

**Plication of Fascia Transversalis in Comparison to no Plication to Reduce Seroma
Formation Post Laparoscopic Transabdominal Preperitoneal Repair for Direct Inguinal
Hernia : a Randomized Controlled Trial.**

Statistical analysis:

Statistical analysis was performed with SPSS 27 ® (Statistical Package for Scientific Studies), Graph pad prism & windows excel.

Exploration of the pain data was performed using Shapiro-Wilk test and Kolmogorov-Smirnov test for normality which revealed that the significant level (P-value) was insignificant as P-value >0.05 which indicated data originated from normal distribution. Accordingly, comparison between 2 groups was performed by using Independent t test. In Qualitative data, all comparisons were performed by using Chi square test and Fishers Exact test. The significant level was set to be at $P \leq 0.05$.

I. Demographic data:

The mean age of the *Plication* group was 50.60 ± 8.28 years, while that of the *No Plication* group was 49.08 ± 12.49 years, with a mean difference of 1.52 ± 1.75 years (95% CI: -1.95 to 4.99, $p = 0.39$).

Similarly, the mean BMI was 27.63 ± 2.89 kg/m² in the *Plication* group and 27.05 ± 2.94 kg/m² in the *No Plication* group, with a mean difference of 0.58 ± 0.48 (95% CI: -0.37 to 1.54, $p = 0.23$). These results indicate no statistically significant differences between the two groups regarding age or BMI, confirming that both groups were demographically comparable at baseline.

Table 1: demographic data of both groups:

	Group				Independent t test				
	Plication		No Plication		Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference		P value
	Mean	Standard Deviation	Mean	Standard Deviation			Lower	Upper	
Age	50.60	8.28	49.08	12.49	1.52	1.75	-1.95	4.99	0.39
BMI	27.63	2.89	27.05	2.94	0.58	0.48	-0.37	1.54	0.23

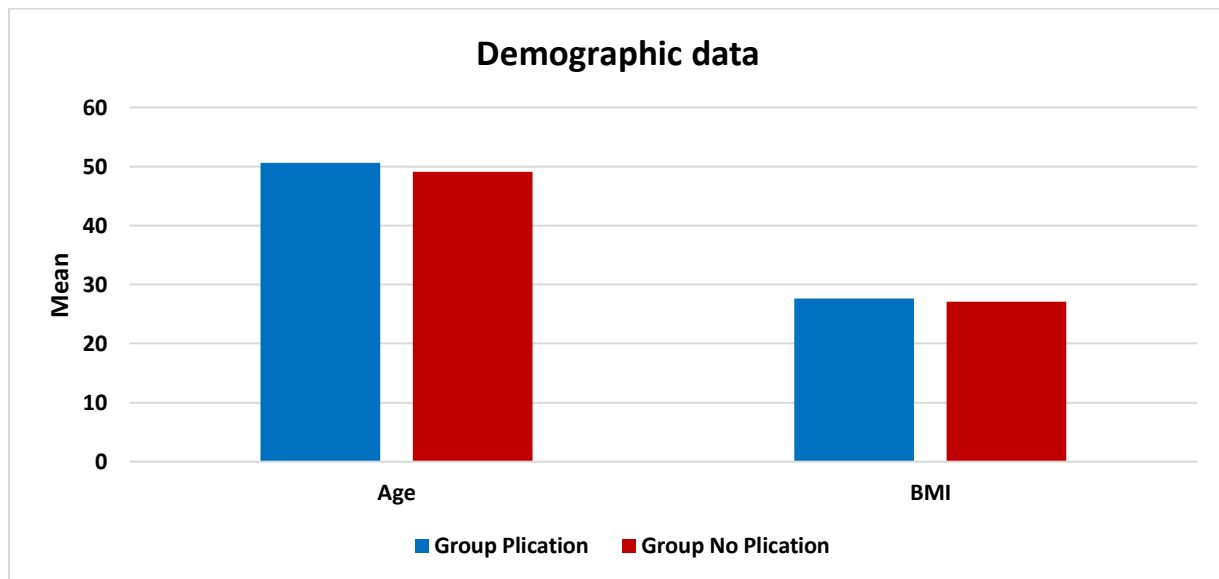


Figure (1): bar chart showing Demographic data.

