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Vascular Rehabilitation Benefits of Tribulus Terrestris (TT), Taurine and High Dose Alpha Lipoic Acid (ALA) Supplementation with Interval Walking Training Program after Surgical Vascular Bypass Treatment (Pilot Study)

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ABSTRACT

Background: Some of main raisons for the elderly graft occlusion after successful aortal-iliac, aortal Femoral and Femoral Distal Vein Bypass, progression of main disease, continuing bad life Habits and uncontrolled risk factors such are mostly: poor nutrition traditional or fast food, Smocking and Lacks of Walking and Physical Activity Habits. **Objective:** The primary objective of the study was to estimate influence of Interval Walking Training Program combine with Tribulus Terrestris, 3-5 gram of Taurine and high dose of 1800mg supplementation of ALA on primary potency and vascular treatment. Secondary goals of this study is determinate by establishing better understanding connection between ordinary vascular walking therapy 30-45 min and interval walking program combine with Tribulus Terrestris, Taurine and high dose of and ALA as secondary supplementation after surgical and endovascular treatment. **Methodology:** The study included 112 patients, at the Clinic of cardiovascular surgery, Clinical Center University of Sarajevo, age between 50 and 75 (50 patients surgical treated with aortic-iliac, aortic-femoral and femoral distal vein bypass with and without Linton-patch/Taylor patch-first group) and (62 endovascular Iliac treated patients (indication TASC II A and B) with and without support Tribulus Terrestris, high dose of ALA and Taurine - second group). **Results:** Final analysis has reveal the rehabilitation outcome in 83% patients with bypass above the knee was fully rehabilitated compared to 46,6% patients with bypass below the knee was statistically considered significant by using p value less than ($p<0,05$) In anamnestic history in 83% patient with amputation above the knee was documented the presence of hypertension, hyperlipidemia, nicotinismus and diabetes compared to 66,7% of patients with amputation level below the knee but there was no statistically significant difference ($p>0,05$). **Conclusion:** Interval Walking Training Program on Tribulus Terrestris, Taurine and high dose of ALA had a significantly and successfully higher bypass potency and rehabilitation prognosis compare to patients without supplementation and postsurgical physical therapy concept. It is obviously the is certain link between physical activity, life style modification and serum testosterone on primary bypass potency.

Key words: Vascular Artery Bypass, Inteval Training, Tribulus Terrestris, Taurine, Vascular Diseases

INTRODUCTION

The classic surgical bypass procedure and/or endovascular/ minimally invasive (modernized therapy) is mainly in synergy with coronary and stenotic occlusive diseases of various localizations and stages of symptomatology (Abbott, Green, Matsumoto et al., 1997; Abu Rahma, Robinson, & Holt, 1999). With systemic (generalized) arterial stenotic occlusive disease, there is also a correlation chronic disease of andropause with the accompanying physiological deficit of testosterone in serum (TS) in modern age men. As such, it is the subject of scientific interest and many debatable issues with wide spread epidemiological proportions, both of advanced countries of the economic

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part of the world, and of the economic world in development (Svartberg, von Muhlen, & Mathiesen, 2006; Hooper, Kraemer, Saenz, et al., 2017). Diabetes mellitus type II belongs to an expansive civilization disease, especially in people who are conceptually physically inactive, poorly nutritionally informed and cultivated, and who have high prevalence of acquired and uncovered risk factors in already developed symptomatology in their history (obesity, smoking, hyperlipidaemia, an inadequate concept of nutrition and the lack of physical activity implementation). Only such condition of the vascular system predisposes the acceleration of the atherothrombosis process with an increased indication for operative reconstructive treatment in patients aged over 50 years (Aronow & Ahn, 2004; Arany, Strutt, & Romanus, 2004; Rutherford, Spriet, & Stellingwerff, 2010; Olas, Hamed, Oleszek et al., 2015).

The progression of critical stenosis and occlusive disease of the affected vascular segment or multiple vascular systems, complementing the pathological process, collateral circulation, reduces the claudication distance of the walk that invalidates the patient. The pain occurs at rest, with increased intensity at night, as well as the appearance of ischemic atrophy and loss of tissue blood supply and increases the severity of the extremity and/or the segment of the affected extremity (Arany, Strutt, Romanus et al., 2004; Brøns, Spohr, Storgaard et al., 2004; Rutherford, Spriet, & Stellingwerff, 2010; Ito, Schaffer, & Azuma, 2012; Olas, Hamed, Oleszek et al., 2015). After primary arterial reconstructive bypass surgery and/or endovascular (PTA stent) and/or surgical-conservative therapy of peripheral arterial stenotic occlusive disease for the stimulation of the immune system in clinical medicine, the expression - immune nutrition in the form of supplementation of Tribulus Terrestris (TT) became naturalized. This supplementation therapeutically works individually or in combination with other preparations (amino acids or other anti-oxidant substances) for enhancing the function of the immune system, optimizing the testosterone in the serum (TS), and improving the properties of blood hemodynamic parameters (Sharifi, Darabi, & Akbarloo, 2003; Svartberg, von Muhlen, & Mathiesen, 2006; Tuncer, Yaymaci, Sati et al., 2009; Berkman, Tanriover, Acar et al., 2009; Silva, Silveira, Ronsani et al.,2011; Li, Guan, Liu et al., 2013; Olas, Hamed, Oleszek et al., 2015; Ivanova, Ivanov, Mladenov et al., 2016; Zhu, Du, Meng, Dong et al., 2017). In addition to andropause and the result of testosterone deficit in serum (TS) and predominantly increased incidence of weakened general condition of patients, Taurine is one compound that arises as the ultimate stable product of 1/3 of metabolism of amino acids Cysteine and Methionine (Taurine 2-amino ethane sulfonic acid). Although the scientific fact that the effect of Taurine on the improvement of the immunity and level of testosterone in the serum from the Tribulus Terrestris supplementation (TT) is still scientific, the scientific debates on its application for the female population is still under way. Proven various health benefits for post-operative purposes of supplementation quality in patients with surgical bypass and endovascular treatment still remains a scientifically open question (Brøns, Spohr, Storgaard et al., 2004; Zhang, Izumi, Kagamimori et al., 2004; Davis, Leiblum, Koochaki, Rodenberg et al., 2006; Dennerstein, Koochaki, Barton et al., 2006; Abirami, & Rajendran, 2011; Esfandiari, Dehghan, Sharifi et al. 2011; Silva, Silveira, Ronsani et al. 2011; Ito, Schaffer, Azuma 2012; Olas, Hamed, Oleszek et al., 2015; Ivanova, Ivanov, Mladenov et al., 2016). Taurine in the human body efficiently improves the stability of the intracellular water balance, and after glutamine it is the most common amino acid in cellular fluid (Arany, Strutt, & Romanus, 2004; Rutherford, Spriet, & Stellingwerff, 2010).

