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The effects of BMI on health-related physical fitness components in secondary school children (15–17 years)

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Abstract

Childhood obesity has been associated with various metabolic and cardiovascular diseases such as type 2 diabetes mellitus, metabolic syndrome, dyslipidemia etc. The purpose of the study is to determine the prevalence of overweight and obesity in school children aged 15-17. Body composition of 114 adolescents (47 boys and 67 girls) aged 15-17 years were measured and body fat percentage and body mass index (BMI) were calculated. Participants were characterized as normal weight, overweight and obesity based on the standard criterion and BMI was used to determine the categories. Physical fitness was assessed by measuring flexibility through the sit-and-reach test as well as upper body and abdominal muscle endurance by measuring the amount of push-ups and sit-ups able to perform in one minute. In the total group 8.8% was obese and 22.8% overweight. Girls were more obese (80%) than boys (20%). The prevalence of overweight was 23.4% in boys and 22.4% in girls. Linear regression was done to establish the effect of BMI on the various physical fitness components. It is clear that BMI had a positive significant relationship with waist circumference and fat percentage and a strong positive relationship with blood pressure in girls. A negative significant relationship was also found in abdominal muscle endurance and flexibility in girls. There was no significant relationship between BMI and heart rate. These findings are significant to help physical education teachers as well as health promoters to design appropriate health related exercise programs with specific relation to gender and weight class.

Key words: Gender/sex, age, children/adolescents, obesity and overweight

Introduction

The prevalence of childhood obesity has been increasing worldwide over the past few decades. In developing countries, the prevalence from 1980 to 2013 has increased dramatically with percentages in boys from 8.1% to 12.9% and in girls from 8.4% to 13.4% (Ng, Fleming, Robinson, Thomson & Graetz et al., 2014). South Africa has not been spared from the obesity epidemic, as indicated by Armstrong, Lambert, Sharwood & Lambert (2006), who collected data from 10,195 South African primary school children between the ages of 6 and 13, from diverse socio-economic backgrounds. It was found that the prevalence of overweight and obesity among boys was 10.9% and 2.4% respectively, whereas the prevalence of overweight and obesity in girls was 17.5% and 4.8% respectively. The First South African National Youth Risk Behaviour Study of grade 8-11 school children aged 13-19 years found that 17% of these children were overweight and 4% were obese when using the body mass index (BMI) equation (Cole, Bellizzi, Fegal and Deitz, 2000; Medical Research Council, 2002).

It has been well-established that a sedentary lifestyle is linked to overweight and obesity, cardiovascular disease, adverse metabolic profiles, osteoporosis, poor fitness, diabetes, breast cancer, and reduced psychosocial functioning (Hu, 2003; Hancox, Milne & Poulton, 2004; Warburton, Nicol & Bredin, 2006; Ussher, Owen, Cook & Whincup 2007; Spruijt-Metz, Nguyen-Michel, Goran, Chou, & Huang, 2008; Katzmarzyk, Church, Craig, & Bouchard, 2009; Biddle, Pearson, Ross, & Braithwaite, 2010; Costigan, Barnett, Plotnikoff, & Lubans, 2013). Sedentary lifestyles are a trend across most of the developed world (Armstrong, Bauman & Davies, 2000). According to Hills, King & Armstrong (2007), children's susceptibility to a

technologically changing environment and issues concerning their supposed safety are the causes of this behaviour. However, there is evidence to suggest that through the use of physical activity, the effect of obesity along with all of the other associated risk factors can be minimalized.

Flexibility is a component of health–related physical fitness, and in along with muscle strength and muscle endurance, it is more associated with the prevention of musculoskeletal health problems (Dorneles, Oliviera, Bergmann, & Bergmann, 2016). Good flexibility can greatly impact an individual's quality of life. According to Glaner (2003), some of the benefits include: improved skills in daily activities and sports; reduced risk of musculotendinous injuries and incidence of muscle pain, reduced stress and improved posture.

According to Parikh & Arora (2015), muscle endurance is the ability of a muscle or muscle group to repetitively move against a sub maximal resistance. Absolute muscular endurance is defined as the ability to perform a total number of repetitions at a given amount of resistance and relative muscular endurance is the ability to perform a number of repetitions at a percentage of the 1-RM (ACSM, 2014). Torso muscular endurance is a significant component of physical fitness and makes a great impact on the effectiveness and efficiency of the upper and lower extremities, provides stability to the spinal column and can lead to the prevention of injuries (Boyer, Tremblay, Saunders, McFarlane, Borghese, Lloyd & Longmuir, 2013).

