

Randomized Controlled Trial Comparing Efficacy Of Conventional And New Single Larger Dose Of Intra-Articular Viscosupplementation In Management Of Knee Osteoarthritis

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INTRODUCTION

Intra-articular hyaluronic acid (HA) injection has been used in management of knee, hand and hip osteoarthritis (OA). While HA injection is included in the list of evaluated therapies, its efficacy and optimum dosing still has no consensus. This study was conducted to explore the possibility of using single injection HA to increase patient convenience while maintaining the therapeutic efficacy.

METHODS

We present a prospective, open label, non-blinded, randomized controlled trial performed in accordance with guidelines in principles of good clinical practice. Block randomization of patients was done with block size of two to receive single 5mls GO-ON injection or the conventional three injections of 2.5mls GO-ON at weekly interval. Baseline Western Ontario McMaster University Osteoarthritis (WOMAC) scores were evaluated and recorded. All subjects were re-evaluated at 3 months and the WOMAC score recorded again as primary end points. Data analyses were performed with IBM SPSS Statistics for Windows software (Version 20.0. Armonk, NY: IBM Corp).

RESULTS

In the cohort of 127 patients, 33 were males and 94 females. Mean age was 59.1 years (SD = 7.25) in single injection arm and 60.1 years (SD = 7.72) in triple injection arm. There was no significant difference recorded in age ($p=0.46$) and Kellgren-Lawrence radiological grade ($p=0.694$) in the two groups. There was a significant increase in the WOMAC scores from the baseline (pre-injection) to that recorded 3 months after the injection ($p<0.001$) in both groups. However, there was no statistically significant difference noticed in this clinical improvement between the two arms ($p=0.889$).

Variable	Mean (SE)		Mean (95% CI)	p-value
	Pre-op	Post-op	Diff. in score	
Overall	57.4 (137)	79 (1.13)	21.6 (19.1, 24.1)	<0.001

Table 1: Descriptive statistics between single and triple injection groups

Variables	Single inj. n (%)	Triple inj. n (%)	p-value
Age in yrs	59.1 (7.25)	60.1 (7.72)	0.461a
GENDER			
Male	10 (30.3)	23 (69.7)	0.010b
Female	53 (56.4)	41 (43.6)	
KELLGREN- LAWRENCE GRADE			
Grade 1	7 (50.0)	7 (50.0)	0.694b
Grade 2	32 (53.3)	28 (46.7)	
Grade 3	24 (45.3)	29 (54.7)	

Table 2: Changes in WOMAC scores post GO-ON injection in 127 patients.

DISCUSSION

Women are twice as likely to suffer from knee OA as men¹. While our study showed a female predominance, it does not contribute statistically to the primary outcome of the study. Lussier et al (1996) noted that patients with early and intermediate disease (Kellgren-Lawrence I-III) did better than patient with more advanced disease (Grade IV)². Most literature report a low incidence of local adverse reactions after conventional small dose repeated intra-articular knee viscosupplement injections^{3,4}. Results of our study showed similar adverse events which were generally self-limiting and transient. This new regime of single larger dose (5mls GO-ON injection) is convenient due to lesser frequency of injection and related events of localized adverse effects and also being cheaper. Our study