For the optimization of intracellular fluid, in order to improve the conditions for most effective proteosynthesis, athletes of the anaerobic and aerobic training concept use the postulated dose post-compensated (3-5g) with other supplements in the form of a quality regenerative and rehydration recovery. On the basis of this, vascular patients may also benefit therapeutically. In a large number of patients, conservative therapy in which alpha-lipoic acid (ALA) is incorporated is indicated in a scientifically justified medical indication, where only a small proportion of patients require relative operative intervention. These are usually patients with worsening of subjective symptoms of intermittent claudication under 100m of free-walk distance, with a clinical picture of exacerbation of ischemia (the stage of Fontain IIa). Most often with a confirmed haemodynamically significant stenotic occlusive disease of the arterial segment and a clinical picture of a short claudication distance of over 70%, taking into account the low level of cardiac, pulmonary and renal complications in order to perform as efficiently as possible an operative reconstructive procedure. Although a number of patients can be helped by conservative measures and measures of interventional radiology, a large number of patients require conventional venous femoral popliteal bypass, especially for disabling claudication problems for the purpose of rescuing extremities (Bergan, Veith, Bernhard, et al. 1986). In a small part of these symptomatic patients there is a small number of patients who have a certain operative indifference free-wheeling disturbance, since there is significant stenotic occlusive haemodynamics. Even today, numerous scientific debates on various scientific positions on the operational indication are being conducted. In general, patients are motivated to change their concept of nutrition and the usual habits of defects in the aerobic and anaerobic concept of physical activity (Sayers, Raptis, Berce et al., 1998; Rogerson, Riches, Jennings et al., 2007).

In addition to the conservative therapies of stenosis and/or occlusion arteries of the femoralis superficialis, arteries of the poplitae, one or two blood vessels, and depending on the clinical picture and the general condition of the patient, as well as the profundo-genicular, compensatory collateral, genicotybilic and compensatory collateral type, in addition to the disappointing endovascular treatment of Distal revascularization is indicated the femoro-distal bypass as the surgical primary treatment concept. Femoro-distal bypass is in most cases of critical stenosis, pain in peace and short claudication distances. In addition to endovascular procedures with the appropriate dose of physical activity, which are still in the phase of scientific testing, especially if it is at the subcutaneous level, the only fundamental surgical response to revascularization of the main arterial arteries that are in chronic ischemic progression is femoro-distal bypass (Abbott, Green, Matsumoto et al., 1997; Abu Rahma, Robinson, & Holt, 1999; Johnson & Lee, 2000). This type of venous

Table 1. Characteristics of patients before study

Total surgical treated patients	112
Average BMI, body mass index	29,62
Age 50-75	13
Average male Age/years/months	54,2
Average Serum Testetsterone values 91-579 pmol/L	97±3,48 pmol/L
Arterial hypertension and prehypertension	113
Angina pectoralis stabilis	2
Current smoker	92
Former somcker	21
History of current smoking in all patients (years)	24±3
History of former smoking in all patients (years)	31±5
Diabetes mellitus typ II non- insulin depent	6±2
HDL-a >1.50 mmol/L	13
LDL-a >4,53 mmol/L	19
Fontaine classify IIa/IIb/III in all surgical patients	
Stage IIa: intermittent claudication after walking a distance of more than 200 meters	13
Stage IIb: intermittent claudication after walking a distance of less than 200 meters	98
Stage III: rest pain	2

arterial replacement of the stenotic occlusive segment is of vital importance to the affected ischemic segment. Vein saphena magna (VSM) as a surgical alternative reconstitution and replacement of arterial pathway of lateral or counter-lateral bridging is the dominant revascularization strategy, as opposed to synthetic graft with modified autological dilated venous patches (patch) Linton-patch/Taylor patch (Rutherford, Baker, Ernst et al. 1997). Although a traditional medically established vascular method in the treatment of limited-duration ischemic progression (depending on further suppression of the risk factor, the general state of the patient, and the age progression of the atherosclerosis process), the question is being asked concerning the adequacy and impact of physical activity with appropriate potential supplements, in addition to the already established antithrombotic conservative therapy at the outcome and bypass pathway of any Dacron or autologous venous conduit vein of saphena magna VSM (Evans, Prendiville, Yeager, O'Donnell et al., 1990; Feldhaus Matsuura, Dattilo et al.,1998).