As seen in the evidence presented above, there is an increase in the prevalence of obesity among children and adolescents. The cause of obesity is complex and multi-factorial; however, it seems that physical inactivity is the primary cause. Obesity impacts negatively on many aspects, including the health-related components of fitness, physical health, and mental status. It has been shown that overweight and obesity in adolescents often progresses into adulthood, and the comorbidities associated with obesity in adolescents becomes more severe in adulthood. Improvement in physical fitness is directly related to the improved health in children in a dose response relationship and subjects with high physical fitness levels during adolescence may have lower levels of body fatness as adults. However, it is still essential to better understand how different components of physical fitness affect body composition in order to design interventions and strategies to promote physical activity and physical fitness. Bearing this in mind the focus of this study was to evaluate the effect of BMI on the health-related physical fitness components of high school children aged 15-17 years.

Methods

This study was conducted in Richards Bay, Kwa-Zulu Natal, South Africa at Richards Bay High School. We recruited 114 grade 10 learners (15-17 years) to take part in the study and they completed anthropometrical measurements as well as physical fitness tests. The participating school was informed about the purpose of the study beforehand, and afterwards written informed consent was obtained from the parents of the participating students as well as school authorities.

Firstly the participants' resting heart rate (HR) and resting blood pressure (BP) measurements was taken, while the participants were rested in a seated position for at least 5min. The Biocare professional stethoscope was used to determine the resting HR of the participants. The stethoscope was placed at the fifth intercostal space at the apex of the heart to hear the most accurate sound of the apical pulse. Two subsequent blood pressure measurements were obtained with the sphygmomanometer to determine blood pressure. The protocol, as described by the ACSM (2014) was followed.

The body composition measurements (height, weight, skinfolds, waist and hip circumference) were measured next and the standard procedures described by the International Society for the Advancement of Kinanthropometry: ISAK was used (Marfell-Jones *et al.,* 2006). Height was measured by the use of the Stadiometer to the nearest 0.1cm with participants standing barefoot, in an upright position, facing forward. Weight was measured with an electronic scale to the nearest 0.1kg with participant wearing as little clothing possible. The subscapular, tricep, suprailliac, abdominal, thigh and calf skinfolds were measured to the nearest 0.2mm, using the average of two measurement. BMI was calculated by using body mass/stature^2 (kg/m^2) and body fat% based on the sum of skinfolds using the six-site skinfold formula. A mea-

suring tape was used to measure the waist and hip circumferences according to the protocol as prescribed by ACSM (2014). The waist-to-hip ratio was also calculated from these measurements by taking the waist circumference and dividing it by the hip circumference.

The physical fitness tests consisted of a sit-and-reach test for flexibility and 1min sit-ups and push-ups to determine muscle endurance. The sit-and-reach box was used for the sit-and-reach test. Participants sat with their backs against a wall and their feet firmly against the box. They placed their hands on top of each other and as they breathed out leaned forward with straight arms and legs as far as they could go. That position was maintained for two seconds and the measure was repeated twice according to the test guidelines (ACSM, 2014). The amount of sit-ups and the amount of push-ups that could be completed in 1 minute respectively was measured to give an indication of upper body and abdominal muscle endurance. Descriptive statistics [means (SD)] for body composition as well as physical fitness components were calculated for the total sample as well as for boys and girls separately. With linear regression the relationship between BMI and each one of the physical fitness components was established.

Results

As illustrated in Table 1, the total group (8.8%) was obese and (22.8%) overweight. Girls were more obese (80%) than boys (20%). The prevalence of overweight was 23.4% in boys and 22.4% in girls. When the analysis was performed gender specifically, the girls showed a higher prevalence of obesity (11%) than boys (4.25%), but there was no significant difference between boys (23.4%) and girls (22.4%) with the prevalence of overweight.

Discussion

In this study data is provided on the prevalence of overweight and obesity in secondary school children aged 15–17 years as well as the relationship between their weight classes, categorized by BMI, and the health-related physical fitness components between boys and girls separately. The results show that there is a larger prevalence of overweight in boys (23.4%) than in girls (22.4%) but larger prevalence of obesity in girls (11%) than in boys (4.25%). Armstrong et al. (2006), found that the prevalence of overweight and obesity in South African was 10.9% and 2.4% respectively in boys and 17.5% and 4.8% respectively in girls. It is clear from the data of our study that there was in-

