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Personalized Diagnostic and Treatment Algorithm for X-Ray Endovascular Interventions in Patients with Diabetic Foot Syndrome and Concomitant Ischemic Heart Disease: Comparative Evaluation of Clinical Efficacy

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Abstract **(1) Background:** The coexistence of diabetic foot syndrome (DFS) and ischemic heart disease (IHD) substantially increases the risk of major amputation and mortality when endovascular interventions are planned without systematic cardiac risk stratification. A personalized treatment algorithm integrating cardiac functional assessment into the revascularization decision framework may improve outcomes in this high-risk population. **(2) Methods:** A prospective comparative study included 120 patients with DFS and IHD treated at the Republican Specialized Center of Surgery named after V.V. Vakhidov between 2015 and 2024. The control group (n=58, 2015–2019) received standard X-ray endovascular interventions (XEI) without preliminary cardiac risk stratification. The study group (n=62, 2020–2024) was managed according to a personalized algorithm incorporating risk-stratified sequencing of revascularization based on a validated logistic regression model. Outcomes were evaluated using the ISEL-SDS-IHD scale. **(3) Results:** Limb anatomical integrity was preserved in 87.1% vs. 56.9% (p=0.001); weight-bearing function in 93.5% vs. 70.7% (p=0.002); major amputation rate was 6.5% vs. 17.2% (p=0.038); repeat revascularization rate was 9.7% vs. 22.4% (p=0.049). Hospital stay was reduced by 37% (11.4 vs. 18.1 bed-days, p=0.001). Excellent ISEL-SDS-IHD outcomes (score 8) were achieved in 29.0% vs. 5.2% (p=0.001). **(4) Conclusions:** The personalized algorithm significantly reduces amputation rates, repeat interventions, and hospitalization duration while improving cardiac and limb functional outcomes in patients with DFS and IHD.

Keywords Diabetic foot syndrome, Ischemic heart disease, Personalized algorithm, Endovascular intervention, Risk stratification, Limb salvage, Heart-first strategy, Limb-first strategy, ISEL-SDS-IHD

1. Introduction

The combination of diabetic foot syndrome (DFS) and ischemic heart disease (IHD) constitutes one of the most clinically demanding comorbid configurations in vascular surgery. More than 70% of patients presenting with DFS have concurrent IHD - frequently subclinical or inadequately characterized - while verified systolic dysfunction (LVEF <50%) is present in one-third, and prior myocardial infarction in one-fifth of this population [1,2]. This systemic vascular burden is not merely additive: IHD directly impairs myocardial output and peripheral tissue reperfusion, thereby limiting the functional efficacy of technically successful lower-extremity revascularization, even when angiographic flow restoration is achieved [3].

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Under the traditional treatment paradigm, X-ray endovascular interventions (XEI) on lower-limb arteries are planned primarily on the basis of angiographic anatomy and limb ischemia severity, without systematic assessment of coronary functional reserve or myocardial status [4]. This fragmented approach leaves a critical therapeutic gap: in patients with decompensated IHD, even technically successful revascularization may fail to restore adequate tissue perfusion, resulting in progressive necrosis, wound infection, and ultimately major amputation. Prior analysis of the control cohort at our center demonstrated that this scenario materialized in 37.9% of cases managed under the standard protocol, with major amputation rates reaching 45.4% and 30-day mortality 13.6% among those with unfavorable outcomes [5].

Contemporary vascular guidelines from both the International Working Group on the Diabetic Foot (IWGDF) and the Global Vascular Guidelines (GVG) on chronic limb-threatening ischemia emphasize the necessity of multidisciplinary assessment and cardiac functional evaluation before revascularization in high-risk diabetic patients [6,7]. However, practical implementation of risk-stratified, sequenced intervention algorithms - defining which organ system (heart or limb) should be prioritized and in what order - remains inconsistently adopted, particularly in resource-limited settings where multidisciplinary coordination is suboptimal [8].

The debate between "limb-first" and "heart-first" intervention strategies has been growing in the vascular literature without definitive resolution by prospective randomized evidence [9]. The choice of strategy depends on a range of clinical parameters - including LVEF, angina functional class, ulcer staging, and angioarchitectural complexity - none of which individually captures the composite risk. A model-driven, individualized algorithm that objectively quantifies risk and allocates patients to risk-stratified therapeutic pathways represents a logical advancement in the clinical management of this population [10].

