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Original Article

Efficacy and Tolerability Evaluation of Nutraceutical Composition Containing Mucopolysaccharides, Collagen Type I, and Vitamin C in Tendinopathy: An Open-Label, Real-World Clinical Study

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ABSTRACT

Background: Tendinopathy is characterized by pain, inflammation, and functional impairment with standard therapies supporting short-term symptomatic improvement. Nutraceuticals have emerged as potential adjuncts in tendon repair and symptom management. This study aimed to evaluate the efficacy and tolerability of a combination of mucopolysaccharides, collagen type I, and vitamin C in participants with tendinopathy. **Materials and Methods:** Participants with clinically diagnosed tendinopathy were enrolled and assigned to either a standard therapy group (n=29) or active group (n=30). All participants received standard treatments, while the active group additionally received the test nutraceutical combination for 90 days. Symptom severity, including pain (at rest and during activity), stiffness, inflammation, mobility difficulty, weakness, and impact on daily and physical activity, along with Quality of Life (QoL), were assessed. **Results:** Both groups demonstrated significant improvements; however, the active group showed a significantly greater reduction in pain at rest (92.37% v/s. 69.53%), pain during activity (87.55% v/s. 40.31%), stiffness (87.05% v/s. 44.25%), and weakness (78.50% v/s. 45.07%) (all p<0.05). Improvements in daily and physical activities were also greater in the active group. Inflammation and mobility showed numerically better outcomes, though not statistically significant. No adverse effects were reported in either group. **Conclusion:** Supplementation with mucopolysaccharides, collagen type I, and vitamin C appears to enhance symptom relief and functional recovery in tendinopathy, supporting its use as a safe and effective adjunctive strategy.

Keywords: Collagen Type I, Mucopolysaccharides, Pain, Tendinopathy, Vitamin C.

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INTRODUCTION

Tendinopathy is a multifactorial tendon disorder involving structural and functional alterations due to disease or injury. It typically presents with pain, stiffness, inflammation, weakness, and reduced physical activity, impairing Quality of Life (QoL) (Agrawal *et al.*, 2020). The condition accounts for 30-50% of sports-related injuries and affects about 30% of individuals with musculoskeletal pain (Agrawal *et al.*, 2020; Loiacono *et al.*, 2019). Current management includes pharmacological, non-pharmacological, and surgical approaches (Agrawal *et al.*, 2020; Burton and McCormack, 2023; Nourissat *et al.*, 2015). Among the available therapeutic modalities, Nonsteroidal Anti-Inflammatory Drugs (NSAIDs) and corticosteroid therapy remain the primary options for managing tendinopathy (Andres and Murrell, 2008); but these therapies may cause adverse effects and hinder tendon regeneration with long-term use (Loiacono *et al.*, 2019; Magra and Maffulli, 2006; Marcum and Hanlon, 2010).

Nutraceutical interventions have shown promise in improving symptoms and tendon health (Agrawal *et al.*, 2020; Loiacono *et al.*, 2019). Numerous clinical studies have demonstrated the beneficial effects of a combination of mucopolysaccharides, collagen type I, and vitamin C in the treatment of tendinopathy (Agrawal *et al.*, 2020); however, the efficacy of these agents

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as adjuncts to standard therapies in Indian patients with tendinopathy has not yet been evaluated. The current study was designed to assess the tolerability and efficacy of a nutraceutical formulation comprising mucopolysaccharides, collagen type I, and vitamin C in Indian subjects diagnosed with various types of tendinopathies.

MATERIALS AND METHODS

Ethical consideration and study design

This real-world, open-label, prospective, parallel-arm, comparative study was conducted in the Department of Orthopaedics at Stavya Spine Hospital and Research Institute, Ahmedabad, India. The study protocol and associated documents were reviewed and approved by the ethics committee of K.B. Institute of Pharmaceutical Education and Research (protocol number: KBIEC/2021/164), and the study was performed in accordance with the principles outlined in the Declaration of Helsinki.

