



Clinical Research

Efficacy of *Ashwagandha* (*Withania somnifera* [L.] Dunal) in improving cardiorespiratory endurance in healthy athletic adults

Bakhtiar Choudhary, A. Shetty¹, Deepak G. Langade²

Hyderabad Spine Clinic, Hyderabad, Andhra Pradesh, ¹Zela Life Health Center, Bengaluru, Karnataka, ²Department of Pharmacology, BVDU Dental College and Hospital, Navi Mumbai, Maharashtra, India

Abstract

Introduction: *Ashwagandha* (*Withania somnifera* [L.] Dunal) has been traditionally used for various actions ranging from vitalizer, improve endurance and stamina, promote longevity, improve immunity, and male and female fertility. However, clinical studies are needed to prove the clinical efficacy of this herb, especially in cardiovascular endurance and physical performance. **Aims:** This prospective, double-blind, randomized, and placebo-controlled study evaluated the efficacy of *Ashwagandha* roots extract in enhancing cardiorespiratory endurance and improving the quality of life (QOL) in 50 healthy male/female athletic adults. **Materials and Methods:** Cardiorespiratory endurance was assessed by measuring the oxygen consumption at peak physical exertion (VO_{2max}) levels during a 20 m shuttle run test. The World Health Organization self-reported QOL questionnaire (physical health, psychological health, social relationships, and environmental factors) was used to assess the QOL. Student's *t*-test was used to compare the differences in a mean and change from baseline VO_{2max} levels, whereas Wilcoxon signed-rank test was used to assess changes in QOL scores from baseline in the two groups. **Results:** There was a greater increase from baseline ($P < 0.0001$) in the mean VO_{2max} with KSM-66 *Ashwagandha* ($n = 24$) compared to placebo ($n = 25$) at 8 weeks (4.91 and 1.42, respectively) and at 12 weeks (5.67 and 1.86 respectively). The QOL scores for all subdomains significantly improved to a greater extent in the *Ashwagandha* group at 12 weeks compared to placebo ($P < 0.05$). **Conclusion:** The findings suggest that *Ashwagandha* root extract enhances the cardiorespiratory endurance and improves QOL in healthy athletic adults.

Key words: *Ashwagandha*, cardiorespiratory endurance, healthy athletics adults, quality of life, VO_{2max}

Introduction

Ashwagandha (*Withania somnifera* [L.] Dunal), also known as Indian Winter Cherry, is extensively used in Ayurveda, the traditional health care system in India. This herb is used as a general tonic and “adaptogen,” helping the body to adapt to stress. Also, it has been shown to possess antioxidant properties as well as an ability to support a healthy immune system.^[1-3]

Ashwagandha is a popular medicinal plant in the South East Asia and Southern Europe. Many people use this herb for

general vitality. It is popularly called “Indian Ginseng” due to its rejuvenating effects.^[2,4] In addition, it causes relaxation, increases energy and promotes weight loss through stress reduction. In Ayurveda, certain herbal formulae known as *Rasayana* are considered to be rejuvenating.^[1,2,5-9] and are

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Address for correspondence: Dr. Deepak G. Langade, Dept. of Pharmacology, B.V.D.U. Dental College and Hospital, Sector 7, C.B.D. Belpada, Navi Mumbai - 400 614, Maharashtra, India.
E-mail: drdgl@hotmail.com

How to cite this article: Choudhary B, Shetty A, Langade DG. Efficacy of *Ashwagandha* (*Withania somnifera* [L.] Dunal) in improving cardiorespiratory endurance in healthy athletic adults. *Ayu* 2015;36:63-8.

taken as a remedy for general weakness, exhaustion, and stress. *Ashwagandha* is valued for its ability to increase vitality, energy, endurance and stamina, promote longevity and strengthen the immune system without stimulating the body's reserves. Numerous studies suggest *Ashwagandha* can directly and indirectly prevent and treat a number of diseases.^[8,10,11]

Earlier studies clearly indicated that the traditional use of *Ashwagandha* had a logical and scientific basis.^[1,2] Nonetheless; clinical studies are needed to prove the clinical efficacy of this herb, especially in cardiovascular endurance and physical performance. Hence, this study was conducted with a two-fold objective: To evaluate the efficacy of a high concentration root extract of *Ashwagandha* in enhancing cardiorespiratory endurance, and to improve the quality of life (QOL) in healthy athletic adults.

