

**Structured Statistical Analysis Plan (SAP) based on the methods and analyses described in my study:**

Statistical Analysis Plan

1. Software Used

All data were analyzed using GraphPad Prism V9.

2. Type of Study Design

Design: Prospective, single-blinded, split-mouth clinical trial.

Comparison: Each patient served as their own control—Gelfoam on the right side vs. Surgicel on the left.

3. Sample Size Calculation

Software: G\*Power v3.1.9.4

Test used: ANOVA

Parameters:

Effect size (f): 0.47

$\alpha$  (significance level): 0.05

Power ( $1 - \beta$ ): 0.95

Minimum required sample size: 40 patients (based on a pilot study of 10 patients).

4. Statistical Tests

4.1 Bleeding Severity (VIBe Score)

Time points: Immediately after extraction (T0), and two hours post-extraction (T1).

Test Used:

Repeated Measures ANOVA – to analyze temporal changes in bleeding scores. Table.3

Independent t-test – to compare aspirin vs. warfarin groups. Table.4

Paired t-test – to compare Surgicel vs. Gelfoam within the same patient. Table.5

Significance threshold:  $p < 0.05$

4.2 Delayed Bleeding (Binary Outcome)

Time point: First 24 hours after extraction.

Test Used:

Chi-square ( $\chi^2$ ) test – to compare the frequency of delayed bleeding between groups. Table. 6

Significance threshold:  $p < 0.05$

#### 4.3 Gingival Healing Index (Ordinal Scale 1–5)

Time points: Day 3 (D3) and Day 7 (D7).

Test Used:

Paired t-test – to compare healing scores between Gelfoam and Surgicel within each group. Table. 8

Independent t-test – to compare aspirin vs. warfarin groups. Table. 9

Significance threshold:  $p < 0.05$

#### 4.4 Pain Assessment (VAS Score 0–10)

Time points: Day 1 (D1), Day 3 (D3), Day 7 (D7).

Test Used:

Repeated Measures ANOVA – to assess change over time. Table. 11

Independent t-test – to compare between aspirin and warfarin groups. Table. 12

Paired t-test – to compare pain between Gelfoam and Surgicel within subjects. Table. 13

Significance threshold:  $p < 0.0001$

### 5. Data Presentation

Descriptive statistics:

Mean  $\pm$  Standard Deviation (SD) for continuous variables (e.g., VAS, healing index).

Frequencies and percentages for categorical variables (e.g., sex, delayed bleeding).