The main goal of this study is, after realized aortic-femoral, aortic-ilicular or femoral-popliteal surgical treatment, to establish the benefits from ALA (in doses up to 1800mg/day) in combination with Taurine (3-5g/day), Tribulus Terrestris TT (1500mg/day) and the concept of physical activity (interval walking program) of patients in andropause. It was necessary to determine the vascular status, BMI status, the primary passage of the venous conduit (vein saphena magne -VSM) and the Dacron conduit using a Doppler color with an ultrasound linear probe of 7.5 MHz, a clinical picture of the primary bypass of different arterial segments of the bypass, as well as laboratory tests of lipid status and the length of the claudication distance.

The secondary goal is to objectify the use of additional supplements on the outcome of discipline, as well as the possibility of remodeling the regimen of life habits, and improving the benefits of treatment after the performed vascular treatment with the application of the possible modality of physical activity as one kind of rehabilitation and remodeling anthropomotor dynamics.

METHODOLOGY

Participants and Design

The study included a randomized, double-blind, multicentre study over a period of three years (January 2015-January 2018). Data were collected that included a total of 112 respondents, aged 50 to 75 years (BMI 25-34,9kg/m²), following surgical treatment monitored for 3 years (Table 1). Of the planned 208 respondents, 30 patients did not meet the criteria for completing the study by the treadmill rehabilitation concept; 24 patients did not meet the criteria for completing the study with the proposed conservative concept; 32 respondents gave up, on average 2 to 25 days (7,34 days average) after the beginning of the study, 10 were lost for follow-up during the whole study.

Inclusion criteria are patients treated with Tribulus terrestris, Taurine and high dose of ALA supplementation, and interval training versus standard protocol training (Exercise prescription for treadmill walking program for Peripheral Artery Disease, by guidelines of PAD for people with intermittent claudication Fontani's stage II a developed by the Vascular Disease Foundation and AACPR.

Exclusion criteria are diabetic patients, patients who didn't suffer angina pectoris, stroke, heart attack and low ejection fraction EF(<45%) within two years period. During period of three years of research, progress of underlying disease was not confirmed; diabetic neuropathy and the presence of absence of lower limb and foot sensibility also, were not clinically confirmed during the study period. During three years training program procedure patients were required to contact vascular surgeon and his medical team if health conditions become progressively worse cold foot ischemia in progress (fontain stage III, IV) graft occlusion, reoperation, absence of sensibility, cancer.

There were no reported deaths, and therefore the respondents did not meet the criteria for monitoring and compiling to statistically relevant evidence. Since this is a post-operative monitoring of patients with the use of supplementation with the improvement of physical activity and the dynamicity of cardiovascular patients without modifications of the ethical indicative medical treatment of healing, no medical ethical principle of this study has been violated nor further.

Primary potency of surgical intervention and post-operative vascular rehabilitation is to change patient state from asymptomatic to symptomatic state, by supporting primary post-surgical medical therapy with supplementation of Tribulus terrestris, Taurine and high dose of ALA combined with interval training. Independent variables: are supple-

mentations support of Tribulus terrestris, Taurine and ALA combined with interval training. Dependent variables: are supervised stable condition of the patients with increase of claudication distance in a surgically vascular treated patients during application of modified versus standard vascular rehabilitation (Exercise prescription for treadmill walking program for Peripheral Artery Disease, by guidelines of PAD developed by the Vascular Disease Foundation and AACPR).

Intervention Protocol

Training duration is 30-60 minutes, with 5-10 minutes of warm-up and cool-down phases. Predicted training volume per week is 3-4 times, and are maintained for three years. The remaining number of 112 respondents with BMI 25-34,99kg/m² on anticoagulant therapy, aged 50 to 75 years with femoral distal bypass, was included for randomized monitoring in the vascular rehabilitation program.

a) First group:
   50 respondents with BMI 25-34,99kg/m² (50-75 years old) with: aortic-iliacal Dacron bypass (TASC IIA and B); aortic-femoral bypass (TASC II A and B); Iliac-femoral bypass (TASC II A and B); femoro-distal venous inverse bypass (Linton-patch/Taylor patch); femoro-distal venous inverse bypass without additional application (Linton-patch/Taylor patch). This group of respondents carried out walking on a treadmill at a standard dose of ALA 600mg once daily (according to the Vascular Disease Foundation-VDF and the American Association of Cardiovascular and Pulmonary Rehabilitation-AACVPR)
b) Second group:
   62 respondents with BMI 25-34,99kg/m² (50-75 years old) with: aortic-iliacal Dacron bypass (TASC II A and B); aortic-femoral bypass (TASC II A and B); Iliac-femoral bypass (TASC II A and B); femoro-distal venous inverse bypass (Linton-patch/Taylor patch); femoro-distal venous inverse bypass without additional application (Linton-patch/Taylor patch) at high doses of ALA supplementation (1800mg/a day and normal doses of Taurine 3-5g/a day) after an interval walking program based on interval standards.