II. Preoperative data:

There were no statistically significant differences between the Plication and No Plication groups regarding preoperative albumin (4.18 ± 0.18 vs 4.19 ± 0.19 g/dL, $p = 0.688$) or defect size (1.55 ± 0.76 vs 1.75 ± 0.78 cm, $p = 0.136$). Similarly, the two groups showed no significant differences in smoking status ($p = 0.55$), anticoagulant use ($p = 0.56$), previous groin surgery ($p = 1.00$), bilaterality ($p = 1.00$), hernia side ($p = 0.88$), hernia size type ($p = 0.96$), diabetes mellitus ($p = 0.90$), or hypertension ($p = 0.91$). These findings indicate that both groups were clinically comparable at baseline, minimizing confounding factors.

Table 2: preoperative data of both groups:

		Group				P value
		Plication		No Plication		
Preoperative Albumin (g/dL) M ± SD		4.18	0.18	4.19	0.19	0.688
Defect Size (cm) M ± SD		1.55	.76	1.75	.78	0.136
Smoking Status N(%)	no	58	79.5%	55	75.3%	0.55
	yes	15	20.5%	18	24.7%	
Anticoagulant Use N(%)	no	71	97.3%	72	98.6%	0.56
	yes	2	2.7%	1	1.4%	
Previous Groin Surgery N(%)	no	73	100.0%	73	100.0%	1
Bilateral Hernia N(%)	no	63	86.3%	63	86.3%	
	yes	10	13.7%	10	13.7%	
Hernia side N(%)	right	33	45.2%	35	47.9%	0.88
	left	28	38.4%	28	38.4%	
	bilateral	12	16.4%	10	13.7%	
Hernia type N(%)	direct	73	100.0%	73	100.0%	----
Hernia Size Type N(%)	Funicular	32	43.8%	32	43.8%	0.96
	bubonocoele	34	46.6%	33	45.2%	
	inguinoscrotal	7	9.6%	8	11.0%	
Diabetes Mellitus N(%)	No	58	79.5%	49	80.3%	0.9
	Yes	15	20.5%	12	19.7%	
Hypertension N(%)	No	58	79.5%	48	78.7%	0.91
	Yes	15	20.5%	13	21.3%	