**Tables and figures were used to illustrate statistical comparisons and time trends.**

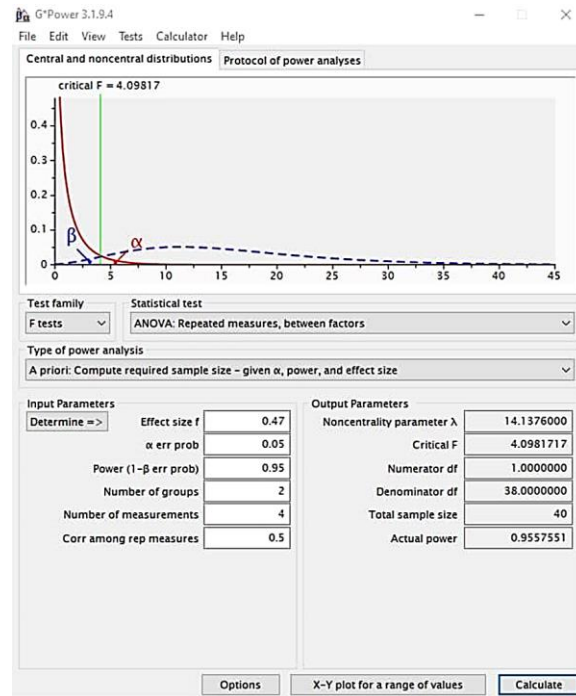


Fig. 1 Sample size using G-power v 3.1

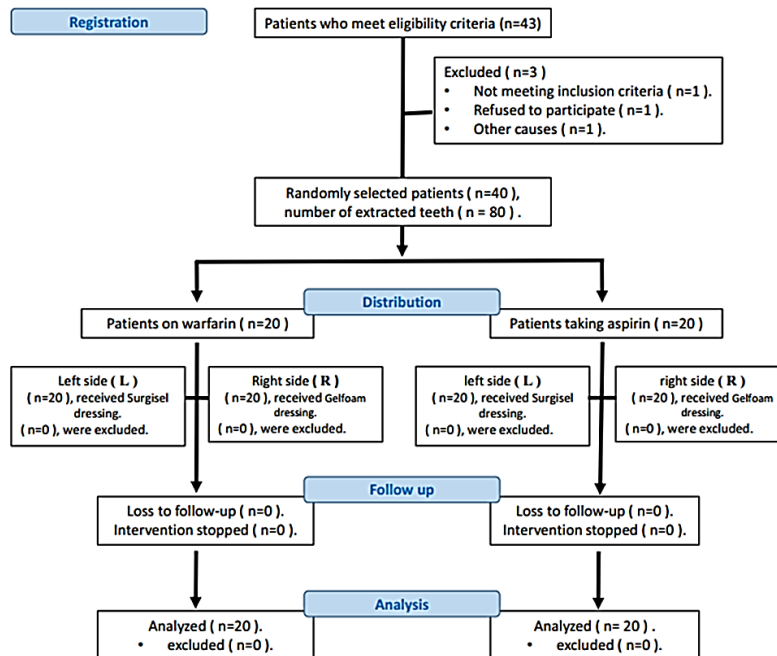


Fig. 2: CONSORT Flow Diagram

**Table 1** Baseline demographic and clinical characteristics of study participants

<b>Characteristics</b>	<b><i>n</i> = 40</b>
<b>Sex</b>	
Female n (%)	22 (55%)
Male n (%)	18 (45%)
<b>Age (years)</b>	
Mean $\pm$ SD	58.1 $\pm$ 6.89
Min – Max	40–75
<b>INR value</b>	
Mean $\pm$ SD	2.58 $\pm$ 0.32
Min – Max	2.1–3.1

#### 4.1 Bleeding Severity (VIBe Score)

**Table 2** Comparison of bleeding severity according to the VIBe Score at time points T0 and T1 for each treatment group.

<b>Group</b>	<b>Distinct Time</b>	<b>R (Gelfoam)</b>	<b>L (Surgicel)</b>
		<b>Average<math>\pm</math> SD</b>	<b>Average<math>\pm</math> SD</b>
<b>Aspirin</b>	<b>T0</b>	2.0 $\pm$ 1.03	1.8 $\pm$ 0.95
<b>Aspirin</b>	<b>T1</b>	2.2 $\pm$ 1.10	1.75 $\pm$ 0.79
<b>Warfarin</b>	<b>T0</b>	2.45 $\pm$ 1.00	2.1 $\pm$ 1.02
<b>Warfarin</b>	<b>T1</b>	2.65 $\pm$ 0.99	2.4 $\pm$ 1.05

**Table. 3** ANOVA results comparing bleeding time for each group.

<b>Group</b>	<b>F</b>	<b>P- value</b>
<b>Asprin</b>	5.258	<b>&lt;0.0001</b>
<b>warfarin</b>	4.345	<b>&lt;0.0001</b>

**Table 4** Paired T-test results comparing the aspirin and warfarin groups

Group		T0	T1
Warfarin	Column E vs. Column A	T0 (W+ S) vs. T0 (W+ G)	T1 (W +S) vs. T1 (W + G)
	Paired t test		
	P value	0.0346	0.1833
	P value summary	****	****
	Significantly different (P < 0.05)?	Yes	Yes
	One- or two-tailed P value?	Two-tailed	Two-tailed
	Number of pairs	20	20
Asprin	Column B vs. Column A	T0 (A+S) vs. T0 (A+G)	T1 (A+S) vs. T1 (A+G)
	Paired t test		
	P value	0.0518	0.0657
	P value summary	****	****
	Significantly different (P < 0.05)?	Yes	Yes
	One- or two-tailed P value?	Two-tailed	Two-tailed
	Number of pairs	20	20