Participants and study procedure

Participants were screened according to pre-defined inclusion and exclusion criteria (Table 1). Following the acquisition of written informed consent, 59 individuals with clinically diagnosed tendinopathy were enrolled under medical supervision and allocated to one of two groups: the Active group (n=30), which received the investigational product in conjunction with standard therapies, and the Standard group (n=29), which received standard therapies alone. The sample size was determined based on practical considerations, including recruitment feasibility and resource availability. As this study is exploratory in nature, the selected sample size provides preliminary estimates of treatment effects and variability, and is consistent with similar pilot studies within the field, thereby balancing both ethical and feasibility considerations.

Therapeutic regimen

All enrolled participants received standard therapies, which primarily comprised commonly prescribed analgesics, including NSAIDs, opioid analgesics, gabapentinoids, muscle relaxants, and bone and joint supplements, as deemed appropriate by the treating physician. Participants in the active group were administered the investigational product in addition to standard therapies. The investigational product, Tendowell, is a nutraceutical formulation containing mucopolysaccharides (220 mg), collagen type I (40 mg), and vitamin C (20 mg) per capsule. The investigational therapy was administered twice daily for 90 days, while standard therapies were provided according to the investigator's clinical judgment.

Evaluation parameters

Primary evaluation parameter

The severity of symptoms-including pain at rest, pain during activity, stiffness, difficulty in physical activity, difficulty in daily activity, inflammation, impaired mobility, and weakness of the affected area-was assessed using the Modified Efficacy Questionnaire (MEQ) scale. The MEQ is a patient-reported questionnaire in which each symptom is scored from 0 (no symptom) to 3 (severe symptom) (Sureja *et al.*, 2023).

Secondary evaluation parameter

Quality of Life (QoL) was evaluated using the SF-12 questionnaire. Adverse events were systematically monitored and recorded from the initiation of therapy until study completion, based on participant self-reporting (Sureja *et al.*, 2023). Participants were required to visit the study center on days 30, 60, and 90.

All evaluation parameters were assessed by the supervising physician and documented at baseline and study completion in a pre-designed case report form.

Statistical analysis

All data are presented as mean±standard deviation. Statistical analyses were conducted using GraphPad Prism (Desktop version 9.0.0; GraphPad Software Inc., San Diego, CA, USA). Data normality was assessed using the Shapiro-Wilk test. For normally distributed data, paired t-tests and Student's t-tests were employed for within-group and between-group analyses, respectively. For non-normally distributed data, the Wilcoxon matched-pairs signed rank test and Mann-Whitney test were used for within-group and between-group comparisons, respectively. A p-value of less than 0.05 was considered statistically significant.

RESULTS

Participants' demographics

A total of 59 participants diagnosed with tendinopathy affecting the Achilles tendon, plantar fascia, gluteal region, peroneal tendon, shoulder, epicondyle, or wrist were enrolled in the study. Seven participants were lost to follow-up (active group: 2; standard group: 5), resulting in a final analysis set of 52 participants (active group: 28; standard group: 24). Baseline demographic data for the participants are presented in Table 2, and the study flowchart is illustrated in Figure 1.

Efficacy on symptoms severity

The effects of the interventions on symptom severity are presented in Table 3. The addition of nutraceutical therapy to standard treatments resulted in a greater reduction in symptom severity compared to standard therapies alone.

Nutraceutical supplementation led to a 22.91% greater reduction in pain at rest and a 47.24% greater reduction in pain during

activity. Similarly, the reduction in stiffness severity was 42.80% greater among active group participants, while improvement in physical activity was 18.69% greater in the active group compared to the standard group.

Participants receiving active therapy demonstrated a 25.89% greater reduction in difficulty with daily activities and a 28.54% greater reduction in difficulty with mobility, relative to those in the standard therapy group. Additionally, active group participants experienced a 10.08% greater reduction in inflammation and a 33.43% greater reduction in weakness of the affected area compared to participants receiving standard therapy.

Efficacy on Quality-of-life parameters

The effects of active and standard therapies on individual QoL parameters are presented in Table 4. The active group demonstrated significant improvement in social activity level, energy level, bodily pain, physical role-stair climbing, physical role-moderate activity, mental role-goal accomplishment, and overall general health compared to the standard group. Relative to baseline, the active group exhibited significant improvement in social activity level, energy level, bodily pain, mental goal accomplishment, physical role-other activity, physical role-stair climbing, physical role-moderate activity, and overall general health. In contrast, the standard group did not demonstrate significant improvement in any of these parameters compared to baseline.