Materials and Methods

This randomized, double-blind, and placebo-controlled study was approved by Suraksha Independent Ethics Committee, Vishnu Institute of Pharmaceutical Education and Research, Andhra Pradesh, India (ref. no. SIEC/04/01/0014; dt. 13.04.2012) and the study was conducted in compliance with good clinical practice guidelines, Declaration of Helsinki and all other applicable regulations.

Study subjects

A total of 50 subjects were assessed with regards to eligibility for inclusion in the study at the Department of Orthopedics, Hyderabad Spine Clinics, Secunderabad, India. This being an exploratory study, the sample size was not based on any assumptions and calculations. Healthy athletic male and/or female adult subjects aged between 20 and 45 years and subjects within the body mass index range of 18.5–24.9 kg/m² were enrolled in the study after obtaining informed written consent. Subjects with previous history of significant renal or hepatic impairment, asthma, urticarial, or other allergic reactions, severe gastrointestinal disorders such as malabsorption syndrome, diabetes, coronary artery disease, and hypertension with or without complications, any chronic physical, hormonal or psychiatric disorder, morbid obesity (body fat percent >40%), and any medical condition where exercise is contraindicated and recent surgery or trauma that incapacitates the subject for exercise, subjects with known hypersensitivity to *Ashwagandha* and related herbal product extracts, and those subjects who were on any kind of herbal preparations (such as other formulations containing *Ashwagandha*, Ginseng, *Brahmi*, and Ginkgo biloba) were also excluded.

Randomization

The enrolled subjects were randomized to either placebo (control) group ($n = 25$), or *Ashwagandha* (study) group ($n = 25$). Randomization was done using a computer based predetermined randomization chart (Rando 1.2, R.Raveendran, 2014). After the subjects were enrolled, they were provided a study serial number in chronological order. The study and placebo capsules were provide in containers without revealing the contents of the capsule and were numbered as per the randomization chart. Only after the subjects were assigned

the study serial number, the corresponding container was given to the subject.

The study subjects in the *Ashwagandha* group were administered one capsule of KSM-66 *Ashwagandha* (containing 300 mg of a high concentration full-spectrum root extract of the *Ashwagandha* plant, Ixoreal Bio-med Private Ltd.) orally, twice daily for a period of 12 weeks, whereas the subjects in placebo group received identical capsules containing sucrose.

The *Ashwagandha* root extract (KSM-66 *Ashwagandha* from Ixoreal Biomed, Hyderabad, India) used in this study has been standardized to 5% withanolides as ascertained by high-performance liquid chromatography (HPLC). It is manufactured using a proprietary water-based process, without the use of alcohol or any chemical solvents. The analysis of withanolides was performed with a Waters 515 HPLC System, using a Sunfire C18 column of dimension 250 mm × 4.6 mm, 5 μm at a flow rate of 1 ml/min. The solvent system was based on methanol: water (60:40). The column temperature was 30°C, and the injection volume was 20 μl.

Study visits and assessments

During the study period, the subjects visited the study center at screening and enrollment and then after 4, 8, and 12 weeks. All enrolled subjects underwent a complete physical examination at all visits.

The efficacy of *Ashwagandha* on cardiorespiratory endurance was evaluated by conducting a 20-m Shuttle Run Test at baseline, week 8 and week 12. Oxygen consumption at peak physical exertion (VO₂max) is one of the most widely used indicator of cardiorespiratory endurance and shuttle run test^[12] is found to be a reliable substitute to assess VO₂max, when laboratory-based assessments of VO₂max are not feasible.^[13]

The QOL was assessed by a self-reported World Health Organization-QOL (WHO-QOL) questionnaire. This QOL had subdomains for assessment of physical health, psychological health, social relationships, and environmental factors. Compliance was assessed using the capsule count and those who consumed over 80% of tablets were classified as compliant. All data were recorded in the source documents and data collection forms for 12 weeks.

