Summary results (PFI/MSF):

Among 79 patients initially assessed for eligibility, 52 were included in the analysis and equally allocated to the control group (tranexamic acid alone, n = 26) and the fibrinogen group (tranexamic acid plus fibrinogen, n = 26). Baseline demographic, anthropometric, anesthetic, and surgical characteristics were comparable between groups. Preoperative laboratory parameters were generally similar, although hematocrit (41.6 ± 3.3% vs 39.4 ± 3.0%; p = 0.018) and aPTT ratio (0.99 ± 0.11 vs 0.94 ± 0.07; p = 0.041) were significantly higher in the control group. Hemoglobin (13.9 ± 1.1 vs 13.2 ± 1.0 g/dL; p = 0.050), and fibrinogen levels (3.4 ± 1.0 vs 2.9 ± 0.5 g/L; p = 0.060; n = 34) were not significantly different.

No significant differences were observed between groups in hemoglobin decrease (ΔHb: 2.9 ± 1.2 g/dL vs 2.8 ± 1.5 g/dL; p = 0.786) or percentage decrease in hemoglobin (%ΔHb: 21.2 ± 9.1% vs 21.2 ± 11.4%; p = 0.994). Estimated perioperative blood loss (1085 ± 461 mL vs 1181 ± 653 mL; p = 0.545) and visible blood loss (1069 ± 701 mL vs 814 ± 389 mL; p = 0.156) were also not significantly different. Red blood cell transfusion was required in 30.7% of patients in the control group and 26.9% in the fibrinogen group (p = 0.760).

No serious adverse events were attributed to fibrinogen administration. Postoperative results were favorable in both groups. One case of hemorrhagic stroke occurred on postoperative day 4, with complete recovery and discharge on day 10.

Table 1. Baseline Characteristics of the Participants

Characteristic	Control Group (n = 26)	Fibrinogen Group (n = 26)	p-value
Age (years)	58.6 ± 11.6	62.1 ± 6.8	0.204
Sex (male/female), n	9 / 17	9 / 17	0.358
Body mass index (kg/m²)	29.0 ± 5.6	29.6 ± 3.4	0.648
Obesity (BMI ≥30), n (%)	8 (32.0%)	10 (38.4%)	0.629
ASA physical status, n (%)			0.579
ASA I	12 (46.1%)	14 (53.8%)	
ASA II	14 (53.8%)	12 (46.1%)	
Smoking, n (%)	5 (19.2%)	4 (15.3%)	1.000
Comorbidity, n (%)	14 (53.8%)	13 (50.0%)	0.781
Hypertension, n (%)	10 (38.4%)	7 (26.9%)	0.375
Diabetes mellitus, n (%)	6 (23.0%)	2 (7.6%)	0.249
Dyslipidemia, n (%)	5 (19.2%)	3 (11.5%)	0.701
Number of fused levels	2.9 ± 1.0	3.1 ± 0.9	0.326
Hemoglobin (g/dL)	13.9 ± 1.1	13.2 ± 1.0	0.050
Hematocrit (%)	41.6 ± 3.3	39.4 ± 3.0	0.018
Platelet count (×10³/μL)	230.6 ± 60.3	226.0 ± 48.1	0.762
aPTT ratio	0.99 ± 0.11	0.94 ± 0.07	0.041
Fibrinogen (g/L) (n=34)	3.4 ± 1.0	2.9 ± 0.5	0.060

Values are presented as mean ± standard deviation or number (percentage).