**Table. 5** Independent T-test results comparing the aspirin and warfarin groups

Group		T0	T1
Gelfoam	Table Analyzed	G	G
	Column G vs. Column A	T0 (A+G) vs. T0 (W+G)	T1 (A+G) vs. T1 (W+G)
	Unpaired t test		
	P value	0.084	0.0913
	P value summary	***	****
	Significantly different (P < 0.05)?	Yes	Yes
	One- or two-tailed P value?	one-tailed	one-tailed
	Sample size, column	20	20

	Sample size, column	20	20
<b>Surgicel</b>	Table Analyzed	S	S
	<b>Column H</b>	<b>T0 (A+S)</b>	<b>T1 (A+S)</b>
	<b>vs.</b>	<b>vs.</b>	<b>vs.</b>
	<b>Column B</b>	<b>T0 (W+S)</b>	<b>T1 (W+S)</b>
	Unpaired t test		
	P value	0.3424	0.0324
	P value summary	ns	*
	Significantly different (P < 0.05)?	No	Yes
	One- or two-tailed P value?	one-tailed	one-tailed
	Sample size, column	20	20
	Sample size, column	20	20

#### 4.2 Delayed Bleeding (Binary Outcome)

**Table. 6** Chi-square test results comparing the bleeding probability between Gelfoam and Surgicel

<b>(chi-square test)</b>				
	<b>Group</b>			
Table Analyzed	<b>W-R</b>	<b>A-R</b>	<b>W-L</b>	<b>A-L</b>
Chi-square, df	16.22, 1	10.53, 2	10.53, 1	5.128, 2
Z`	4.027	3.244	3.244	2.265
P value	<0.0001	0.0012	0.0012	0.0235
P value summary	****	**	**	*
<b>Statistically significant (P &lt; 0.05)?</b>	<b>Yes</b>	<b>Yes</b>	<b>Yes</b>	<b>Yes</b>
Percentage of column total	W-R	A-R	W-L	A-L
يوجد نزف	15.00%	10.00%	10.00%	5.00%
لا يوجد نزف	85.00%	90.00%	90.00%	95.00%

**Table 7** Frequency and Percentage Distribution of Delayed Bleeding Occurrence or Non-Occurrence in the Groups

Group	Bandage	Frequency Distribution			Percentile Distribution		
		Bleeding	Non-Bleeding	P (n)	Bleeding	Non-Bleeding	P (%)
Aspirin	R (Gelfoam)	n=2	n=18	n=20	10%	90%	100%
	L (Surgicel)	n=1	n=19	n=20	5%	95%	100%
Warfarin	R (Gelfoam)	n=3	n=17	n=20	15%	85%	100%
	L (Surgicel)	n=2	n=18	n=20	10%	90%	100%

#### 4.3 Gingival Healing Index (Ordinal Scale 1–5)

**Table. 8** Paired T-test results comparing Gelfoam and Surgicel within each group

Group	Day 3		Day 7
Warfarin	Column E	D3 (W+ S)	D7 (W +S)
	vs.	vs.	vs.
	Column A	D3 (W+ G)	D7 (W + G)
	Paired t test		
	P value	0.01036	0.01625
	P value summary	****	****
	Significantly different (P < 0.05)?	Yes	Yes
	One- or two-tailed P value?	Two-tailed	Two-tailed
Asprin	Column B	D3 (A+S)	D7 (A+S)
	vs.	vs.	vs.
	Column A	D3 (A+G)	D7 (A+G)
	Paired t test		
	P value	0.0896	0.02345
	P value summary	****	****
	Significantly different (P < 0.05)?	Yes	Yes
	One- or two-tailed P value?	Two-tailed	Two-tailed
	Number of pairs	20	20