Statistical analysis

The data were analyzed using windows based statistical program Medcalc® (Version 12.7.0.0). The VO₂max and QOL scores are expressed as a means with SD. Mann-Whitney U-test was used to compare the VO₂max values with 20-m Shuttle Run Test between the two groups. Similarly, Wilcoxon signed-rank test was used to compare the two groups for differences in the QOL scores and change from baseline in QOL scores for different subdomains of QOL questionnaire.

Results

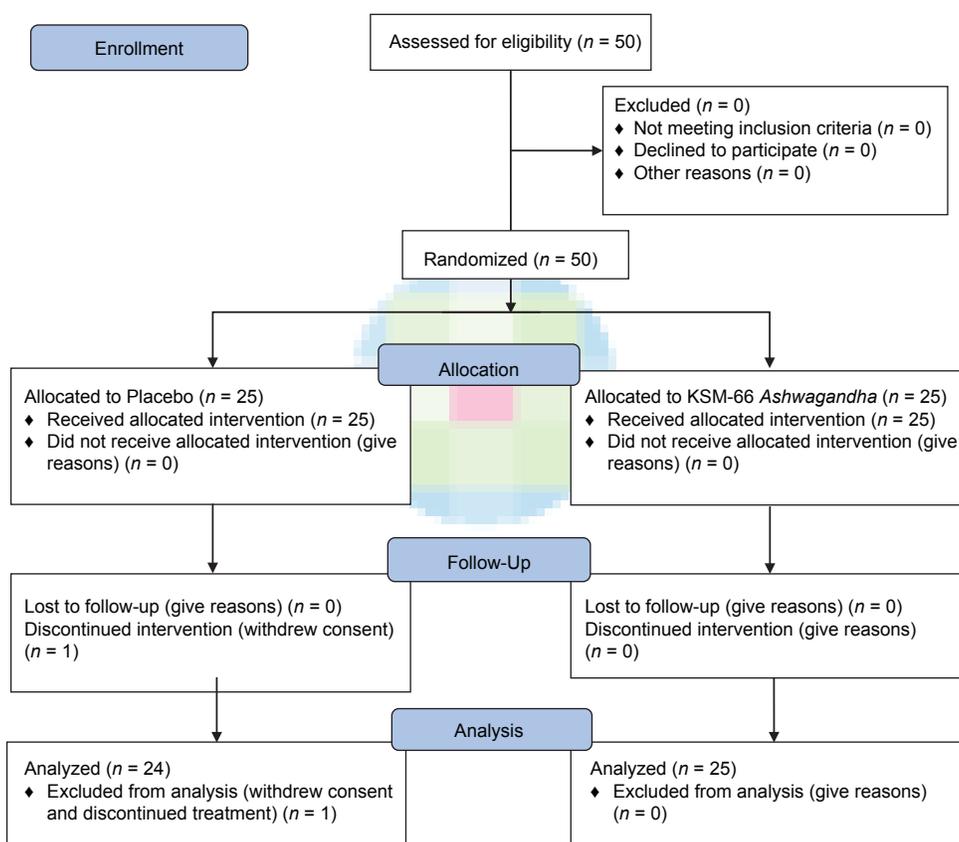
One subject from the *Ashwagandha* group withdrew consent from the study and was not included for analysis. Thus, data of 49 subjects were used for analysis [Flow chart 1]. The subjects from the two groups were comparable and had a matching demographic profile. The compliance was satisfactory in both the groups.

Treatment with the root extract of *Ashwagandha* resulted in a significantly greater increase ($P < 0.0001$) in mean $VO_2\text{max}$ at week 8 and week 12 compared to placebo subjects [Table 1]. The QOL sub-domain scores are presented in Table 2. *Ashwagandha* has shown to exert a greater improvement in all the QOL sub-domain scores as compared to placebo.

The data of this study showed a significant ($P < 0.05$) improvement in the physical and psychological health and the social relationship status of the study subjects by the end of 12 weeks of the study. However, the status of the environmental impact on the QOL of the study subjects was found to have increased substantially; albeit, not significant at 8 weeks and significant ($P < 0.01$) at 12 weeks of the study period. There were no changes in the vital parameters such as pulse rate, blood pressure (systolic and diastolic), and respiratory at resting state in the subjects of both groups.