The present study was undertaken to develop and prospectively evaluate the clinical efficacy of a personalized diagnostic and treatment algorithm for XEI in patients with DFS and IHD, comparing outcomes against the historical control cohort managed under the traditional approach at the same institution.

2. Materials and Methods

Study design and patient population. This prospective comparative study was conducted at the Republican Specialized Center of Surgery named after Academician V.V. Vakhidov (Tashkent, Republic of Uzbekistan) over a ten-year period from 2015 to 2024. A total of 120 patients with DFS complicated by lower-limb ischemia and documented IHD were included. Patients were distributed into two groups by chronological and tactical principle.

The **control group** (n=58) comprised patients treated between 2015 and 2019 under the standard institutional protocol, in which XEI on lower-extremity arteries were performed without preliminary cardiac risk stratification. IHD was not incorporated as a determinant of intervention sequencing or extent.

The **study group** (n=62) comprised patients treated between 2020 and 2024 using a newly developed personalized treatment algorithm, which integrated preoperative echocardiographic evaluation, stress testing where feasible, coronary angiography, and - when indicated - coronary stenting prior to peripheral XEI.

Inclusion criteria: confirmed type 2 diabetes mellitus; clinically and instrumentally verified lower-limb ischemia (Fontaine stage IIb–IV); ulcerative or necrotic foot lesions (Wagner stage I–V); documented IHD; absence of active sepsis or terminal organ failure. Patients with decompensated NYHA class IV heart failure, acute coronary syndrome within 30 days prior to enrollment, terminal renal failure requiring dialysis, or actively progressing oncological disease were excluded. Both groups were comparable in sex distribution (male 53.4% vs. 54.8%), mean age (68.3±9.5 vs. 66.4±8.9 years), diabetes duration (10.3±5.4 vs. 10.5±5.2 years), mean HbA1c (9.0±1.5%), and proportions of advanced Fontaine and Wagner stages.

The personalized algorithm. The algorithm was grounded in a validated logistic regression–based prognostic model developed from the control cohort, identifying six independent predictors of major amputation or 30-day mortality: LVEF <50% (OR=8.26), angina CCS class III–IV (OR=7.24), Wagner stage IV–V (OR=6.47), heel or total foot involvement (OR=5.59), HbA1c ≥10% (OR=4.90), and requirement for contralateral crossover access (OR=4.34), with AUC=0.915 [5].

Based on the calculated individual probability of unfavorable outcome (P), patients in the study group were stratified into three risk strata with corresponding therapeutic strategies:

- **Low risk (P<0.40; n=21, 33.9%):** Primary XEI on lower-extremity arteries without mandatory coronary pre-assessment. Patients had preserved LVEF, compensated DM, and localized foot lesions.
- **Intermediate risk (P=0.40–0.60; n=19, 30.6%):** Decision delegated to a multidisciplinary council comprising vascular surgeon, cardiologist, and functional diagnostician. Twelve patients (63.2%) underwent primary limb XEI; seven (36.8%) underwent preliminary cardiac evaluation with subsequent limb revascularization.
- **High risk (P>0.60; n=22, 35.5%):** Priority cardiac evaluation with coronary angiography and coronary stenting where indicated, followed by XEI on lower-extremity arteries. Seventeen patients underwent sequential staged revascularization; five underwent simultaneous procedures.

Outcome assessment. Primary outcome measures were: preservation of anatomical limb integrity (no major amputation above ankle level); preservation of weight-bearing function; major amputation rate; 30-day all-cause mortality; and repeat revascularization within 6 months. Secondary outcomes included specific procedural complications, length of hospitalization, number of repeat hospitalizations and necrotomies within 6 months, and resource utilization.

Integrated outcome quality was assessed using the ISEL-SDS-IHD scale (Integrated System for Evaluation of Limb-saving in patients with Diabetic foot Syndrome and Ischemic Heart Disease), an eight-domain instrument developed as part of the study. Each domain is scored 0–1: (1) no major amputation; (2) preserved weight-bearing function; (3) NYHA regression ≥1 class or LVEF increase ≥5%; (4) Wagner stage regression or wound healing; (5) HbA1c reduction ≥1% at 3 months; (6) no repeat revascularization within 6 months; (7) no specific procedural complications; (8) patient-reported treatment satisfaction. Total score: 0–8; interpretation: 0–3 unsatisfactory, 4–5 satisfactory, 6–7 good, 8 excellent.