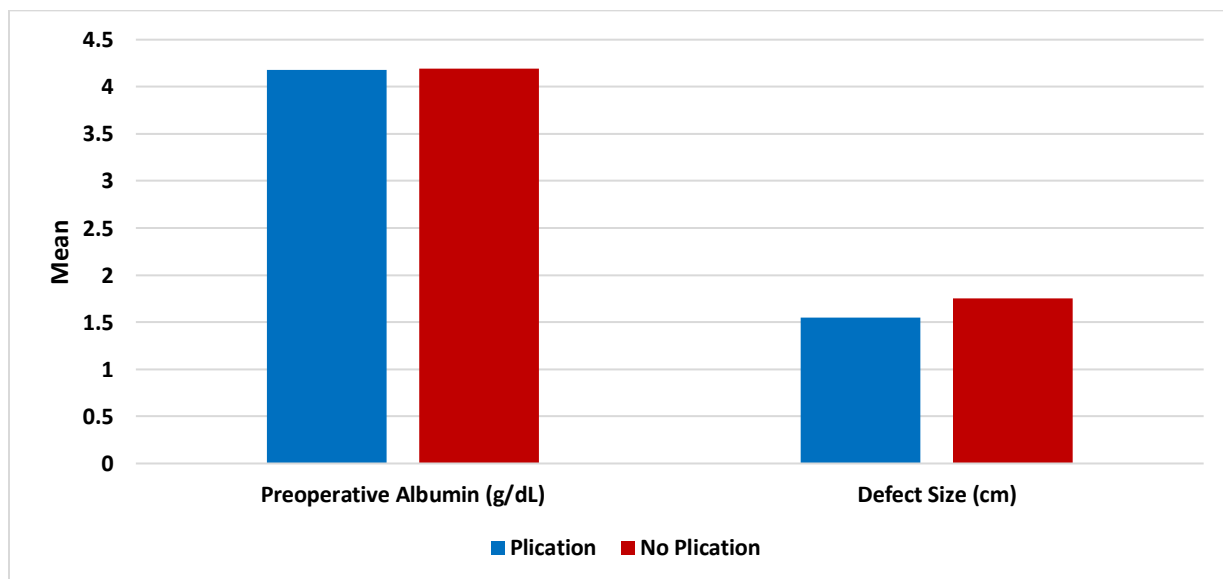


Figure (2): bar chart showing preop comparison between groups regarding albumin levels and defect size.

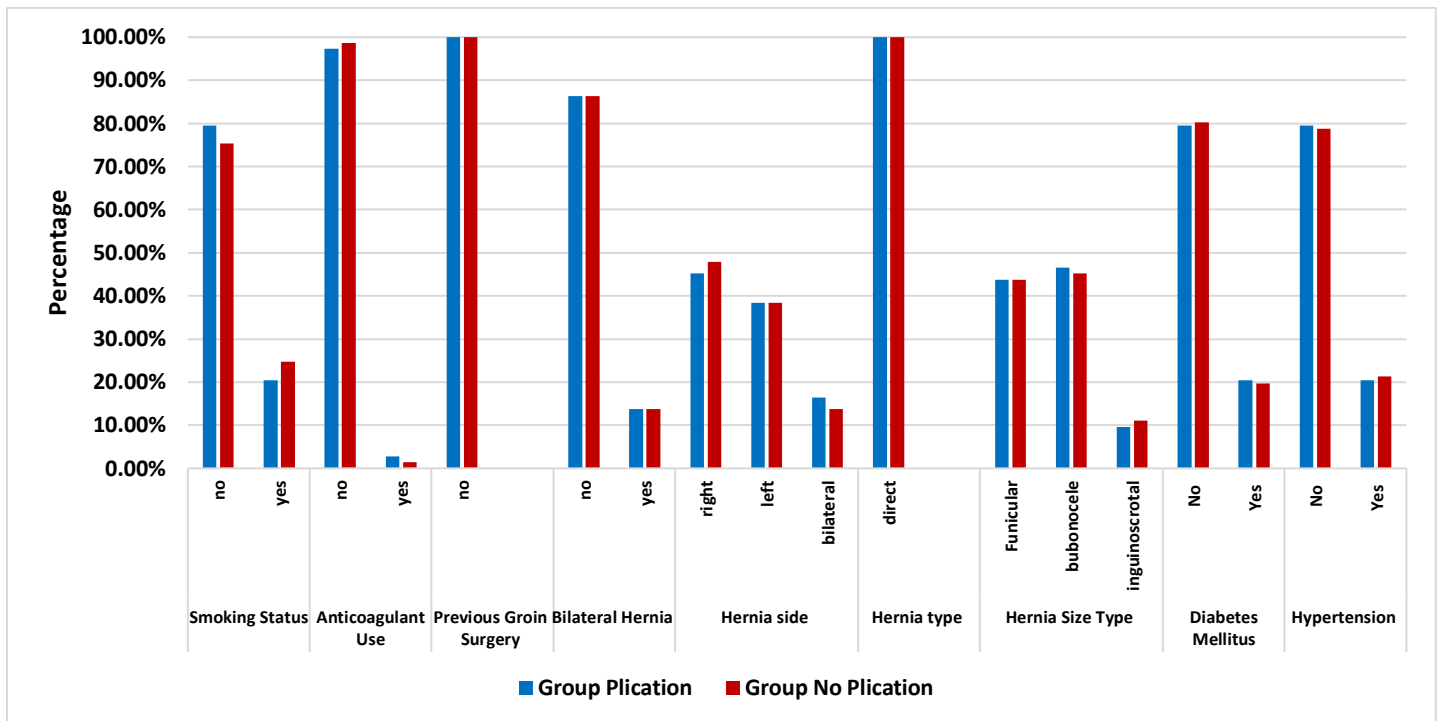


Figure (3): bar chart showing preoperative comparison between both groups.