Measurement Protocol

Coagulopathies, haemophilia, malignancies, and any other cardiovascular disease in the background have not been reported in all respondents. All respondents were given the diet redemption recipe, which also excludes everyday traditional national fast food in the form of daily food style implementation (permitted consuming 1-2 per week based on recorded calorie intake). Prior to the study, patients did not have high blood pressure; lipid status was in reference values. With all respondents an informative interview was held, with a given consent in the written form of the individual about a poten-

Table 2. One years of primary vascular intervention potency with tribulus terrestris (TT), taurine, high dose ALA supplementation and intervall and standard method physical support (p<0,05)

		Interval method	Standard method
With supplements	Total surgical treated patients	62	50
	Iliaco- femoralni bypass (dacron) 6-9mm	14	14
	Aorto-femoralni bypass (dacron) 6-9mm	16	16
	Aorto -iliacal bypass (dacron prothesis)	2	2
	Aorto -biiliacal bypass (bifurcation dacron prothesis)	2	2
	Average BMI, body mass index. male	28,12	27,02
	Average Exercise performanse tretated patents peer week (in hours/min)	3:54±25	2:34±5
	Average Serum Testetsterone (ST) values 91-579 pmol/L	129±2,08	112±2,78
	Claudication distance over 200m Fontain IIb	3	3
	Claudication distance under 200m Fontain IIa	1	1
	Rest pain	0	0
	Lost to follow up	1	0
Control	Femoro-distal vein bypass withoout Linton-patch/Taylor patch	25	25
	Femoro-distal vein bypass with Linton-patch/Taylor patch	2	2
	Average BMI, body mass index. male	28,12	28,12
	Average Exercise performanse tretated patents peer week (in hours/min)	2:45±25	2:05±15
	Average Serum Testetsterone (ST) values 91-579 pmol/L	109±4,08	101±2,78
	Average (MET) 3-6		
	Claudication distance over 200m Fontain IIb	6	6
	Claudication distance under 200m Fontain IIa	0	0
	Rest pain	0	0
	Lost to follow up	0	0

tial health disorder, and proven cardiovascular damage, so each respondent was informed and notified, prior to self-initiative application of the possible potential adverse effect of testosterone, as well as the psycho-physical health benefits of this training.

The aim of this study is to demonstrate the potency of the venous or Dacron bypass with color Doppler, with the appropriate standard and modified application (interval with the physical stress method) supplemental therapy (ALA at doses up to 1800mg/a day) in combination with Taurine (3-5g/a day, Tribulus Terrestris 1500mg/a day) and modification of physical activity. The aim of the study was to prove the benefits of vascular therapy and to determine by supplementation the quality and concept of the physical activity of obese vascular patients with an insight into the bypass passage. It will also have an insight into BMI and laboratory-medical parameters in respondents aged 50-75, and on the basis of the obtained data, indicate the severity of the vascular rehabilitation program or the possibility of treatment options, as well as the secondary prevention measures to indicate the culture of life, and avoidance of potentially permanent cardiovascular disability.

Primary medicamentous anticoagulant therapy for ethical reasons remains the same.

All patients were included in the vascular rehabilitation program by the sports team and experts in the field of sports and sports medicine as well as from the sports universities of Bosnia and Herzegovina, with the authority of the vascular team.

Characteristics of interval modified therapeutic procedures (Solaković, Vrcić, & Pavlović, 2016)

- Interval training
- program was composed of: walking 30-60 minutes
- with repetitions of short walking distance 100-400m of middle and high intensity over 70% fast walking with a recovery period following each repetition,
- also with self-control heart frequency 100-155 beats/min at max.
- walking intensity of 60 to 70% of heart rate for three years

Statistical Analysis

Descriptive statistics were done for all variables. For comparison of the selected variables and necessary information, One way ANOVA analysis was used when three groups were compared. When values from two groups were analyzed we have used t-test. Level of significance is set on $p<0,05$. For statistical analysis Medcalc 15.8 statistical package was used, produces by MedCalc software bvba, alongside with MS Office 2016 package.

RESULTS

Patients and interval group have benefits from supplementation extending the walking distance. Average of testosterone levels (Interval group115 ± 2,78 vs.standard group123 ± 2,78) during interval method in vascular patient are sig-

Table 3. Two year primary vascular intervention potency with tribulus terrestris (Tt), taurine, high dose ALA supplementation support and intervall and standard method physical support ($p<0,05$)

		Interval method	Standard method
With supplements	Total surgical treated patients	62	50
	Iliaco- femoralni bypass (dacron) 6-9mm	14	14
	Aorto-femoralni bypass (dacron) 6-9mm	16	16
	Aorto -iliacal bypass (dacron prothesis)	2	2
	Aorto -biiliacal bypass (bifurcation dacron prothesis)	2	2
	Average BMI, body mass index	26,92	26,12
	Average Exercise performanse tretated patents peer week (in hours/min)	3:54±25	3:14±25
	Average Serum Testetsterone (ST) values 91-579 pmol/L	119±2,08	103±2,78
	Claudication distance over 200m Fontain IIb	3	3
	Claudication distance under 200m Fontain IIa	1	1
	Rest pain	0	0
	Lost to follow up	0	0
Control	Femoro-distal vein bypass withoout Linton-patch/Taylor patch	25	25
	Femoro-distal vein bypass with Linton-patch/Taylor patch	2	2
	Average BMI, body mass index. male	27,12	27,18
	Average Exercise performanse tretated patents peer week (in hours/min)	2:45±25	2:43±20
	Average Serum Testetsterone (ST) values 91-579 pmol/L	99±2,08	103±2,78
	Claudication distance over 200m Fontain IIb	6	6
	Claudication distance under 200m Fontain IIa	0	0
	Rest pain	0	0
	Lost to follow up	0	0

Table 4. Tree years of primary vascular intervention potency with tribulus terrestris (Tt), taurine, high dose ALA supplementation support and intervall and standrad method physical support (p<0,05)