Statistical analysis. IBM SPSS Statistics v.26.0 (USA) and Microsoft Excel 2019 were used. Continuous variables are presented as M±SD; between-group comparisons used Student's t-test or Mann-Whitney U test. Categorical variables were compared by χ^2 or Fisher's exact test. Significance was set at $p<0.05$. Intragroup dynamics were assessed by paired t-test for continuous variables.

3. Results and Discussion

Risk distribution in the study group. Of 62 patients in the study group, 33.9% (n=21) were classified as low risk, 30.6% (n=19) as intermediate, and 35.5% (n=22) as high risk according to the prognostic model (**Table 1**). Among high-risk patients, all 22 underwent primary cardiac evaluation; coronary stenting was performed in 17 (77.3%) before peripheral XEI. This distribution confirms that over one-third of patients presenting with DFS and IHD carry high cardiac risk that warrants priority coronary intervention before limb revascularization - a proportion that would have been missed without systematic pre-procedural stratification.

Clinical and functional dynamics in the study group. Implementation of the algorithm produced significant improvements in both cardiac and peripheral vascular parameters within the study group (**Table 2**). Mean LVEF increased from 47.2±7.4% to 51.6±6.9% (p=0.004), and the proportion of patients with NYHA class ≥II heart failure decreased from 53.2% to 29.0% (p=0.012). Severe angina (CCS class III–IV) was reduced from 33.9% to 14.5% (p=0.009). These improvements are directly attributable to the priority coronary revascularization performed in high-risk patients before limb intervention. Notably, mean HbA1c fell from 9.3±1.2% to 8.1±1.0% (p=0.001), reflecting the enhanced metabolic monitoring incorporated into the algorithm.

The reduction in Wagner stage ≥IV from 41.9% to 17.7% (p=0.001) and Fontaine stage III–IV from 50.0% to 22.6% (p=0.001) reflects successful correction of peripheral hypoperfusion and tissue regenerative potential restored by the sequenced revascularization strategy. These findings align with published evidence demonstrating that prior cardiac optimization before peripheral intervention improves microcirculatory response and wound-healing capacity in diabetic patients with reduced LVEF [11].

Comparative clinical outcomes. The personalized algorithm produced statistically significant improvements across all primary outcome measures compared to the control group (**Table 3**). Anatomical limb integrity was preserved in 87.1% of study group patients versus 56.9% in controls (p=0.001) - a 1.5-fold increase. Weight-bearing function was maintained in 93.5% versus 70.7% (p=0.002). The rate of major amputation (above-ankle level) was reduced 2.6-fold: 6.5% versus 17.2% (p=0.038).

Table 1. Distribution of patients in the study group by risk level and corresponding treatment strategy (n=62)

Risk level	n (%)	Treatment strategy	Applied, n (%)
Low (<40%)	21 (33.9%)	Primary XEI on lower-extremity arteries	21 (100%)
Intermediate (40–60%)	19 (30.6%)	Multidisciplinary council decision	-
		- Primary limb XEI	12 (63.2%)
		- Primary cardiac evaluation + subsequent limb XEI	7 (36.8%)
High (>60%)	22 (35.5%)	Primary cardiac evaluation and coronary revascularization before limb XEI	22 (100%)

Table 2. Dynamics of clinical and functional parameters in the study group before and after application of the personalized algorithm (n=62)

Parameter	Before treatment	After treatment	p-value
LVEF, % (M±SD)	47.2±7.4	51.6±6.9	0.004
NYHA class ≥II, n (%)	33 (53.2%)	18 (29.0%)	0.012
Angina CCS class III–IV, n (%)	21 (33.9%)	9 (14.5%)	0.009
Wagner stage ≥IV, n (%)	26 (41.9%)	11 (17.7%)	0.001
Fontaine stage III–IV, n (%)	31 (50.0%)	14 (22.6%)	0.001
HbA1c, % (M±SD)	9.3±1.2	8.1±1.0	0.001