III. Operation data:

All patients in the *Plication* group underwent suture plication, whereas none in the *No Plication* group did ($p < 0.0001$). Both groups used lightweight mesh with suture fixation exclusively.

The mean operative duration was **109.13 ± 27.77 minutes** in the *Plication* group and **108.36 ± 24.57 minutes** in the *No Plication* group, with **no significant difference** between them ($p = 0.80$).

Table 3: Operative data of both groups:

		Group				P value
		Plication		No Plication		
Plication N (%)	no suture	0	0.0%	73	100.0%	<0.0001*
	suture	73	100.0%	0	0.0%	

Type of Mesh N (%)	Lightweight	73	100.0%	73	100.0%	-----
Mesh Fixation N(%)	Suture	73	100.0%	73	100.0%	-----
Duration of Surgery (min) M ± SD		109.13	27.77	108.36	24.57	0.8

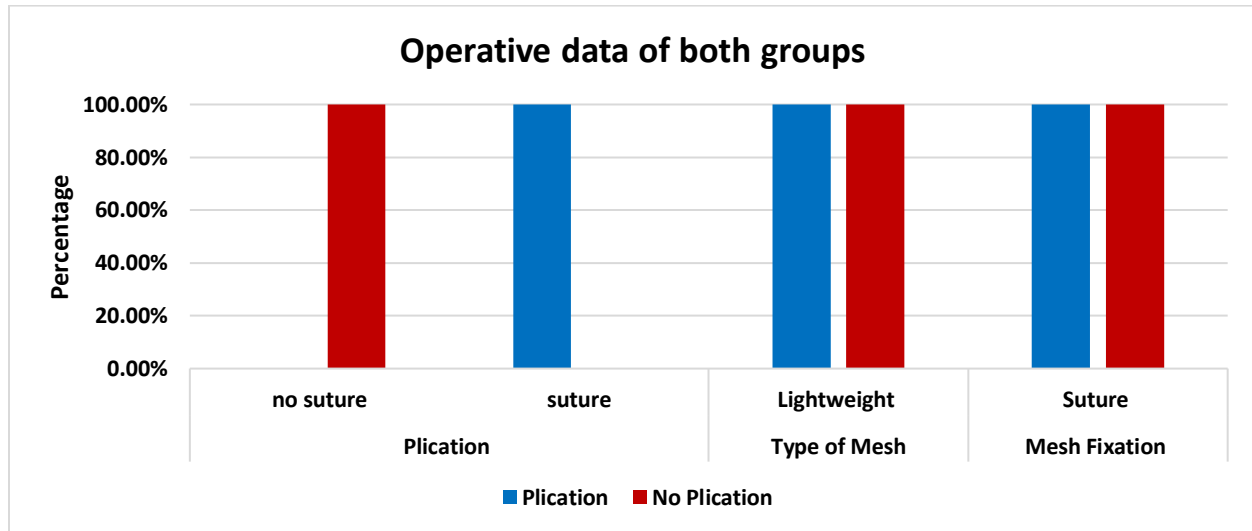


Figure (4): bar chart showing Operative data of both groups.

IV. Pain score:

Pain scores were significantly lower in the Plication group compared with the No Plication group at all postoperative time points. On postoperative day 2, the mean pain score was 4.08 ± 0.00 versus 4.04 ± 0.00 ($p < 0.0001$). At day 10, pain decreased to 1.68 ± 0.00 versus 2.24 ± 0.00 ($p < 0.0001$), and by day 30, further declined to 0.60 ± 0.00 versus 1.36 ± 0.00 ($p < 0.0001$). These results indicate a consistently lower postoperative pain level in the Plication group throughout the follow-up period.

