EFFECTIVENESS OF LYOPHILIZED GROWTH FACTORS FOR SUBACROMIAL IMPINGEMENT: RANDOMIZED DOUBLE BLIND PLACEBO CONTROLLED STUDY

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Introduction

Subacromial impingement syndrome (SIS) is the most commonly reported shoulder pathology that affects various aspects of patients' daily activities. It implies the mechanical compression of rotator cuff tendons, long head of biceps and subacromial/subdeltoid bursae under the coracoacromial arch. Several factors are thought to be involved, such as acromioclavicular joint arthritis, acromial spurs, weakness of rotator cuff muscles, rotator cuff tendinopathy and abnormal kinematic pattern of periscapular muscles. Some or all of these factors work together resulting in the reduction of the potential space for rotator cuff tendons in the subacromial space and thus triggers the pathological cascade associated with the development of SIS. Treatment remains controversial as implicated by its multifactorial nature and its disparate theories of pathogenesis. Recently, the injection of lyophilized growth factors (L-GF) has proved to be a safe and effective novel injection material for different degenerative musculoskeletal disorders. It is thus interesting to study its effect on SIS.

Aim of the work

The aim of this study was to evaluate the efficacy of ultrasound-guided injection of platelet-derived lyophilized growth factors in treatment of SIS.

Subjects & Methods

- Sixty patients with SIS (subacromial bursitis, supraspinatus tendinosis and partial thickness tear) were included in the study. They were clinically diagnosed with SIS when they had anterolateral shoulder pain, a painful arc of motion and positive impingement signs (Neer's or Hawkins-Kennedy). Then, diagnosis was confirmed ultrasonographically when a transient arc of pain was elicited during shoulder abduction, coinciding with the visualization of the passage of the supraspinatus insertion beneath the coracoacromial arch.
- The study was double blind. Simple randomization method was used to allocate patients into 2 groups. The trained nurse prepared a wrapped syringe (to conceal its content), either saline or L-GF and the injection was done under ultrasonographic guidance.
- Exclusion criteria included previous shoulder surgery, fracture, frozen shoulder or full-thickness supraspinatus tendon tear.

Results

The patients in this study had a mean age of 47 years. Forty were females and twenty males. There was no statistically significant difference between the two groups as regards age, gender, disease duration, occupation or handedness.

At follow up, number of patients with subacromial tenderness was significantly less in the L-GF group than in saline group.

The L-GF group has shown significantly greater reduction in Visual analogue scale (VAS) score at follow up than the saline group.

Table 1: Comparison within and between the 2 groups at baseline and follow up, according to active and passive internal rotation ROM.

		Saline group n=30 mean ± SD	L-GF group n=30 mean ± SD	t2	p2
Active internal rotation (degrees)	Baseline	74.83 ± 15.40	75.67 ± 16.01	-.205	.838
	Follow up	78.83 ± 13.18	87.33 ± 11.43	-2.669	**.010***
	t1	-1.574	-4.96		
	p1	.126	**<.001***		
Passive internal rotation (degrees)	Baseline	77.33 ± 14.72	80.33 ± 14.85	-.786	.435
	Follow up	81.33 ± 12.38	91.00 ± 9.51	-3.392	**.001***
	t1	-1.445	-4.016		
	p1	.159	**<.001***		

t1: Paired samples t-test, t2: Independent samples t-test, p1: of paired samples t-test, p2: of independent samples t-test.

There was statistically significant improvement in both active and passive internal rotation ROM in the L-GF group at follow up compared to the saline group.

Table 2: Comparison within and between the 2 groups at baseline and follow up, according to VAS, SPADI total and SPADI subscales.

		Saline group n=30 mean ± SD	L-GF group n=30 mean ± SD	t2	p2
VAS	Baseline	7.67 ± 1.92	6.90 ± 1.83	1.585	.118
	Follow up	5.87 ± 2.60	3.97 ± 2.57	2.851	**.006***
	t1	3.949	7.478		
	p1	**<.001***	**<.001***		
SPADI-Pain scale (%)	Baseline	69.37 ± 17.19	60.03 ± 16.75	2.130	**.037***
	Follow up	55.95 ± 27.02	39.20 ± 24.26	2.527	**.014***
	t1	2.843	4.851		
	p1	**.008***	**<.001***		
SPADI-Disability scale (%)	Baseline	56.40 ± 19.35	47.73 ± 19.96	1.708	.093
	Follow up	48.50 ± 25.58	28.67 ± 20.52	3.312	**.002***
	t1	1.819	4.565		
	p1	.079	**<.001***		
SPADI-Total (%)	Baseline	61.28 ± 16.76	52.63 ± 16.65	2.005	**.050***
	Follow up	51.36 ± 24.92	32.87 ± 20.61	3.132	**.003***
	t1	2.356	5.084		
	p1	**.025***	**<.001***		

VAS: Visual analogue scale, SPADI: Shoulder Pain And Disability Index, t1: Paired samples t-test, t2: Independent samples t-test, p1: of paired samples t-test, p2: of independent samples t-test.

There was statistically significant improvement regarding VAS, SPADI-Pain scale and SPADI-Total baseline and follow up mean values in each of the 2 groups. Only the L-GF group has shown statistically significant improvement regarding SPADI-Disability scale.

Table 3: Comparison between the two studied groups as regards improvement at follow up of painful arc.

	Comparison point	Saline group n=30	L-GF group n=30	p
Painful arc	Negative	1 (3%)	12 (40%)	**.001***
	Positive	29 (97%)	18 (60%)	
SPADI-Total change	Improvement	19	27	**.03***
	Worsening	11	3	

p: of Fischer's Exact Test

A significantly higher number of cases in the L-GF group have shown a negative painful arc sign at follow up compared to the saline group.

Any reduction in SPADI-total score at follow up was considered improvement and any increase was considered worsening. The L-GF group has shown improvement in 27 cases (90%) compared to 19 cases (63%) in the saline group. The difference was statistically significant.

Table 4: Comparison within and between the 2 groups at baseline and follow up, according to ultrasound measurment of supraspinatus tendon thickness

		Saline group n=30 mean ± SD	L-GF group n=30 mean ± SD	t2	p2
US-L (mm)	Baseline	6.3 ± 1.1	6.0 ± 1.3	.933	.355
	Follow up	6.2 ± 1.2	5.8 ± 1.2	1.132	.262
	t1	1.340	2.147		
	p1	.191	**.040***		

US-L: Ultrasonographic measurement of supraspinatus tendon thickness in longitudinal view, t1: Paired samples t-test, t2: Independent samples t-test, p1: of paired samples t-test, p2: of independent samples t-test.

Only the L-GF group has shown statistically significant improvement in the supraspinatus tendon thickness in longitudinal view at follow up.

Conclusions

From this study it can be concluded that L-GF injection in patients with SIS has resulted in significant improvement as regards pain and disability according to the improvement in painful arc, VAS and SPADI, as compared to the saline group, as well as significant reduction in the thickness of the supraspinatus tendon.