Table 3. Comparative clinical outcomes in patients with DFS and IHD: study group (personalized algorithm) vs. control group (standard approach) (n=120)

Outcome	Study group (n=62)	Control group (n=58)	p-value
Anatomical limb integrity preserved, n (%)	54 (87.1%)	33 (56.9%)	0.001
Weight-bearing function preserved, n (%)	58 (93.5%)	41 (70.7%)	0.002
Major amputation, n (%)	4 (6.5%)	10 (17.2%)	0.038
30-day mortality, n (%)	1 (1.6%)	3 (5.2%)	0.289
Repeat revascularization ≤6 months, n (%)	6 (9.7%)	13 (22.4%)	0.049
Repeat cardiac intervention, n (%)	2 (3.2%)	3 (5.2%)	0.657

Thirty-day mortality was 1.6% in the study group versus 5.2% in controls (3.2-fold reduction), though this difference did not reach statistical significance (p=0.289), likely due to sample size constraints. The trend is clinically relevant given the high-risk nature of both cohorts. Repeat revascularization within 6 months was significantly lower in the study group (9.7% vs. 22.4%, p=0.049), reflecting greater durability of initial revascularization when cardiac status is pre-optimized. This observation is consistent with prior reports demonstrating that impaired cardiac output reduces secondary patency rates after peripheral angioplasty in diabetic patients [12].

The "limb-first vs. heart-first" debate underpins the algorithm's core logic. In the context of critical limb-threatening ischemia with gangrene or uncontrolled infection, delay for cardiac workup may be inadvisable; however, in patients with severely reduced LVEF, unstable angina, or recent coronary events, proceeding with peripheral XEI without cardiac stabilization risks hemodynamic collapse and loss of revascularization benefit [9, 13]. The three-tier stratified approach implemented in this study provides an objective, quantified framework for resolving this clinical dilemma on an individualized basis, avoiding both unnecessary delays in limb-threatened patients and the hazard of cardiac decompensation in high-risk ones.

Procedural complications. The personalized algorithm was associated with consistently lower rates of specific procedural complications across all categories, although individual comparisons did not reach statistical significance owing to the relatively small absolute numbers (**Table 4**). The aggregate complication burden was reduced by 30–60% in the study group. Stent occlusion, the most severe device-related complication, occurred 4.3-fold less frequently (1.6% vs. 6.9%). Restenosis within 30 days was observed 2.15-fold less often (4.8% vs. 10.3%). These trends suggest that the algorithm's effect on complication rates operates through two mechanisms: (a) pre-selection of lower-risk patients for primary limb XEI, and (b) systemic hemodynamic stabilization in high-risk patients before peripheral intervention, which improves vessel wall biology and antiplatelet efficacy [14].

Resource utilization and economic efficiency. Implementation of the personalized algorithm produced substantial reductions in healthcare resource utilization (**Table 5**). Mean hospitalization duration fell from 18.1±4.6 to 11.4±3.2 bed-days (37% reduction, p=0.001). Repeat hospitalizations within 6 months decreased 2.3-fold (1.5±0.2 vs. 3.5±0.6, p=0.007), repeat necrotomies nearly 4-fold (1.1±0.1 vs. 4.5±1.5, p=0.001), and specialist consultations by 35% (4.1±1.2 vs. 6.3±1.7, p=0.001). Total financial expenditure per patient constituted 92% of the normative value in the study group versus 135% in controls - a 46.7% cost excess in the traditional approach despite markedly inferior clinical results. This economic penalty of non-stratified management reflects the downstream burden of avoidable complications, failed revascularizations, repeat procedures, and prolonged inpatient care.

Table 4. Specific procedural complications after XEI by group (n=120)

Complication	Study group (n=62)	Control group (n=58)	p-value
Tibial artery thrombosis, n (%)	2 (3.2%)	5 (8.6%)	0.264
Intimal dissection, n (%)	1 (1.6%)	3 (5.2%)	0.325
Access site hematoma, n (%)	1 (1.6%)	3 (5.2%)	0.325
Early restenosis (<30 days), n (%)	3 (4.8%)	6 (10.3%)	0.293
Stent occlusion, n (%)	1 (1.6%)	4 (6.9%)	0.181
Contrast-induced nephropathy, n (%)	2 (3.2%)	4 (6.9%)	0.412