		Interval Method	Standard method
With supplements	Total surgical treated patients	62	50
	Iliaco- femoralni bypass (dacron) 6-9mm	14	14
	Aorto-femoralni bypass (dacron) 6-9mm	16	16
	Aorto -iliacal bypass (dacron prothesis)	2	2
	Aorto -biiliacal bypass (bifurcation dacron prothesis)	2	2
	Average BMI, body mass index. male	27,12	26,12
	Average Exercise performanse tretated patents peer week (in hours/min)	3:54±25	2:54±28
	Average Serum Testetsterone (ST) values 91-579 pmol/L	115±2,78	123±2,78
	Claudication distance over 200m Fontain IIb	3	3
	Claudication distance under 200m Fontain IIa	1	1
	Rest pain	0	0
	Lost to follow up	0	0
Control	Femoro-distal vein bypass withoout Linton-patch/Taylor patch	25	25
	Femoro-distal vein bypass with Linton-patch/Taylor patch	2	2
	Average BMI, body mass index. male	28,12	27,32
	Average Exercise performanse tretated patents peer week (in hours/min)	2:54±25	1:35±17
	Average Serum Testetsterone (ST) values 91-579 pmol/L	108±3,23	103±3,23
	Claudication distance over 200m Fontain IIb	6	6
	Claudication distance under 200m Fontain IIa	0	3
	Rest pain	0	0
	Lost to follow up	0	0

nificant rised leaving no symptomatic walking pain such as claudication sympmtoms (Tables 2-4). In fact, we concluded during the study that interval training is a perfect and a great option for vascular surgical trateted patient, on any arterial vascular level, conserving individual comorbidity and leaving no negative cardiovascular effects. Results of Average Exercise performance with interval treated patients peer week (Interval group 2:54 ± 20 vs standard group 1:35 ± 17) are medical imposing (Tables 4 and 5). Therefore bring us to bring to the conclusion such strategies should be primarily adopted.

When analyzed BMI was at the end of first year of treatment significantly higher in subjects who have consumed supplements, but in second year that was on border of statistical significance. In third year BMI was significantly higher in group that consumed supplements. In total there was significant difference, with trend of BMI getting lower, One Way ANOVA F=62,93, p<0,001 (Figure 1). Average testosterone level showed decline in group that consumed supplements over the three years, and values differ from control (p<0,001) (Figure 2).

When standard methods were used, there wasn't any difference in BMI, but testosterone levels have significantly different values from control, p<0,001 (Table 6).

For the need of testing time intervals, we have converted time into minutes, and after that comparison was made. In all group t-test showed statisticly better time intervals when supplements were used (Table 5). Also even without them, interval method showerd much better results than control (p<0,001) (Figures 3 and 4).

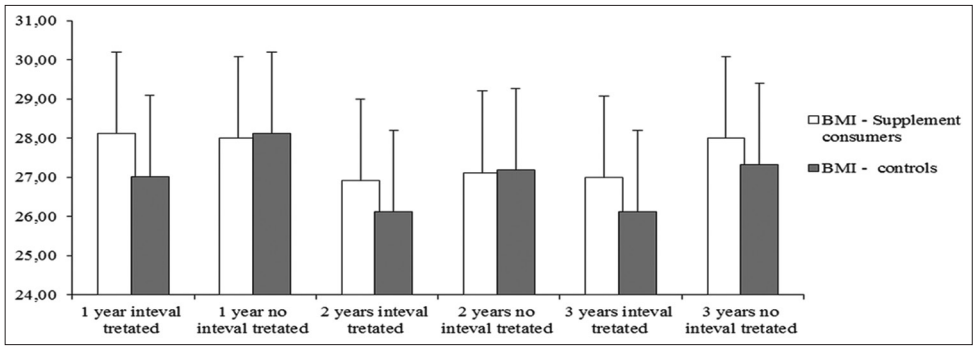
Table 5. Average Exercise performanse in patients with surgical treatment with orwithout supplements (in hours/min)

		With supplements	Control	p
I year	Interval	3:54 ± 25	2:45 ± 25	<0,001
	Standard	2:54 ± 5	2:05 ± 15	<0,001
	p	<0,001	<0,001	
II year	Interval	3:54 ± 25	2:45 ± 25	<0,001
	Standard	3:14 ± 25	2:43 ± 20	<0,001
	p	<0,001	0,75	
III year	Interval	3:54 ± 25	3:54 ± 27	0,99
	Standard	2:54 ± 28	1:35 ± 17	<0,001
	p	<0,001	<0,001	

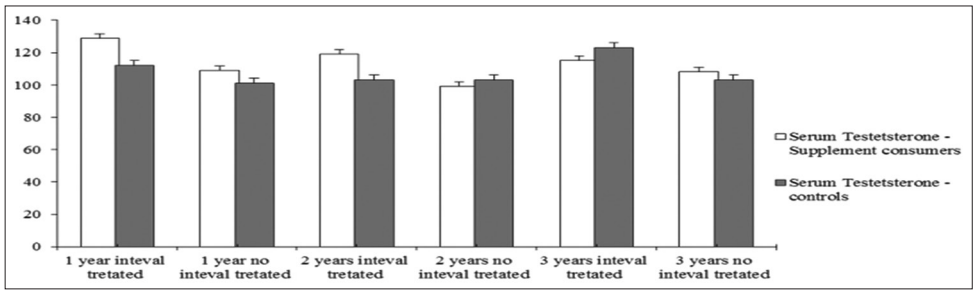
For the need of testing time intervals, we have converted time into minutes, and after that comparison was made. In all group t-test showed statisticly better time intervals when supplements were used. Also even without them, interval method showerd much better results than control (p < 0,001)