**Table. 9 Independent T-test results comparing Gelfoam and Surgicel within each group**

Group		Day 3	Day 7
<b>Gelfoam</b>	Table Analyzed	G	G
	<b>Column G</b>	<b>D3 (A+G)</b>	<b>D7(A+G)</b>
	<b>vs.</b>	<b>vs.</b>	<b>vs.</b>
	<b>Column A</b>	<b>D3 (W+G)</b>	<b>D7(W+G)</b>
	<b>Unpaired t test</b>		
	P value	0.3142	0.1265
	P value summary	***	****
	Significantly different (P < 0.05)?	Yes	Yes
<b>Surgicel</b>	Table Analyzed	S	S
	<b>Column H</b>	<b>D3 (A+S)</b>	<b>D7 (A+S)</b>
	<b>vs.</b>	<b>vs.</b>	<b>vs.</b>
	<b>Column B</b>	<b>D3 (W+S)</b>	<b>D7 (W+S)</b>
	<b>Unpaired t test</b>		
	<b>P value</b>	0.7022	0.959
	P value summary	****	*
	Significantly different (P < 0.05)?	Yes	Yes
	One- or two-tailed P value?	one-tailed	one-tailed
	Sample size, column	20	20
	Sample size, column	20	20

#### 4.4 Pain Assessment (VAS Score 0–10)

**Table 10** Descriptive Statistics for Mean VAS Scores at Different Time Points for the Study Groups

	Day	Group	Average	SD	Max	Min
<b>Warfarin (n=20)</b>	<b>D1</b>	<b>(W+G)</b>	8.25	0.79	9	7
		<b>(W+S)</b>	6.90	0.97	9	6
	<b>D3</b>	<b>(W+G)</b>	5.60	0.60	7	5



<b>Asprin (n=20)</b>	<b>D7</b>	(W+S)	4.55	0.60	6	4
		(W+G)	3.65	0.59	5	3
		(W+S)	2.15	0.67	3	1
	<b>D1</b>	(A+G)	8.05	0.69	9	7
		(A+S)	5.85	0.81	7	5
	<b>D3</b>	(A+G)	4.75	0.64	6	4
		(A+S)	3.50	0.61	5	3
	<b>D7</b>	(A+G)	2.65	0.49	3	2
		(A+S)	1.65	0.49	2	1

**Table. 11** ANOVA results comparing pain across time for each group

Group	F- value	P- value
Asprin	271.1	<0.0001
warfarin	191.1	<0.0001

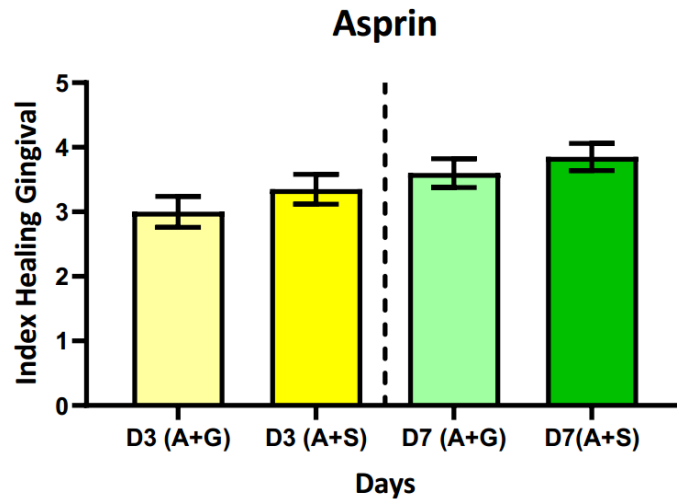
**Table. 12** Paired T-test to compare Gelfoam and Surgicel within each group