Safety and tolerability

Both standard and nutraceutical therapies were well tolerated, and none of the participants experienced side effects attributable to the assigned interventions. The observed dropouts during the study were solely due to loss to follow-up, with no discontinuations resulting from tolerability issues or adverse effects.

DISCUSSION

The findings of the present study indicate that the addition of a nutraceutical composition containing mucopolysaccharides, collagen type I, and vitamin C to standard therapies results in a greater reduction in symptom severity and greater improvement in Quality of Life parameters among patients with tendinopathy.

The combination of mucopolysaccharides, collagen type I, and vitamin C has demonstrated anti-inflammatory and anti-catabolic effects in an *in vitro* study utilizing human tenocytes pre-treated with IL-1β (Shakibaei *et al.*, 2011). This combination inhibited IL-1β-induced up-regulation of COX-2 and MMP-1, and reversed IL-1β-mediated down-regulation of collagen type I and β1-integrin receptor expression. These actions suppressed the catabolic state in tendons and promoted tenocyte proliferation, migration, and activation, thereby facilitating accelerated tendon healing (Shakibaei *et al.*, 2011).

Preclinical studies using tendinopathy models have shown that vitamin C supplementation enhances collagen fiber diameter, maturation, and fibroblast activity, indicating improved tendon healing (Omeroğlu *et al.*, 2009; Zanoni *et al.*, 2013). These findings suggest that the nutraceutical formulation exerts anti-inflammatory, anti-catabolic, and reparative effects supporting tendon health. The present study supports these mechanisms, correlating with greater symptom reduction and improved quality of life in tendinopathy patients.

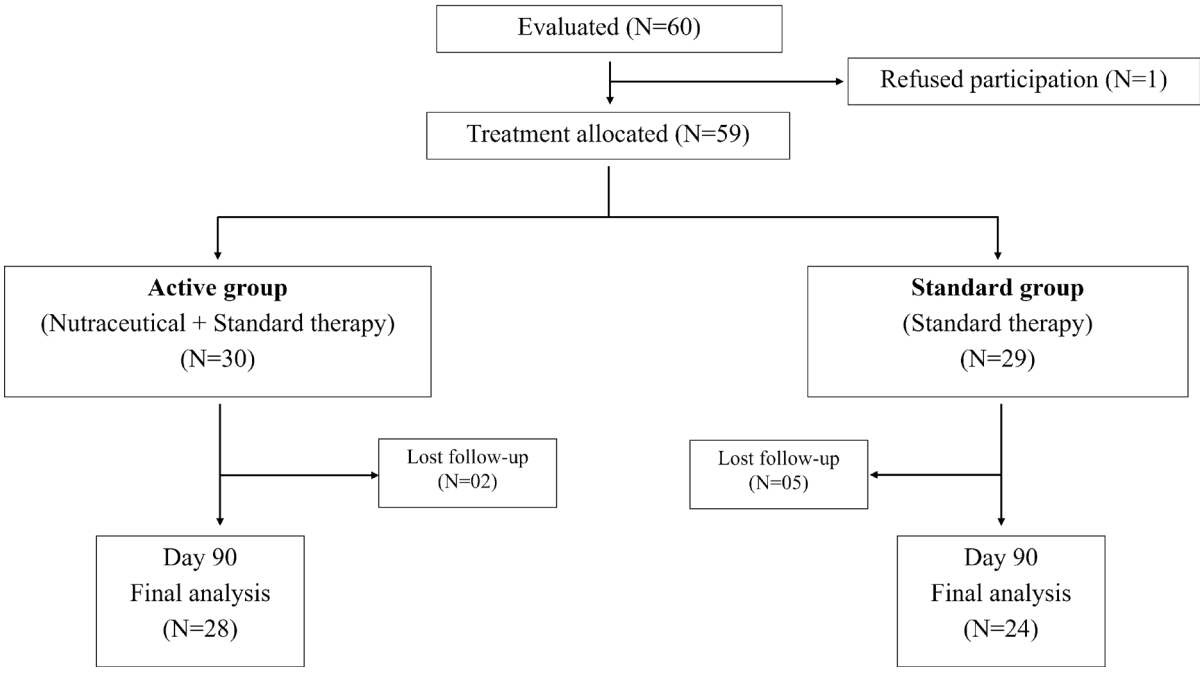

Figure 1: Flow of participants through entire study duration.