DISCUSSION

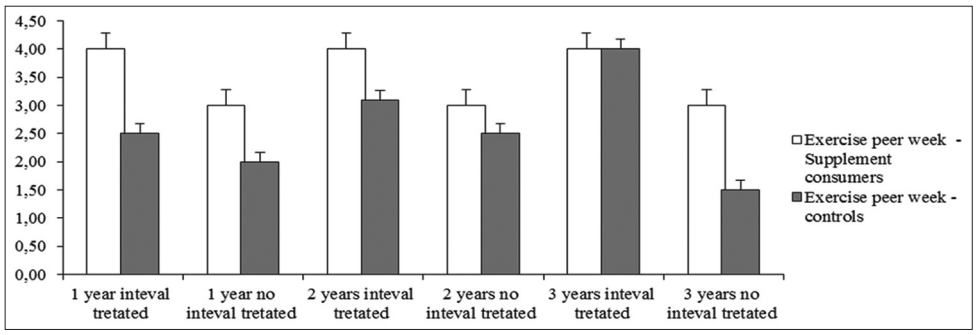
The results of the research have proven that primary potency after all variation of vascular bypass intervetion in surgical



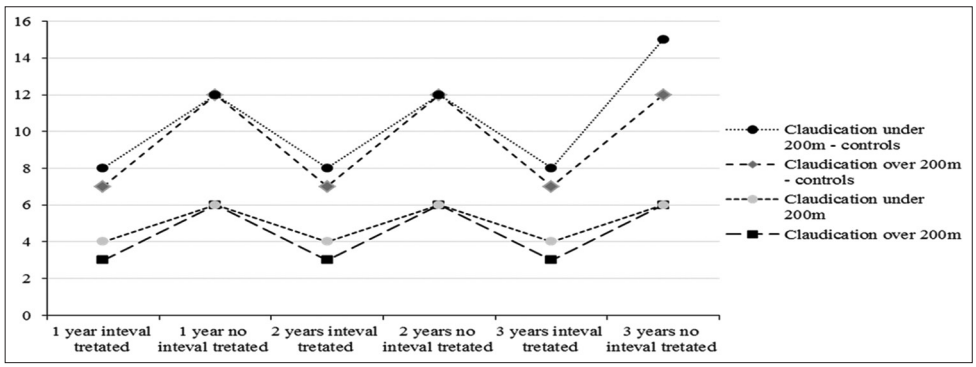
Figiure 1. Supllementation for 3 years (consumers and controls)



Figiure 2. Distribution for serum testesterone (Supplements consumers and controls)



Figiure 3. Exercise peer week- supplement (consumers and controls)



Figiure 4. Distribution for 3 years claudication distance (over and under 200m)

treated patients with Tribulus Terrestris (TT), Taurine and High Dose Alfa Lipoic Acid (ALA) supplementation with interval method durig 3 years of reserch were improved durng exercise performanse. Benefitis of vascular rehabilitation were also improved witch are not precisely and concisely established. This research has confirmed superiority of interval method over standard method, and therefore interval method should be adequately applied in vascular rehabilitation.

In patients with pronounced andropause, almost 18% peripheral arterial disease is the second-ranked form of manifestation of atherosclerosis, and over 53% is epidemiological disease in the leading European industrial countries with a degree of increasing tendency every year (Dormandy, Mahir, Ascady et al. 1989; Kueger, et al. 2002). Especially in the stage of claudication problems of Fontain IIa stage, the therapeutic possibility is limited by conservative vasothera-

Table 6. Differences in values of bmi and average serum testosterone (ST) through three years of therapy and excersice using interval or standard method

	Variable	I year	II year	III year	F	p
Interval method	Average BMI - supplement consumers	28,12 ± 2,7	26,92 ± 2,23	27,12 ± 1,76	62,93	<0,001
	Average BMI - Controls	27,02 ± 1,82	26,12 ± 2,03	26,12 ± 1,68	0,44	0,645
	P (t test)	0,015	0,053	0,003		
	Average Serum Testosterone (ST) - supplement consumers	129 ± 2,08	119 ± 2,08	115 ± 2,78	1,54	0,215
	Average Serum Testosterone (ST) - controls	112 ± 2,7	103 ± 2,28	123 ± 2,78	0,82	0,441
	P (t test)	<0,001	<0,001	<0,001		
Standard method	Average BMI - supplement consumers	28,11 ± 1,98	27,12 ± 1,78	28,14 ± 1,47	0,02	0,976
	Average BMI - controls	28,12 ± 2.1	27,18 ± 1,84	27,32 ± 1,79	0,86	0,426
	P (t test)	0,986	0,909	0,083		
	Average Serum Testosterone - supplement consumers	109 ± 4,08	99 ± 2,08	108 ± 3,23	9,34	<0,001
	Average Serum Testosterone - controls	101 ± 2,71	103 ± 2,65	103 ± 2,73	2,26	0,107
	P (t test)	<0,001	<0,001	<0,001		

When analyzed BMI was at the end of first year of treatment significantly higher in subjects who have consumed supplements, but in second year that was on border of statistical significance. In third year BMI was significantly higher in group that consumed supplements. In total there was significant difference, with trend of BMI getting lower, One Way ANOVA F=62,93, p<0,001. Average testosterone level showed decline in group that consumed supplements over the three years, and values differ from control (p<0,001).
When standard methods were used, there wasn't any difference in BMI, but testosterone levels have significantly different values from control, p<0,001

py with adequate strategic physical concept and possible reduction of arterosclerotic process of increased angiogenesis and collateralization and return to reversible asymptomatic condition. In the case of Fontain III peripheral arterial disease, concomitant diseases are the prognostic criteria for the quality of benefit of surgical treatment and the prognosis of operative outcomes of femoral-popliteal bypass treatments where cerebral, pulmonary and cardiac manifestations of the degree of disease play a key and irreplaceable indicative role, directly influencing individual approach to the physical concept and the bypass itself (Aronow & Ahn, 2004).