Table 1. Characteristics of the sample group: Total group and Gender

	Total (n = 114)	**Boys (n = 47)**	**Girls (n= 67)**
Age (years)	16±0.83	16.02±0.86	15.98±0.83
Height (m)	1.67±0.09	1.75±0.07	1.62±0.06
Body weight (kg)	66.73±13.26	70.63±12.48	64±13.20
BMI (kg/m^2)	23.71±4.61	22.89±3.86	24.29±5.08
Waist Circumference (cm)	75.02±11.29	76.63±8.65	73.89±12.77
Fat %	11.52±9.16	11.73±4.48	25.59±6.93
Flexibility	41.4±9.53	39.29±10	42.88±8.94
Push Ups	31.81±13.05	37.40±15.97	27.89±8.73
Sit ups	30.30±11.51	33.6±14.23	28±8.54
Heart Rate	86.24±15.37	58.89±16.34	86.49±14.77
Systolic Blood Pressure	127.77±13.59	128.31±21.54	125.89±12.92
Diastolic Blood Pressure	78.86±11.37	78.61±13.98	79.04±9.23
BMI CATEGORY			
Normal (%)	68 (59.6%)	**31 (65.95%)**	**37 (55.2%)**
Overweight (%)	26 (22.8%)	**11 (23.4%)**	**15 (22.4%)**
Obese (%)	10 (8.8%)	**2 (4.25%)**	**8 (11%)**
GENDER			
Males	46 (40.3%)	**Females**	68 (59.6%)