Table 4: Pain score of both groups:

Pain Score	Group M ± SD				Mean Difference	Std. Error Difference	95% Confidence Interval of the Difference		P value
	Plication		No Plication				Lower	Upper	
Post-op Day 2	4.080	0.000	4.040	0.000	0.04	0.0	0.04	0.04	<0.0001*
At Day 10	1.680	0.000	2.240	0.000	-0.56	0.0	-0.56	-0.56	<0.0001*
At Day 30	0.600	0.000	1.360	0.000	-0.76	0.0	-0.76	-0.76	<0.0001*

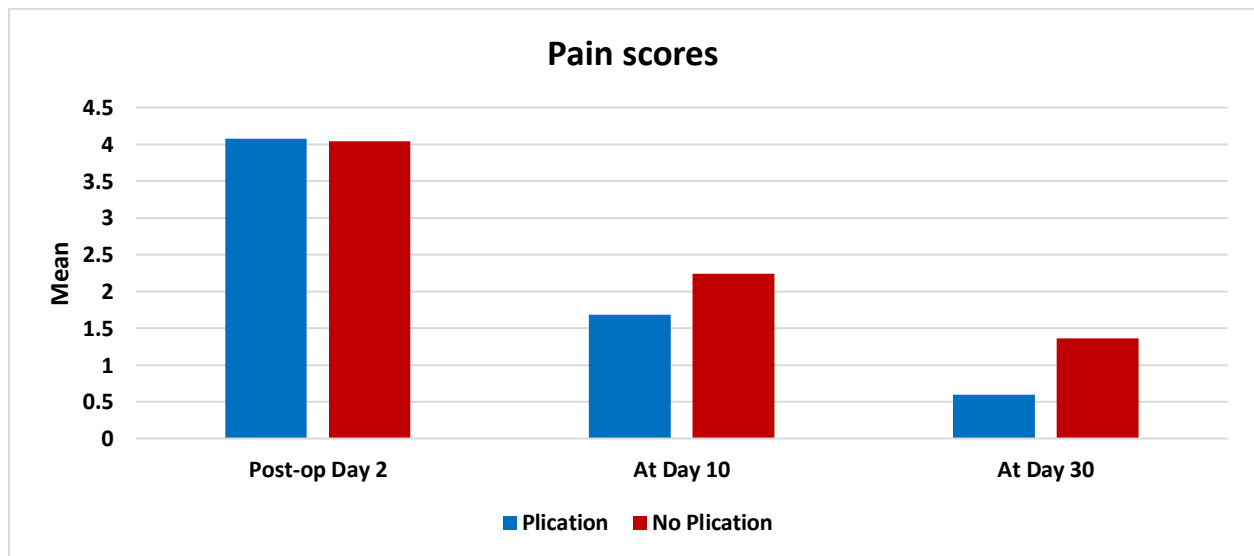


Figure (5): bar chart showing Pain score of both groups.

V. Postoperative evaluation

Both groups had identical hospital stays of 1 day postoperatively. However, the incidence of seroma was significantly higher in the No Plication group compared with the Plication group at all time points — Day 2 (19.2% vs 2.7%, $p = 0.001$), Day 10 (16.4% vs 2.7%, $p = 0.005$), and Day 30 (12.3% vs 0.0%, $p = 0.002$). There were no cases of chronic pain in either group at 3 months. Hernia recurrence occurred in only one patient (1.4%) in the No Plication group, with no significant difference between groups ($p = 0.32$). No other postoperative complications were reported.

