A RANDOMIZED PROSPECTIVE COMPARATIVE TRIAL BETWEEN FiLaC WITH LIFT VS LAY OPEN IN TREATMENT OF SIMPLE FISTULA IN ANO

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Introduction

Through the past decades, various surgical techniques have been introduced as modern modalities for the treatment of perianal fistula, to provide an effective and minimally invasive option in comparison with the conventional lay open technique which is the gold standard surgical treatment.

Aim of the Work

The aim of this study was to compare two different techniques for management of simple perianal fistula which are FiLaC™ combined with LIFT as a modern technique vs classic lay-open technique as regarding the following parameters:-
incidence of postoperative pain using Visual Analogue Scale pain scoring (VAS), duration needed for wound healing, fecal incontinence using Cleveland Clinic Fecal Incontinence Severity Scoring System (CCIS), quality of life using Global Quality of Life Scale and recurrence. The last three parameters were assessed till six months post-operative.

Patients and Methods

This study was conducted at Alexandria Main University Hospital. Sixty cases with simple trans-sphincertric perianal fistula were enrolled in our study, thirty cases were treated with FiLaC™+ LIFT (group A) and thirty cases with classic lay open (group B). Assessment of postoperative pain for one month and duration needed for wound healing were reported. Also assessment of fecal incontienece,quality of life and recurrence were recorded for six months and all the data was analyzed.

Results

Table 1: Comparison between the two studied groups according to anal pain according to VAS

Anal pain	Group A (n = 30)		Group B (n = 30)		χ^2	MCp
	No.	%	No.	%		
1st day - postoperative						
No pain	11	36.7	0	0.0	19.190*	<0.001*
Mild	15	50.0	13	43.3		
Moderate	4	13.3	17	56.7		
Severe	0	0.0	0	0.0		
1st week – postoperative						
No pain	27	90.0	18	60.0	7.233*	0.017*
Mild	3	10.0	11	36.7		
Moderate	0	0.0	1	3.3		
Severe	0	0.0	0	0.0		
1st month – postoperative						
No pain	30	100.0	30	100.0	-	-
Mild	0	0.0	0	0.0		
Moderate	0	0.0	0	0.0		
Severe	0	0.0	0	0.0		

χ^2: Chi square test , MC: Monte Carlo test
p: p value for comparing between group **A** and **B**
*: Statistically significant at $p \leq 0.05$

Table 2: Comparison between the two studied groups according to post-operative fecal incontinence assessed by Wexner score

Fecal incontinence	Group A (n = 30)	Group B (n = 30)	U	P
1st day - postoperative				
Min. – Max.	0.0 – 7.0	0.0 – 10.0	320.0*	0.028*
Mean ± SD.	1.23 ± 2.16	2.57 ± 2.66		
Median (IQR)	0.0 (0.0 – 4.0)	4.0 (0.0 – 5.0)		
1st month – postoperative				
Min. – Max.	0.0 – 7.0	0.0 – 10.0	342.50	0.062
Mean ± SD.	1.10 ± 2.11	2.13 ± 2.52		
Median (IQR)	0.0 (0.0 – 0.0)	1.0 (0.0 – 4.0)		
3rd month - postoperative				
Min. – Max.	0.0 – 7.0	0.0 – 10.0	340.50*	0.044*
Mean ± SD.	0.83 ± 1.97	1.87 ± 2.52		
Median (IQR)	0.0 (0.0 – 0.0)	0.0 (0.0 – 4.0)		
6th month – postoperative				
Min. – Max.	0.0 – 7.0	0.0 – 10.0	340.50*	0.044*
Mean ± SD.	0.83 ± 1.97	1.87 ± 2.52		
Median (IQR)	0.0 (0.0 – 0.0)	0.0 (0.0 – 4.0)		

U: Mann Whitney test
*: Statistically significant at $p \leq 0.05$
p: p value for comparing between group **A** and **B**
IQR: **Inter quartile range**, SD: **Standard deviation**

Conclusion

Both lay-open and FiLaC™ +LIFT techniques were secure and efficient in the treatment of simple trans-sphincteric perianal fistula. The laser procedure is feasible, appears to be relatively easy technique to learn and has been documented to be safe with no reports of fecal incontinence. The FiLaC™ +LIFT technique has proven superiority to lay-open technique in terms of post-operative pain score (VAS), fecal incontinence (CCIS), wound healing and quality of life. However, the incidence of recurrence was approximate to each other with no statistically significant difference.