Group		Day 1	Day 3	Day 7
<b>Warfarin</b>	<b>Column E</b>	<b>D1 (S+W)</b>	<b>D3 (S+W)</b>	<b>D7 (S+W)</b>
	<b>vs.</b>	<b>vs.</b>	<b>vs.</b>	<b>vs.</b>
	<b>Column A</b>	<b>D1 (G+W)</b>	<b>D3 (G+W)</b>	<b>D7 (G+W)</b>
	<b>Paired t test</b>			
	P value	<0.0001	<0.0001	<0.0001
	P value summary	****	****	****
	Significantly different (P < 0.05)?	Yes	Yes	Yes
	One- or two-tailed P value?	Two-tailed	Two-tailed	Two-tailed
	Number of pairs	20	20	20
<b>Asprin</b>	<b>Column B</b>	<b>D1 (A+S)</b>	<b>D3 (A+S)</b>	<b>D7 (A+S)</b>
	<b>vs.</b>	<b>vs.</b>	<b>vs.</b>	<b>vs.</b>
	<b>Column A</b>	<b>D1 (A+G)</b>	<b>D3 (A+G)</b>	<b>D7 (A+G)</b>
	<b>Paired t test</b>			
	P value	<0.0001	<0.0001	<0.0001
	P value summary	****	****	****
	Significantly different (P < 0.05)?	Yes	Yes	Yes

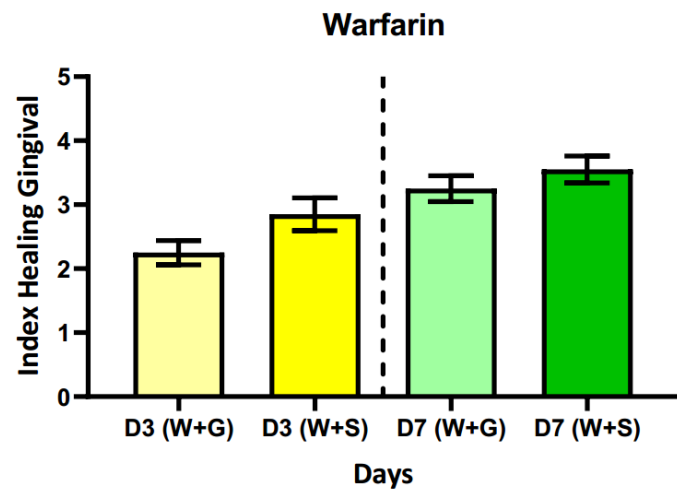
	One- or two-tailed P value?	Two-tailed	Two-tailed	Two-tailed
	Number of pairs	20	20	20