Discussion

This study aimed to assess the effects of root extract of *Ashwagandha* on cardiorespiratory endurance in healthy athletic adults and to evaluate the QOL of these subjects. Isometric exercise involves daily and athletic activity, which significantly increases blood pressure, heart rate, myocardial contractility, and cardiac output; this enhanced physiological activity requires a fit cardiorespiratory system. A study in children and adolescents suggests that low cardiorespiratory fitness is strongly associated with the clustering of cardiovascular disease risk factors in children, independent of country, age, and sex.^[14,15] Cardiorespiratory endurance is generally recognized as a major component of physical fitness. The maximum oxygen consumption ($VO_2\text{max}$) is considered by many as the most valid measure of cardiorespiratory fitness.^[16,17]



Flow chart I: Consort 2010 flow diagram

Table 1: Assessment of $VO_2\text{max}$ by 20-m shuttle run test

Assessment period	Mean (SD)		Mann–Whitney U-test <i>P</i>
	Placebo (n=24)	Ashwagandha (n=25)	
Baseline	42.18 (5.3)	41.74 (5.21)	0.7714
Week 8	43.59 (4.97)	46.65 (6.29)	0.0651
Week 12	44.03 (5.95)	47.41 (6.63)	0.0668
Mean change from baseline	Mean (%)		
Week 8	1.42 (1.92)	4.91 (1.72)	<0.0001
Week 12	1.86 (2.28)	5.67 (2.15)	<0.0001

$VO_2\text{max}$ measurements are generally displayed in l/min. (i.e., liters per minute, representing the volume of oxygen consumed by the entire body each minute). SD: Standard deviation, $VO_2\text{max}$: Maximum oxygen consumption

Table 2: Assessments of WHO-QOL questionnaire

Assessment period	Mean (SD)		Wilcoxon test P
	Placebo (n=24)	Ashwagandha (n=25)	
QOL subdomains physical health			
Baseline	58.88 (15.12)	62.88 (12.31)	0.3159
Week 8	60.71 (13.86)	70.96 (10.36)	0.0055
Week 12	56.58 (10.82)	72.16 (13.64)	<0.0001
Mean change from baseline			
Week 8	1.83 (7.7)	8.08 (6.3)	0.0033
Week 12	-2.3 (5.7)	9.28 (7.6)	<0.0001
Psychological			
Baseline	60.71 (21.85)	63.28 (11.64)	0.6125
Week 8	61.08 (13.86)	71.5 (12.15)	0.0076
Week 12	63.17 (14.12)	75.72 (12.78)	0.0021
Mean change from baseline			
Week 8	0.37 (11.41)	8.22 (7.65)	0.0075
Week 12	2.46 (15.07)	12.44 (9.16)	0.0083
Social relationships			
Baseline	57.79 (23.21)	60 (21.94)	0.7339
Week 8	60.54 (18.89)	70.2 (20.56)	0.0932
Week 12	63.12 (18.13)	72.96 (17.11)	0.0571
Mean change from baseline			
Week 8	2.75 (08.4)	10.20 (6.16)	0.001
Week 12	5.33 (08.5)	12.96 (9.46)	0.0047
Environmental			
Baseline	58.79 (16.97)	65.52 (12.37)	0.1214
Week 8	63.42 (12.07)	71.64 (14.79)	0.0381
Week 12	60.17 (13.21)	71.88 (12.44)	0.0025
Mean change from baseline			
Week 8	04.63 (7.86)	6.12 (5.91)	0.4575
Week 12	01.38 (7.39)	6.36 (4.62)	0.0076

WHO-QOL: World Health Organization-Quality of Life, SD: Standard deviation

The test for VO_2 max is perhaps the most commonly employed procedure in exercise physiology. This measurement determines an athlete's ability to take in, transport, and utilize oxygen and is probably the best assessments of the athlete's endurance capabilities. The maximum oxygen consumption (VO_2 max) is a measure of long-term aerobic and cardiovascular endurance parameters. VO_2 max represents a long-term aerobic and cardiovascular endurance and is considered to be a gold standard for measuring the cardiorespiratory fitness level.^[16,18] Endurance activities characteristically require high repetitions and low resistance.^[16] A study states that 20 m shuttle run test is valid and reliable for prediction of the VO_2 max of male and female adults.^[19] The 20 m shuttle run test is as a valid test of cardiorespiratory endurance as other distance run tests in American Students of 12–15 years old.^[20] In this study, 20 m shuttle run test was used to measure VO_2 max levels which in turn depicted the cardiorespiratory endurance. It was observed that there was a significant increase in VO_2 max by the end of 8 weeks and by the end of 12 weeks as compared to placebo group. The data of the present study defined an excellent range of VO_2 max following administration of *Ashwagandha*.