Atherosclerosis of the treated surgical iliccal segment and generalized systemic form in multiple arterial arterial stenotic occlusive segmental diseases is still a strong risk factor, especially if it is a synergistic ischemic disease on the coronary system. Taurine contributes to the prevention of progression of pathology of atherosclerosis in the coronary system, and can also be an important factor in suppressing the progression of arterosclerosis with the inhibition of the lipid peroxidation with the decrease of the lipid LDL level in blood and the increase of HDL, with the prevention of endothelial dysfunction. Consequently, an obese patient on an individual concept of physical activity with the use of Taurine with high doses of alphalipoic acid (ALA) would most likely benefit from peripheral arterial disease (PAD). In this way, it would directly and indirectly affect the quality of the pathway of the venous and Dacron bypass with the limitation of the very quality of the venous conduit. The size of the risk factors, such as obesity and overweight, can be controlled, with motivational help from a disciplined, adequate training concept. However, scientific studies are limited in connection with abstinence of old habits of life, diet modification and the addition of adequate supplementation after vascular surgical bypass treatment.

Taurine in combination with ALA has an impressive effect on the reduction of LDL and plays an important role as an antioxidative factor in the suppression of the atherosclerosis and endothelial anti-inflammatory inflammation. Numerous studies have suggested that human-beneficial benefits of Taurine for peripheral arterial circulation are underutilized. Taurine modulates the vascular tonus of circulation, especially in hypotensive conditions with low calcium. Taurine also plays an important role in vasoconstriction, by directly maintaining blood pressure, affecting the increase in testosterone concentrations. In the progression of ischemia (hypoxia), Taurine dilates blood vessels with strong homeostatic potential on smooth and cardiac muscle cells. Its potential increases with operative-conservative treatment, and allows for femoral-popliteal outcome and for potentially maintaining the passage of autologous venous treatment bypass (Arany, Strutt, Romanus et al. 2004; Rutherford, Spriet, & Stellingwerff 2010).

Atherosclerotic progression of the peripheral disease itself with combined ischemic disease has in the past years caused an increased rate of mortality. Patients with an andropause who suffer from the progression of an atherosclerotic disease could benefit from Taurine which contains beta-amino acids (amino acids which contain sulfur) with endothelial dysfunction prevention. This would prevent lipid accumulation and the formation of stable plaques on multiple vascular systems with the alleviation of damage to the monocyte function, as well as the prevention of lipid accumulation on the aortic valve and hypercholesterolemic animal models of the samples. According to Takashi et al. [13] Taurine increas-

es the production of testosterone in serum (TS) in rats with diabetes mellitus, so that diabetic patients affected by atherosclerosis would potentially also benefit therapeutically. They proved that in patients with claudication (training of endurance) Taurine results in a reduction in total cholesterol up to 8% with a reduction in LDL of an average of 12% in 3 times a week, 30-60 minutes for 9 weeks with an intensity increase of 7km/h to > 10km/h. As part of our research, Interval Walking Training (IWT) with periodization of intensity increase and adequate supplement Tribulus Terrestis, Taurine and high doses of ALA, as a supplementary support to primary therapeutic therapy in therapy conditions, gives better results at the central fatness as general fitness. There are also subjective and objective benefits of physical constitution as an increase and neutralization of the pathological claudication distance, with an increase in the ABI index and the passage of autologous or Dacron bypass treatment at the lower extremities. In general, the endothelium protection takes as much training as possible with individually dosed intensity and it goes better. Silva, et al. (2011) showed a significant increase in HDL in a healthy population (1837 runners) where HDL is 0.133mg/dl, in each week higher. According to the data, during walking training after 30-60 minutes, 3 workouts per week for 16-22 weeks, can be seen a significant increase in HDL (between 2.4% and 15.6%) without additional supplements. Also known are the effects of Taurine on stress and metabolism in elite cyclists (Rutherford, Spriet, & Stellingwerff, 2010). There is a direct significant correlation between HDL and maximum oxygen intake, which directly affects the increase in HDL levels through a physical stress concept. Patients who undergo coronary surgery or after a heart attack, need an individual adaptation physical concept after being discharged from the hospital (walking at least 10 minutes a day to increase that distance along the pace of walking that would not cause cardiac disturbances). Pulsometer for measuring heart rate makes subjective disturbances in the patient, and due to irregular oscillations of the pulse it additionally psychologically burdens the patient. From our point of view, we believe that such an issue could be solved with adequate individual testing and preparation, and the patients would further profit and have direct insight and control of their subjective cardiac status, and possibly monitor the deterioration and improvement of the training concept. With the introduction of adequate doses of 3.5-10 g/kg daily of supplementation of Taurine, scientific debates have been conducted that have demonstrated benefits in animal models and respondents (Arany, Strutt, Romanus et al.2004; Brøns, Spohr, Storgaard et al.2004).