**Table. 13 Independent T--test to compare Gelfoam and Surgicel within each group**

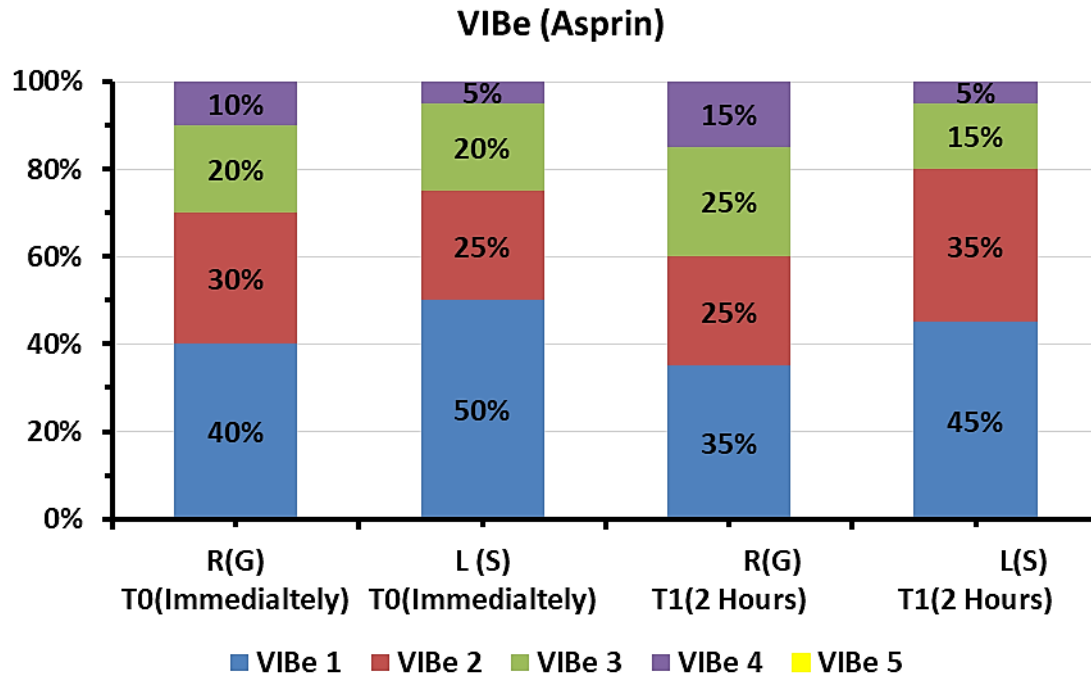
Group		Day 1	Day 3	Day 7
Gelfoam	Table Analyzed	G	G	G
	<b>Column G</b>	<b>D1 (A+G)</b>	<b>D3 (A+G)</b>	<b>D7(A+G)</b>
	<b>vs.</b>	<b>vs.</b>	<b>vs.</b>	<b>vs.</b>
	<b>Column A</b>	<b>D1 (W+G)</b>	<b>D3 (W+G)</b>	<b>D7(W+G)</b>
	Unpaired t test			
	P value	0.3969	0.0001	<0.0001
	P value summary	ns	***	****
	Significantly different (P < 0.05)?	No	Yes	Yes
	One- or two-tailed P value?	Two-tailed	Two-tailed	Two-tailed
	Sample size, column	20	20	20
	Sample size, column	20	20	20
Surgicel	Table Analyzed	S	S	S
	<b>Column H</b>	<b>D1 (A+S)</b>	<b>D3 (A+S)</b>	<b>D7 (A+S)</b>
	<b>vs.</b>	<b>vs.</b>	<b>vs.</b>	<b>vs.</b>
	<b>Column B</b>	<b>D1 (W+S)</b>	<b>D3 (W+S)</b>	<b>D7 (W+S)</b>
	Unpaired t test			
	P value	0.0007	<0.0001	0.0105
	P value summary	***	****	*
	Significantly different (P < 0.05)?	Yes	Yes	Yes
	One- or two-tailed P value?	Two-tailed	Two-tailed	Two-tailed
	Sample size, column	20	20	20
	Sample size, column	20	20	20



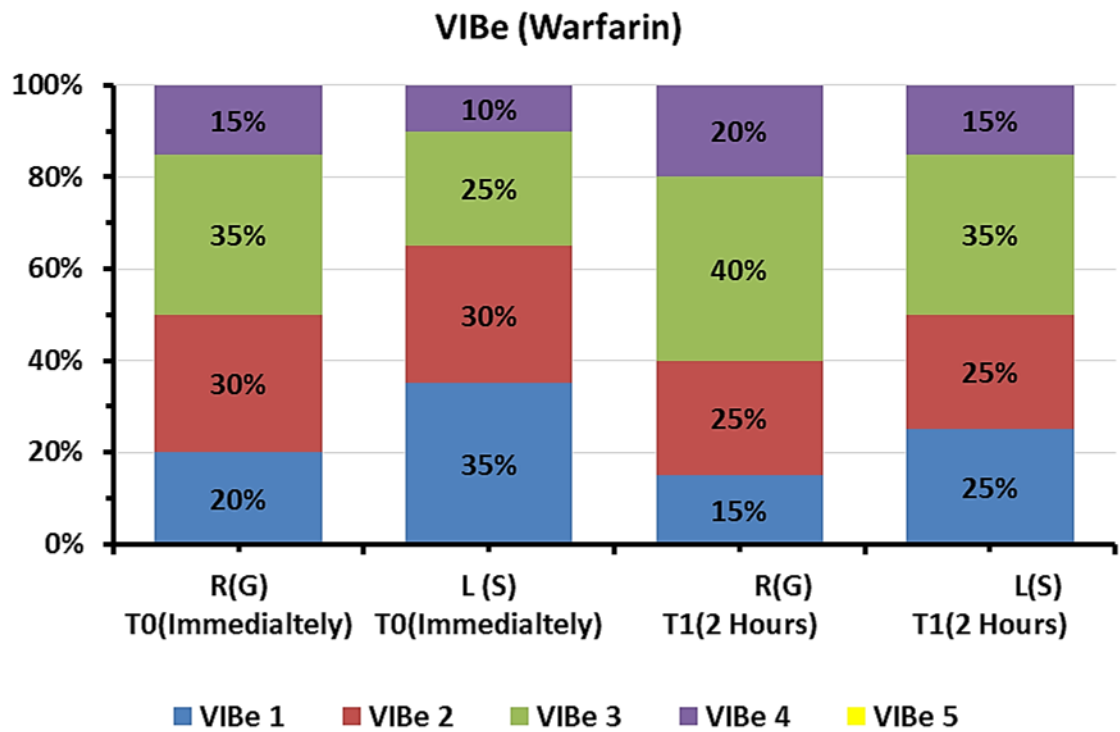
**Fig. 3** Healing rate for aspirin patients over days