Ashwagandha is known as an “adaptogen,” as it increases resistance to physical, chemical, and biological stressors, builds

energy and general vitality.^[2,7,18,21] Previous studies assessing physical and cardiorespiratory endurance of healthy adult subjects have also reported similar beneficial results with the use of *Ashwagandha*, underscoring the significant increase in VO_2 max and muscle strengthening.^[18,21] *W. somnifera* administered in the form of aqueous extract in capsules with gradual escalating doses from 750 to 1250 mg/day was found to be safe and well tolerated. The study also demonstrated marked muscle strengthening, exercise tolerance, and lipid-lowering potential of *Ashwagandha*, along with improved quality of sleep and QOL.^[21]

Adenosine triphosphate is responsible for the maintenance of the energy processes at the cellular level. *Ashwagandha* has been shown to exert significant effects on the energy levels and mitochondrial health. It beneficially influences Mg^{2+} dependent ATPase activity and reduces the succinate dehydrogenase enzyme activity in the mitochondria of granulation tissue of carrageen induced air pouch granuloma as demonstrated in an experimental study.^[22] In agreement with the fact that exercise endurance capacity is largely determined by the functional mitochondrial content of muscle, this study confirms the energizing effect of *Ashwagandha*. It has been shown that *Ashwagandha* increased both the red blood corpuscles (RBC)

and hemoglobin count. The increase in RBC results in an increased capacity of the blood to transport oxygen directly to the exercising muscles; thus, enhancing the aerobic capacity of the athletes.^[23,24] These findings suggest a possible mechanism of the ergogenic effect of *Ashwagandha* root extract.

An animal study reported a 2–3-fold increase in free radical (R*) concentrations of muscle and liver following exercise to exhaustion. Exhaustive exercise also resulted in decreased mitochondrial respiratory control and increased levels of oxidative stress.^[25] *Ashwagandha* on a long period of administration markedly augmented antioxidants and significantly reduced ischemia reperfusion induced myocardial injury as reported in an earlier experimental study.^[26,27] These observations are indicative of its cardio protective potential.

Ashwagandha as an herbal drug finds its mention in various reference books/literature on traditional medicines and is being used widely and since long. There are no reported Phase-I or Phase-II studies being conducted due to its known knowledge of safety and efficacy. In view of the fact that *Ashwagandha* is an herb which is extensively used traditionally in Ayurveda, Phase-I and Phase-II trials may not be necessary. The herb under investigation is being clinically evaluated for the same indication for which it is being used or as has been described in ancient texts. Furthermore, the design of the trial is appropriate to provide the expected outcomes for the traditional medicine.

The WHO-QOL questionnaire is used to evaluate a given subject's QOL. It comprises 26 items, which measures the following broad domains: Physical health, psychological health, social relationships, and the environment (WHO-QOL Questionnaire, 1996).^[28] The procedure entails each question being read out to the subjects, along with the response options. In this study, QOL was checked by self-reported WHO-QOL Questionnaire. *Ashwagandha* was shown to improve all subdomains of the QOL (physical health, psychological health, social relationships, and environmental factors) of the healthy athletic adult subjects as compared to placebo. The data of the present study showed significant ($P < 0.05$) improvement in physical and psychological health and these domains have a greater contribution in the QOL than the other domains of social relationships, and environmental factors. This study was first of its kind and limited by a small sample size. Further studies with a larger sample with an additional aims of understanding the underlying mechanism of action of *Ashwagandha* may further validate the findings of this study.