Table 5: Postoperative of both groups:

Post operative	Group N(%)					P value
		Plication		No Plication		
Hospital Stay (days)	1 day	73	100.0%	73	100.0%	----
Seroma at Post-op Day 2	No	71	97.3%	59	80.8%	0.001*
	Yes	2	2.7%	14	19.2%	
Seroma at Day 10	No	71	97.3%	61	83.6%	0.005*
	Yes	2	2.7%	12	16.4%	
Seroma at Day 30	No	73	100.0%	64	87.7%	0.002*
	Yes	0	0.0%	9	12.3%	
Chronic Pain at Month 3 (1/0)	No	73	100.0%	73	100.0%	----
Hernia Recurrence at 30 Days (1/0)	No	73	100.0%	72	98.6%	0.32
	Yes	0	0.0%	1	1.4%	

Post-op Complications	No	73	100.0%	72	100.0%	-----
-----------------------	----	----	--------	----	--------	-------

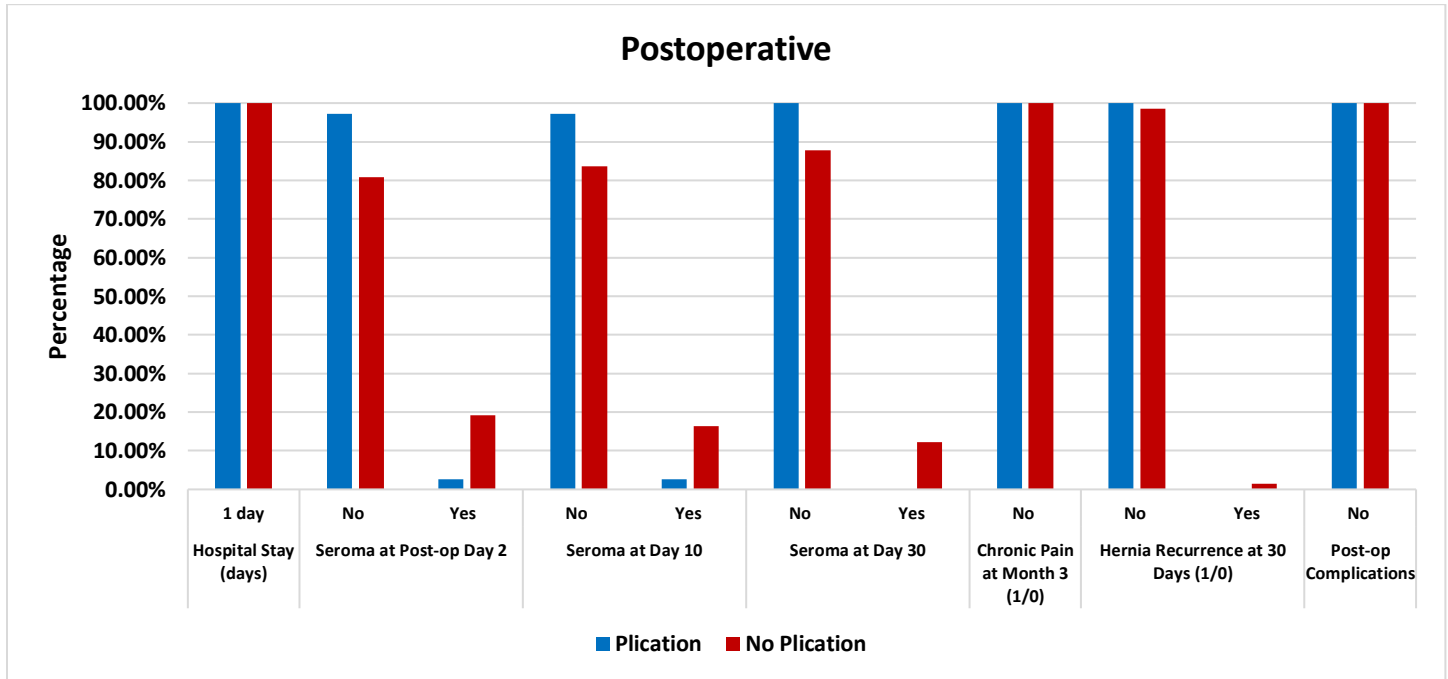


Figure (6): bar chart showing Postoperative of both groups.