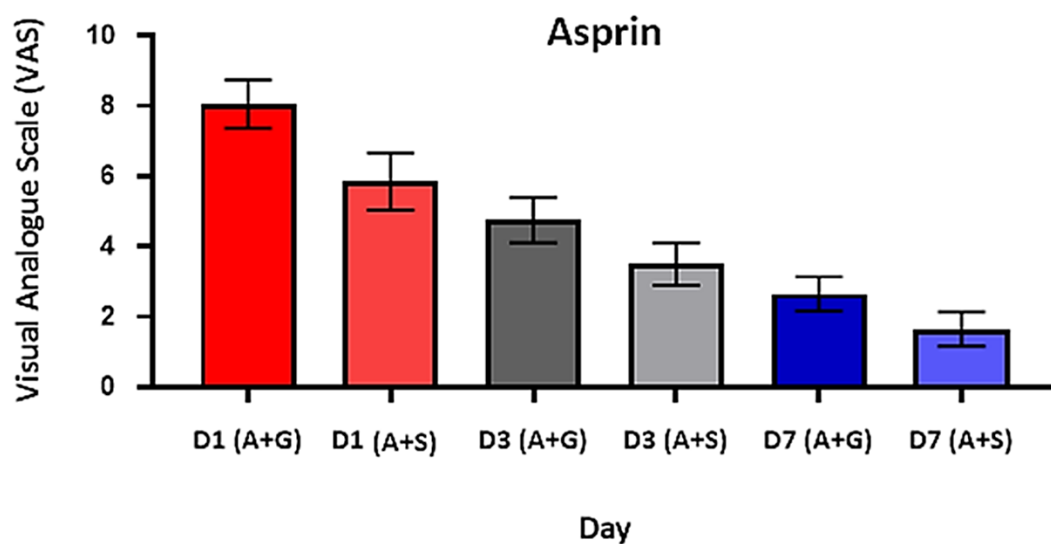
**Fig. 4** Healing rate for warfarin patients over days



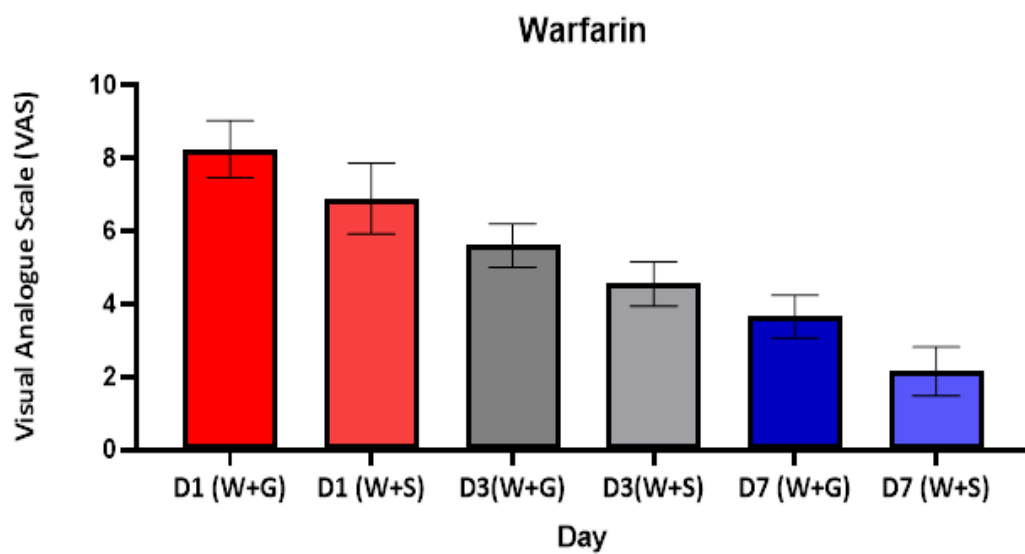
**Fig.5** Bar chart showing the percentile distribution of VIBe values in the aspirin group across study periods.