Conclusions

Ashwagandha an important herb in Ayurveda, the traditional Indian medicine system is considered to be a *Rasayana*. *Ashwagandha* root extract has been used for several 1000 years in Ayurveda as a tonic, prophylactic agent and “restorative.” It has been used by athletes for improved muscular strength, resistance to fatigue, recovery from exercise, and as an ergogenic aid for many years. In this study, oral administration of a high concentration root extract of *Ashwagandha* led to increased VO_2 max, enhanced cardiorespiratory endurance, and improved QOL in healthy athletic adults. Findings of this study suggest that *Ashwagandha* root extract improves the cardiovascular

dynamics by increasing the VO_2 max levels thereby enhancing the cardiorespiratory endurance, and also brings an improvement in QOL in healthy adults. However, due to the limited cross-section of the population considered in this study, the findings may not generalize to all populations. Further studies are needed to validate these findings.

Financial support and sponsorship

Nil.

Conflicts of interest

There are no conflicts of interest.

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हिन्दी सारांश

स्वस्थ एथलेटिक वयस्कों में कार्डियोरेस्पिरेटरी सहनशक्ति में सुधार लाने में अश्वगंधा (विथेनिया सोमनीफेरा) की प्रभावकारिता

बख्तियार चौधरी, ए. शेटी, दिपक लंगडे

अश्वगंधा पारंपरिक रूप से, शक्तिवर्धक से लेकर विभिन्न कार्यों, सहनशक्ति और दमखम सुधारने, दीर्घायु को बढ़ावा देने, प्रतिरक्षा सुधारने, और पुरुष और महिला प्रजनन क्षमता में सुधार के लिए इस्तेमाल किया जाता रहा है। हालांकि, इस जड़ी बूटी की चिकित्सीय प्रभावकारिता को सिद्ध करने के लिए चिकित्सकीय अध्ययन की जरूरत है, विशेषकर कार्डियोवस्कुलर सहनशक्ति और शारीरिक प्रदर्शन में। इस भावी, डबल-ब्लाइंड, बेतरतीब, प्लेसिबो नियंत्रित अध्ययन में कार्डियोरेस्पिरेटरी सहनशक्ति बढ़ाने और ५० स्वस्थ पुरुष/महिला एथलेटिक वयस्कों में जीवन की गुणवत्ता में सुधार लाने में अश्वगंधा की जड़ के सार तत्व की प्रभावकारिता का मूल्यांकन किया है। कार्डियोरेस्पिरेटरी सहनशक्ति को एक २० मीटर शटल रन परीक्षण के दौरान शिखर शारीरिक श्रम (वीओ२मैक्स) के स्तर पर ऑक्सीजन की खपत को मापने के द्वारा मूल्यांकन किया गया। विश्व स्वास्थ्य संगठन की स्व रिपोर्ट जीवन की गुणवत्ता (क्यूओएल) प्रश्नावली (शारीरिक स्वास्थ्य, मानसिक स्वास्थ्य, सामाजिक रिश्ते और पर्यावरणीय कारकों) को जीवन की गुणवत्ता का आंकलन करने के लिए इस्तेमाल किया गया। छात्रों के टी-परीक्षण कई औसत में अंतर और आधारभूत वीओ२मैक्स स्तर से परिवर्तन की तुलना करने में इस्तेमाल किया गया, जबकि विल्कोक्सन साइन रैंक परीक्षण को दो समूहों में आधारभूत क्यूओएल स्कोर में परिवर्तन का आंकलन करने के लिए इस्तेमाल किया गया। ८ सप्ताह (४.९९ और ९.४२ क्रमशः) और १२ सप्ताह (५.६७ और ९.८६ क्रमशः) में प्लेसिबो (एन=२५) की तुलना में औसत वीओ२मैक्स में केएसएम-६६ अश्वगंधा (एन=२४) में आधारभूत (पी<०.०००९) से तीव्र वृद्धि थी। सभी सब-डोमेन के लिए क्यूओएल स्कोर में प्लेसिबो (पी<०.०५) की तुलना में अश्वगंधा समूह में १२ सप्ताह में काफी हद तक सुधार हुआ। निष्कर्ष सुझाव देते हैं कि अश्वगंधा की जड़ का सार तत्व कार्डियोरेस्पिरेटरी सहनशक्ति को बढ़ाता है और स्वस्थ पुष्ट वयस्कों में क्यूओएल में सुधार करता है।