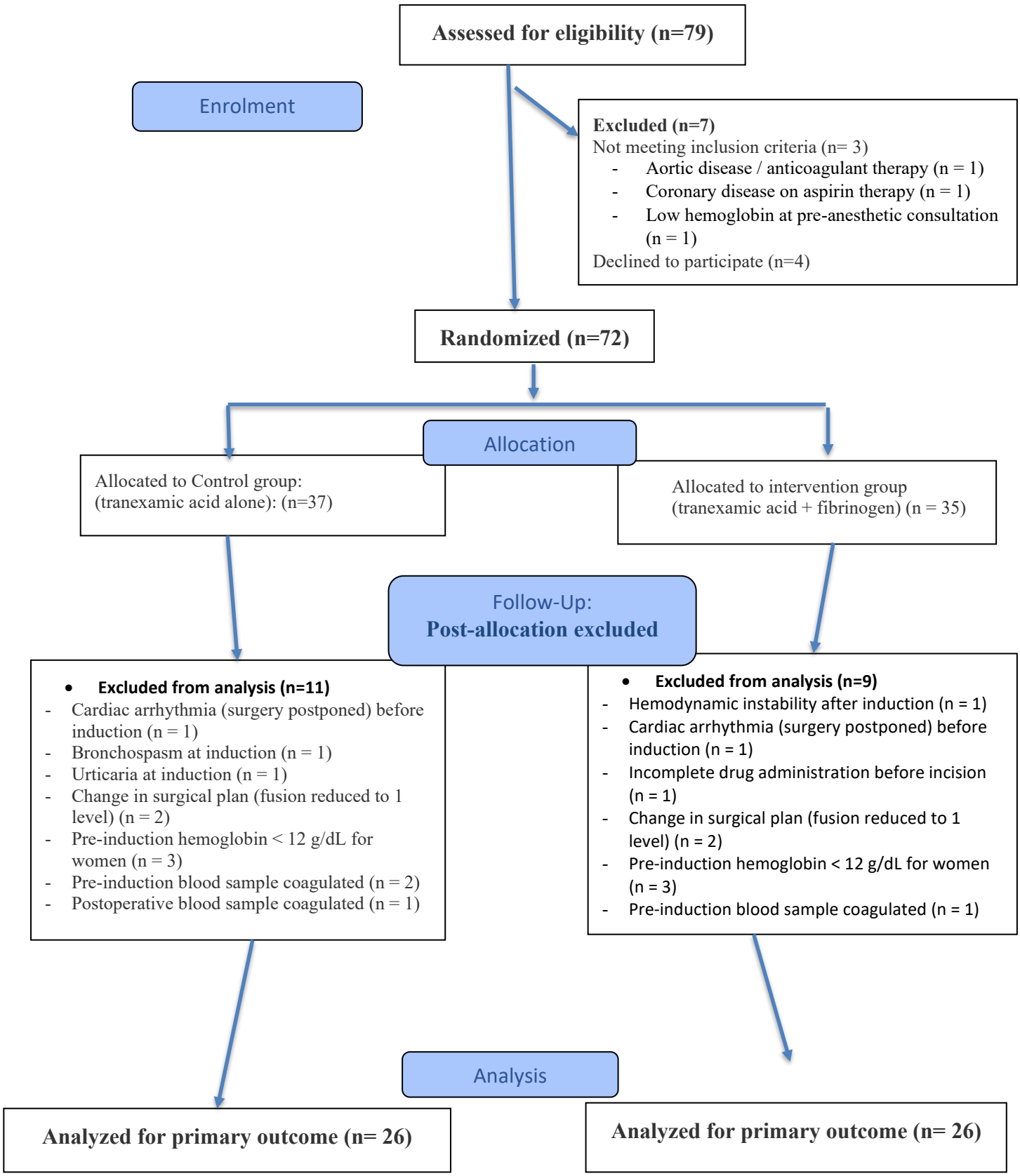

Figure 1: CONSORT Flow Diagram of the Randomized Controlled Trial (PFI/MSF

Adverse Events Results: PFI/MSF

The incidence of postoperative adverse events was comparable between the two groups (p = 1.000).

In the control group, an adverse event was reported (1/26, 3.8%): a case of fever attributed to cystitis, which resolved after removal of the urinary catheter without prolonging hospital stay (2 days).

In the fibrinogen group, two adverse events (2/26, 7.7%) were observed: one case of hyperglycemia (3.5 g/L) without ketoacidosis, with rapid resolution, and one case of hemorrhagic stroke occurring on postoperative day 4, with impaired consciousness. The patient was fully recovered and discharged on postoperative day 10 without neurological sequelae.

No adverse events related to fibrinogen administration.

Outcomes:

Table 3. Primary outcome: Hemoglobin decrease

Outcome	Control (n=26) Mean ± SD	Fibrinogen (n=26) Mean ± SD	Mean Difference (95% CI)	p-value
ΔHb (g/dL)	2.9 ± 1.2	2.8 ± 1.5	−0.1 [−0.6; 0.8]	0.786
%ΔHb (%)	21.2 ± 9.1	21.2 ± 11.4	0.0 [−5.8; 5.7]	0.994

ΔHb: hemoglobin decrease; %ΔHb: percentage decrease in hemoglobin

Table 4. Secondary outcomes: Perioperative blood loss

Outcome	Control (n=26) Mean ± SD	Fibrinogen (n=26) Mean ± SD	Mean Difference (95% CI)	p-value
Estimated blood loss (mL)	1085 ± 461	1181 ± 653	96 [−410; 219]	0.545
Visible blood loss (mL)	1069 ± 701	814 ± 389	−255 [−102; 613]	0.156

Estimated blood loss = PEBL; Visible blood loss = PVBL

Table 5. Other bleeding-related outcomes

Outcome	Control Group (n=26) n (%)	Fibrinogen Group (n=26) n (%)	p-value
Blood transfusion	8 (30.7%)	7 (26.9%)	0.760
Surgeon-reported bleeding	5 (19.2%)	3 (11.5%)	0.440