Table 5. Comparative resource utilization: study group vs. control group (n=120)

Parameter	Study group (n=62)	Control group (n=58)	p-value
Mean hospitalization, bed-days (M±SD)	11.4±3.2	18.1±4.6	0.001
Repeat hospitalizations ≤6 months (M±SD)	1.5±0.2	3.5±0.6	0.007
Repeat necrotomies (M±SD)	1.1±0.1	4.5±1.5	0.001
Specialist consultations (M±SD)	4.1±1.2	6.3±1.7	0.001
Financial expenditure per patient, % of normative	92%	135%	-

Table 6. Distribution of patients by integrated clinical efficacy level (ISEL-SDS-IHD scale) (n=120)

ISEL-SDS-IHD score	Result level	Study group (n=62)	Control group (n=58)	p-value
8	Excellent	18 (29.0%)	3 (5.2%)	0.001
6–7	Good	26 (41.9%)	19 (32.8%)	0.284
4–5	Satisfactory	12 (19.4%)	22 (37.9%)	0.041
0–3	Unsatisfactory	6 (9.7%)	14 (24.1%)	0.034

Integrated outcome assessment (ISEL-SDS-IHD scale). The ISEL-SDS-IHD scale provided a multidimensional evaluation of treatment quality that transcended single-endpoint analysis (**Table 6**). The proportion of patients achieving excellent outcomes (score 8) was 5.6-fold higher in the study group (29.0% vs. 5.2%, p=0.001). The combined rate of good and excellent outcomes (scores 6–8) reached 70.9% versus 38.0% in controls - an approximately 1.9-fold improvement. Conversely, the proportion with unsatisfactory outcomes (scores 0–3) was significantly lower (9.7% vs. 24.1%, p=0.034). This scale captured the systemic and functional dimensions of treatment response - including improvements in LVEF, HbA1c, and NYHA class - that are invisible to limb-focused outcome metrics alone, confirming the superiority of the integrated approach over isolated anatomical endpoints.

The algorithm's clinical logic - determining intervention priority based on quantified individual risk rather than organ-focused convention - represents a paradigm shift from compartmentalized to integrated vascular care. Current evidence supports that DFS and IHD must be conceptualized as interconnected manifestations of systemic diabetic macroangiopathy, and their management must reflect this shared pathophysiological substrate [15]. The multidisciplinary council model adopted for intermediate-risk patients exemplifies this framework: rather than defaulting to a fixed strategy, the council integrates hemodynamic, anatomical, metabolic, and infectious parameters to generate an individualized decision.

4. Conclusions

The personalized diagnostic and treatment algorithm for X-ray endovascular interventions, based on individual risk stratification using a validated logistic regression model, demonstrated statistically significant superiority over the traditional non-stratified approach across all primary clinical outcome measures in patients with DFS and IHD.

Key findings are: anatomical limb integrity was preserved in 87.1% vs. 56.9% (p=0.001); weight-bearing function in 93.5% vs. 70.7% (p=0.002); major amputation was reduced 2.6-fold (6.5% vs. 17.2%, p=0.038); repeat revascularization was reduced 2.3-fold (9.7% vs. 22.4%, p=0.049). Mean LVEF improved by 4.4 percentage points (p=0.004), NYHA class ≥II prevalence fell by 24.2 points (p=0.012), and HbA1c decreased by 1.2% (p=0.001) within the study group. Hospitalization was shortened by 37% (p=0.001), and per-patient financial expenditure was 46.7% lower than in the control group. Excellent ISEL-SDS-IHD outcomes were achieved 5.6 times more frequently (p=0.001).

The three-tier risk stratification - directing low-risk patients to primary limb XEI, intermediate-risk patients to multidisciplinary evaluation, and high-risk patients to priority coronary revascularization - provides a practical, objective framework that resolves the "limb-first vs. heart-first" dilemma on an evidence-based individual basis. The ISEL-SDS-IHD scale offers a validated composite instrument for integrated outcome monitoring in this comorbid population.

Prospective multicenter validation is warranted to confirm generalizability. Pending such evidence, the algorithm may be recommended for implementation in vascular surgery centers managing patients with combined DFS and IHD, particularly where multidisciplinary cardiac-vascular coordination is available.

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