Randomized, Open-Labelled Controlled Trial Comparing Efficacy And Cost Of Single-And Weekly Multiple-Dose Regimens Of Intra-Articular Viscosupplementation In Knee Osteoarthritis – 1 Year Follow Up

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INTRODUCTION

Intra-articular hyaluronic acid (HA) injection is used in the management of knee, hand and hip Osteoarthritis (OA)[1]. This study was designed to compare the effectiveness of two different doses (5mL versus 2.5mL) and dosing intervals (single dose versus 3 times of weekly doses) of GO ON® (0.8–1.5 x 106 Da) in knee OA patients. Additionally, the costs incurred in government hospital setting by both regimens were compared.

METHODS

A prospective, open labelled, non-blinded, randomized controlled trial was performed in accordance with guidelines in principles of Good Clinical Practice (GCP). Block randomization was done for both groups. Baseline Western Ontario McMaster University Osteoarthritis (WOMAC) pain, stiffness, function and overall scores were evaluated and recorded. All subjects were re-evaluated at 3 & 12 months. Data analyzed with SPSS v21.0.

RESULTS

130 patients were randomised to two arms. 65 patients received single GO-ON® 5mls injection and 65 patients received triple GO-ON® injections. All patients improved markedly during the post injection period of 3 months and the effect was seen to be maintained up to 12 months (Table 1) while no statistically significant differences were seen in both groups (Table 2). About RM 91,717.68 was the estimated cost saving possible per year (provider and patient) in current setting.

Table 1: Comparison of the Pre and Post (3 and 12 months) GO-ON® injection WOMAC Score

	Pre		Post 3 months		Post 12 months		p-value[a]
	adj mean	(SE)	adj mean	(SE)	adj mean	(SE)	
Womac Pain	7.2	(0.40)	3.0	(0.33)	3.7	(0.38)	0.025
Womac Stiffness	3.3	(0.22)	1.4	(0.17)	3.2	(0.25)	0.188
Womac Function	28.7	(1.22)	13.9	(1.15)	15.0	(1.33)	0.020
Womac Overall	39.3	(1.76)	18.2	(1.54)	21.9	(1.85)	0.018

Note: [a] Repeated measure ANCOVA, adjusted by age, gender, X-ray K-L grade

adj= adjusted, SE=standard error

Table 2: Mean difference of pre and post (12 months) WOMAC score between single GO-ON® 5mls injection and triple GO-ON® 2.5mls Injections

	Single GO-ON® 5mls injection		Triple GO-ON® 2.5mls Injections		mean diff	95% CI	p-value[a]
	mean	(SD)	mean	SD			
Womac Pain	-4.1	(4.09)	-3.4	(3.85)	-0.67	(-2.08 , 0.74)	0.349
Womac Stiffness	-0.6	(2.37)	0.2	(2.61)	-0.74	(-1.62 , 0.14)	0.100
Womac Function	-15.2	(12.17)	-13.8	(12.16)	-1.46	(-5.77 , 2.84)	0.502
Womac Overall	-20.0	(17.53)	-17.0	(17.27)	-2.87	(-9.03 , 3.29)	0.358

Note: [a] independent-Samples T-test

diff = difference, SD = standard deviation, CI = confidence interval

DISCUSSIONS

Overall, patients showed significant improvement in WOMAC score post GO-ON® HA injection. Both groups exhibited a trend of better pattern of response throughout the study, and behaved similarly over the first three months when most of the therapeutic gain was observed, and afterwards the benefits obtained from the both groups tended to plateau, as acknowledge with most HA preparations[2].

CONCLUSION

The results demonstrated that one injection of 5mls GO ON® and 3 injections of 2.5mls GO ON® are comparably effective and well tolerated in knee OA, while single injection appeared to be more cost saving than conventional triple injections in the management of OA.

REFERENCES

1.Balazs EA, Denlinger JL. Viscosupplementation: a new concept in the

ABSTARCT TRUNCATED