A previous clinical trial reported that 90-day administration of this nutraceutical combination improved tendon structure and health, reduced symptom severity, and lowered NSAID use in Achilles, lateral epicondyle, and patellar tendinopathy (Arquer *et al.*, 2014). The current results align with these findings, showing significant improvements in pain and overall quality of life. Another clinical investigation confirmed that supplementation led to pain reduction and complete recovery on ultrasonography (Binh *et al.*, 2014). Similarly, treatment combining mucopolysaccharides, collagen type I, and vitamin C with physiotherapy for 12 weeks significantly decreased symptom severity, enhancing physiotherapy outcomes (Balius *et al.*, 2016). Comparable findings were observed in another study, where treatment with mucopolysaccharides, collagen type I, and vitamin C resulted in significant pain reduction, improvement in joint biomechanical properties, and enhanced physical functionality (Nadal *et al.*, 2009). Overall, the results of the present study are consistent with previous observations and further support the use of this combination therapy in tendinopathy management.

The present study has several strengths. First, it provides additional scientific support for the efficacy of the combination of mucopolysaccharides, collagen type I, and vitamin C in tendinopathy management. Second, the study demonstrates the synergistic efficacy of this nutraceutical combination when used alongside primary therapeutic regimens. Third, the findings confirm that the nutraceutical combination is safe for concomitant use with standard therapies. However, the study has some limitations. The open-label design and the relatively small sample size may affect the generalizability of the findings. Additionally, the nutraceutical combination was administered in conjunction with standard therapies; future clinical investigations are warranted to evaluate the efficacy of this combination as monotherapy. Finally, as a non-controlled, non-randomized

Table 1: Study inclusion and exclusion criteria.

Inclusion criteria	Exclusion criteria
Male and female participants with 18 years of age or above.	Participants age less than 18 years of age.
Newly diagnosed tendinopathy as per the judgment of the examining doctor.	Hypersensitivity to allocated therapies.
Comply with the study procedures.	Pregnant and/or lactating female participants.
Willing to provide signed informed consent.	Participants with active cancer, systemic diseases suspected musculoskeletal diseases (like arthritis), or neurological complications.
	Participants using any medications or therapies for treatment of tendinopathy at the time of baseline evaluation.
	Participants with history of surgery 6 months before study initiation or planning to undergo surgery during the study period were excluded from the study.
	Participants deemed ineligible by the principal investigator.

Table 2: Demographic characteristics of study participants.

	Standard group (*n*=24)	Active group (*n*=28)	*p-value
Age (in years)	48.21±14.04	43.04±11.54	0.1581
Male/Female (N)	6/18	9/19	NA
Primary evaluation parameter score			#p-value
Pain (at rest)	2.33±0.64	2.36±0.62	0.9558
Pain (while activity)	2.58±0.58	2.57±0.57	>0.9999
Stiffness	1.13±0.90	1.39±0.99	0.2813
Difficulty in physical activity	2.38±0.65	2.00±0.82	0.0993
Difficulty in daily activity	1.88±0.61	1.50±0.88	0.0800
Inflammation	1.58±1.10	1.79±0.88	0.5268
Difficulty in mobility	1.46±1.14	2.14±0.76	0.0235
Weakness in affected area	2.13±1.03	2.14±0.71	0.7401

Data presented as Mean±Standard Deviation. *Between-group analysis conducted using student *t*-test. #Between-group analysis conducted using Mann Whitney test. Abbreviations - N: Number of participants; NA: Not applicable.

Table 3: Effect of interventions on symptoms severity.