**Fig.5** Frequency distribution of warfarin group patients by VIBe values across study periods.



**Fig.6** Descriptive data for VAS values in the aspirin group.



**Fig. 7** Descriptive data for VAS pain index in the warfarin group.

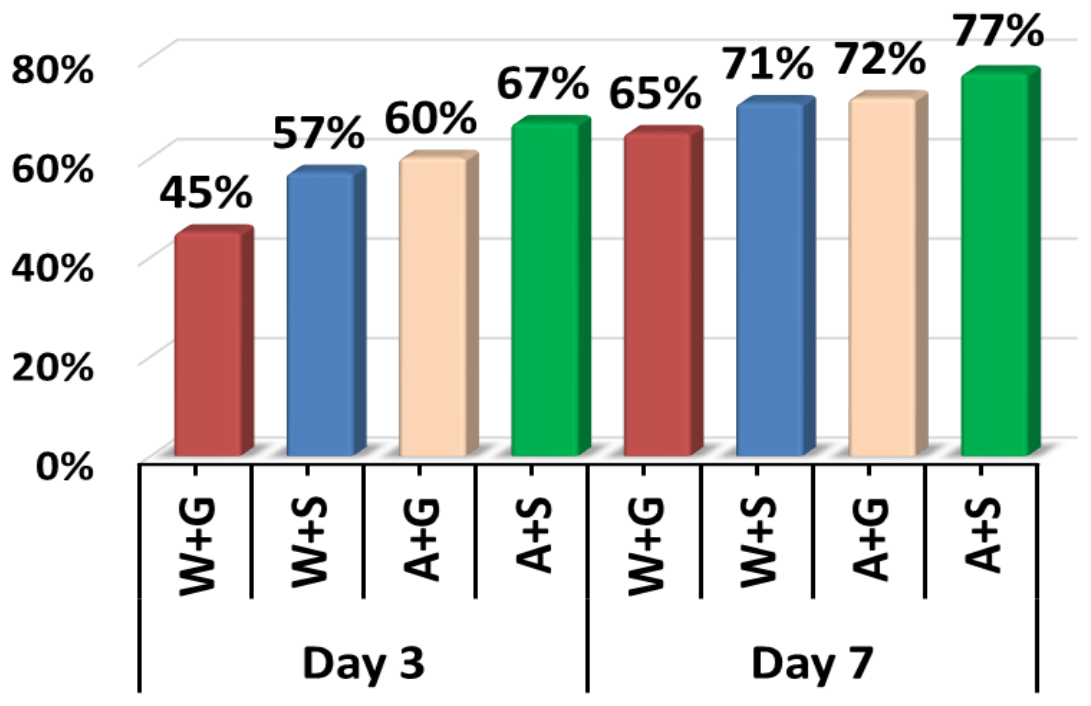


Fig. 8 Comparison of recovery rates between the two groups.

Ages of patients admitted to the study (females and males)

female	male
49	53
65	72
45	48
63	52
57	55
60	48
70	67
55	59
67	63
61	47
58	65
66	55
54	59
69	49
58	61
62	49
54	65

	62	54
	57	
	52	
	58	
	61	
avrage	59.2272727	56.72222
n	22	18
sd	6.30141192	7.513169