High doses of ALA in obese patients, with appropriate rehydration guidelines after the implementation of femoral-popliteal, aortic-femoral, and iliac-femoral bypass procedure with diet remodeling in combination with Tribulus Terrestis in the form of Tribulosin (saponin), would influence the stimulation of the level of testosterone in serum (TS). This would result in significant improvements in the reduction of lipid levels, the very potential for the remodeling of endothelial dysfunction on the blood vessels, on the aortic and distal blood vessels of the extremities in surgically treated patients with reperfusion injury and the remodeling of the heart tissue in non-diabetic and potentially diabetic patients (Tuncer, Yaymaci, Sati et al. 2009). Therefore, we think that its potentials are not fully used, and that synergy with ALA and Taurine would be a powerful supplementary support for conservative anticoagulant and hyperlipid therapy following the application of surgical vascular bypass procedure. Its use would also have effects in patients who suffered myocardial infarction by remodeling ischemic pathology of heart function and ejection fraction in early regenerative subjective recovery (Olas, Hamed, Oleszek et al.2015). Cardiologic patients with surgically treated coronary and femoral-popliteal bypass could also benefit from the diuretic effect of Tribulus and benefit on the decrease in systolic and diastolic blood pressure (Sharifi, Darabi & Akbarloo, 2003). This is followed by a decrease in triglyceride levels with the blockade of angiotensin II and hydrogen peroxide on vasculature and degenerative cerebral-protective effects with an adequately controlled physical and dietary diet, and represents the ideal of vasodilatative supplementation (Sharifi, Darabi & Akbarloo, 2003) as support to primary medicament therapy (Sharifi, Darabi, & Akbarloo, 2003; Tuncer, Yaymaci, Sati et al. 2009; Berkman, Tanriover, Acar, et al. 2009; Li, Guan, Liu et al. 2013). An important role is played by the combination of ALA that is present in physiologically low concentrations in mythodondrias. Adequately adapted increased dosing would accelerate the metabolic state through adequate physical exercise, and the remodeling of the diet would produce potential therapeutic benefits for the state of lipid values (Herzberg et al. 2004; Harding, Rideout, Jones et al. 2012). Of course, after performing the surgical treatment, in addition to primary medical internist therapy, an adequate concept of physical activity continues to play the key role, which scientifically proves to reduce the risk of progression of cardiovascular disease on all systems. Although scientific facts on the part of the concept of sports science speak of the same benefit, there are various disagreements about intensity, gender, types of physical activity, and length of physical activity in various body forms, especially after potential surgical bypass procedure (Keating, Johnson, Mielke et al. 2017; Carrasco, 2017; Türk, Theel, Kasteleyn et al.,2017). Simon Higgins' study points to the benefits of training in the obese female population, and also for calorie consumption and the reduction of cirumferent fatness. Although science has limited data for male populations in andopause of this type of patients, it has been proven that in the female population sprint-interval training gives a stronger lipotropic effect in contrast to the middle intensity of strain. Although walking guidelines are established and not individually conceptualized in surgically treated patients with ischemic disease, sprint-interval training would not be recommended for them, but interval training of the middle intensity of strain which would allow the patient to adequately manifest daily activities.

We can also say that disciplined continuous interval training with medication therapy and support of said supplementation directly improves the extension of surgical bypass in any arterial segment, regardless of conduction material, other than haemodynamic autologous reverse lateral or ipsilateral venous conduit or synthetic Dacron material on aortic-femo-

ral, iliacal and femoral levels as well as at the level of improving the objectivity of strength and improving the quality of life (Ivanova, Ivanov, Mladenov et al. 2016; Zhu, Du, Meng et al., 2017; Rogerson, Riches, Jennings et al., 2007).

Limitation of Study and Further Research

Study is limited to surgically treated patients, endovascular group is not included in the study. Comparing these two groups (surgically treated patients and endovascular group) would furtherer improve study quality.

The primary passage of surgical intervention is partially dependent on the general state of the blood vessels and many other factors, and is in the correlation and dependence of additional pharmacological remedies in the form of improving the dynamics of the patient's everyday life in all fields and aspects of life. We can safely say that supplements after the surgical procedure can achieve a better indirect graft passage through the enhanced dynamics of patients treated on conventional surgical way. However, the patients treated with aortic-ilicular Dacron graft and the iliac-femoral Dacron graft are in advantage over the classic surgical femoro-distal treated graft in expressing the anthropological performances of patients as well as slowing down the development of the pathological process in the ilicular mainstream segmented endovascular technique. Other studies would also be needed to improve or individually improve the applications of vascular surgical and medically advanced endovascular interventions that are still in the study phase. The study alone demonstrated the poor performance of Tribulus Terrestris at the serum testosterone level in patients treated with surgical treatment in the aortic-ilicular, aortic-femoral level. The smallest benefit of supplementation was shown in patients treated with venous conduits. Therefore, patients with a synthetic Dacron graft of aortic-iliocural and aortic-femoral level may benefit from additional supplementation. However, more research is needed on a larger number of patients to confirm this claim and additionally support primary anticoagulation therapy.

CONCLUSION

The conclusion is that in surgically treated patients with individual metabolic and general conditions, the quality of physical activity (interval training method) and lifestyle modeling with the addition of Taurine, alpha lipoic acid (ALA) and multiple effects of Tribulus supplementation to the vascular system, would improve the benefits of supplementary support for vascular conservative therapeutic treatment in an iliacal magistral segment treated with endovascular technique as opposed to primary classical surgical treatment. Benefits of physical activity and targeted supplementation with Tribulus are in direct correlation with the bypass passage with the longevity of the active dynamics of the treated patients, and would be potentially more effective strategy with a disciplined remodeled lifestyle regimen that is a major problem of today. This study confirmed the benefits of the primary clearance of Dacron and venous bypass with the superiority of the supplements application as a support to primary vascular antithrombotic therapy, and it would be a good individual recommendation after the surgical procedure to establish it as the appropriate post-therapeutic strategic supplementation.

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