IRB number: 00012098) was approved by the Ethics Committee of Alexandria University Hospital, Egypt (Approval Number: 0202045; Issued on 08/09/2024). The study was conducted in accordance with the Declaration of Helsinki. Written informed consent was obtained from all participants prior to enrollment.

Consent for publication

Not applicable. The manuscript does not contain any individual person's data, images, or identifying information.

Availability of data and materials

The datasets generated and/or analyzed during the current study are not publicly available due to institutional privacy regulations but are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

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Authors' Contributions

EAY contributed to conceptualization, methodology, data collection, investigation, statistical analysis, and drafting of the original manuscript. MM contributed to data interpretation, manuscript drafting, and critical revision of the manuscript. NAA contributed to protocol development and critical manuscript revision. AOK contributed to data validation and manuscript review. RJ contributed to data review and manuscript review. ULE contributed to statistical results review and interpretation of the findings. AAE contributed to conceptualization, supervision, project administration, manuscript review and editing, and final approval of the manuscript. All authors read and approved the final version of the manuscript and agree to be accountable for all aspects of the work.

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