Outcome measured	Standard group (*n*=24)			Active group (*n*=28)			#*p*-value
	Baseline	Study end	*p-value	Baseline	Study end	*p-value	
Pain at rest	2.33±0.64	0.71±0.86	<0.0001	2.36±0.62	0.18±0.39	<0.0001	0.0091
Pain during activity	2.58±0.58	1.54±0.98	0.0002	2.57±0.57	0.32±0.48	<0.0001	<0.0001
Stiffness	1.13±0.90	0.63±0.82	0.0727	1.39±0.99	0.18±0.39	<0.0001	0.0195
Difficulty in physical activity	2.38±0.65	0.79±0.88	<0.0001	2.00±0.82	0.29±0.46	<0.0001	0.0173
Difficulty in daily activity	1.88±0.61	0.75±0.79	<0.0001	1.50±0.88	0.21±0.42	<0.0001	0.0050
Inflammation	1.58±1.10	0.38±0.58	<0.0001	1.79±0.88	0.25±0.44	<0.0001	0.3740
Difficulty in mobility	1.46±1.14	0.71±0.69	0.0126	2.14±0.76	0.43±0.57	<0.0001	0.1214
Weakness of affected area	2.13±1.03	1.17±0.76	0.0009	2.14±0.71	0.46±0.58	<0.0001	0.0005

Data presented as Mean±Standard Deviation. *p-value compared to baseline value evaluated using Wilcoxon matched-pairs signed rank test. #p-value indicates difference from baseline for individual parameters between-group difference evaluated using Mann Whitney test.

Table 4: Effect of interventions on quality-of-life parameters.

Outcome measured	Standard group			Active group			#*p*-value
	Baseline	Study end	*p-value	Baseline	Study end	*p-value	
General health	3.08±0.72	2.63±0.88	0.0582	3.11±0.69	1.46±0.51	<0.0001	<0.0001
Physical role - Moderate activity	1.96±0.62	2.17±0.70	0.3843	1.71±0.53	2.64±0.49	<0.0001	0.0033
Physical role - Stair climbing	1.88±0.74	2.04±0.69	0.6084	1.79±0.63	2.79±0.42	<0.0001	0.0066
Physical role - Goal accomplishment	1.46±0.51	1.54±0.51	0.7905	1.54±0.51	1.86±0.36	0.0117	0.2797
Physical role - Other activity	1.33±0.48	1.50±0.51	0.3877	1.50±0.51	1.86±0.36	0.0213	0.3290
Mental role - Goal accomplishment	1.79±0.41	1.54±0.51	0.1796	1.43±0.50	1.71±0.49	0.0574	0.0126
Mental role - Alertness	1.50±0.51	1.67±0.48	0.4545	1.68±0.48	1.79±0.42	0.6072	0.7617
Bodily pain	3.13±0.68	2.79±0.78	0.1609	3.79±0.79	1.39±0.50	<0.0001	<0.0001
Mental health - Calm and peacefulness	1.92±0.65	2.00±0.66	0.8036	2.11±0.57	1.89±0.42	0.1094	0.1698
Energy level	2.13±0.61	2.29±0.69	0.3810	3.11±0.74	1.93±0.60	<0.0001	<0.0001
Depression level	5.71±0.46	5.71±0.46	>0.9999	5.75±0.44	5.68±0.48	0.7744	0.8207
Social activity level	3.42±0.72	3.67±0.64	0.2432	2.75±0.89	5.25±0.70	<0.0001	<0.0001

Data presented as Mean±Standard Deviation. *p-value compared to baseline value evaluated using Wilcoxon matched-pairs signed rank test. #p-value indicates difference from baseline for individual parameters between-group difference evaluated using Mann Whitney test.

study, factors such as physical activity status, dietary intake, and other variables that could directly or indirectly influence tendon health recovery were not controlled. Therefore, further randomized controlled studies are necessary to address these limitations.

CONCLUSION

The present study highlights the potential of a nutraceutical composition containing mucopolysaccharides, collagen type I, and vitamin C to enhance the effectiveness of standard therapies in real-world clinical settings for improved management of tendinopathies. The results are promising and suggest that this nutraceutical composition may be considered as an adjunct in clinical practice for optimal management of tendinopathy.

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ABBREVIATIONS

QoL: Quality of Life; **NSAID:** Non-Steroidal Anti-Inflammatory Drug; **MEQ:** Modified Efficacy Questionnaire; **SF-12:** Short Form-12 Health Survey; **IL-1β:** Interleukin-1 Beta; **COX-2:** Cyclooxygenase-2; **MMP-1:** Matrix Metalloproteinase-1

CONFLICT OF INTEREST

VS, VD, JK, BK, and VG are employees of Sundyota Numandis Probioceuticals Pvt. Ltd., (India). No other potential conflict of interest to declare.

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