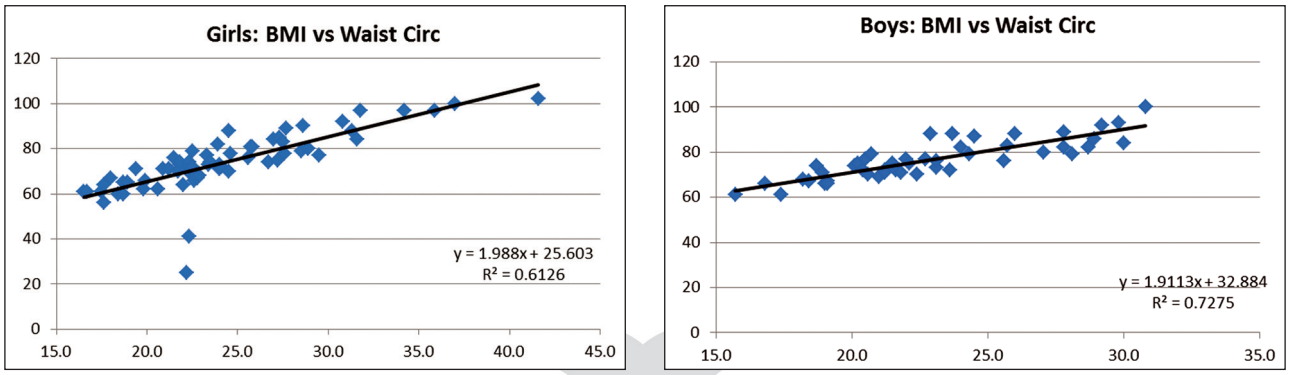

Figure 1. Relationship between BMI and Waist Circumference in Girls and Boys

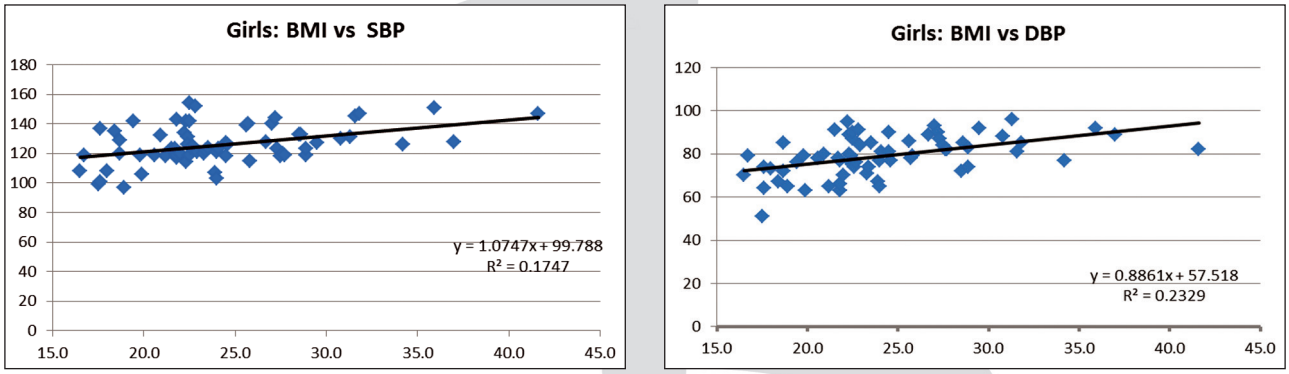

Figure 2. Relationship between BMI and systolic and diastolic BP in girls

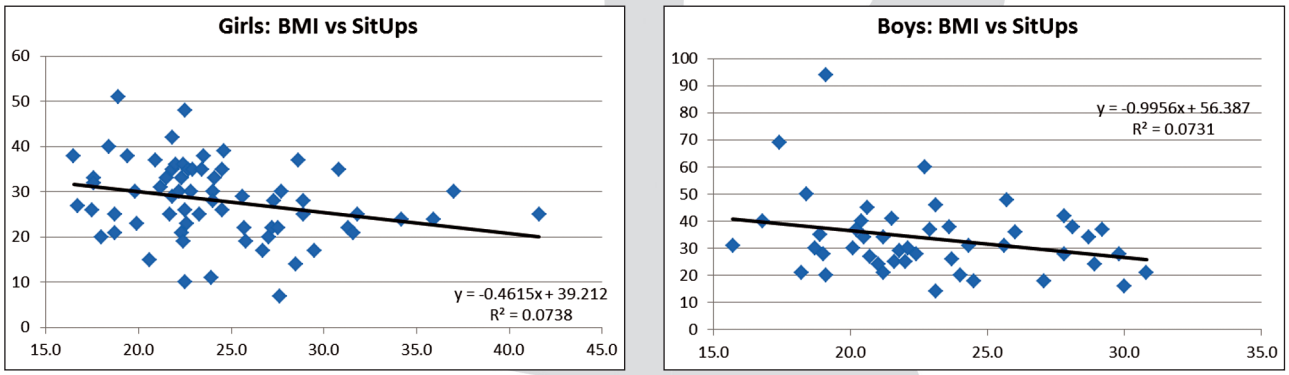

Figure 3. Relationship between BMI and Abdominal Muscle Endurance

deed an increase in the prevalence of overweight and obesity in boys and girls.

Figure 1, shows a very significant relationship with waist circumference in girls (r = 0.78) and boys (r = 0.85). There was also a significant positive relationship between BMI and body fat percentage in girls (r = 0.89) and boys (r = 0.79) respectively. In the girls there was a significant relationship between BMI and systolic and diastolic blood pressure with r values of 0.41 and 0.48 respectively as seen in Figure 2.

Interestingly there was no significant relationship between BMI and systolic blood pressure in boys but a borderline significant R-value in the diastolic blood pressure of 0.33. Another borderline significant negative relationship was found with abdominal muscle endurance in boys (r = 0.27) and girls (r = 0.27) seen in Figure 3, but upper body muscle endurance showed a small significance in the girls (r = 0.19) and no significance in boys (r = 0.09). The same happened with flexibility where there was no significance in the girls (r = 0.18) and no significance with the boys (r = 0.02). There was a non-significant positive relationship between resting heart rate and BMI with boys (r = 0.18) and girls (r = 0.004).

The results support the hypothesis of this study stating that BMI is strongly related to waist circumference and body fat percentage. Our findings show that there was a very strong relationship between BMI and waist circumference being a stronger relationship with the boys than with the girls. Taylor, Jones, Williams & Goulding, (2000) and Savva, Tornaritis, Savva, Kourides, Panagi, Silikiotou, Georgiou & Kafatos, (2002), stated that waist circumference is a useful index for the measurement of regional and total body fat and because of its strong relationship with BMI it can be used in conjunction with BMI to determine the risks for cardio-metabolic diseases. There was a strong positive relationship between fat percentage and BMI with a greater significance in girls than in boys. This difference in significance may be because of the fact that boys have a lesser fat percentage in general than girls and also because of their muscle mass. This is very significant seeing that BMI does not take muscle mass into account and someone with a large muscle mass may appear overweight or even obese when looking at their BMI.

If their fat percentage is taken into account, the muscle mass will be eliminated and an accurate measurement of body fatness can be determined. Another positive significant relationship was found between BMI and the systolic and diastolic blood pressure of girls. This coincides with the findings of Sorof, Lai, Turner, Poffenbarger & Portman, (2004) and Paradis, Lambert, O'Loughlin, Lavallée, Aubin, Delvin, Levy & Hanley, (2004), that indicated that excess body weight strongly correlates with the prevalence of hypertension in children. In the boys there was a borderline significant relationship of BMI with diastolic blood pressure but no significance with systolic blood pressure. Heart rate could be considered as an independent risk factor for cardiovascular diseases due to various factors such as its positive relationship with blood pressure (Cooney, Vartiainen, Laakitainen, Juolevi, Dudina & Graham, 2010). Cooney et al. (2010), also states that obese children tend to present higher heart rate levels than non-obese children. Our data does not support that statement and there was no significant relationship between heart rate and BMI. This might be because of the sample size and a larger sample size might give a different result.

It is necessary to acknowledge the fact that the increased prevalence of overweight and obesity is due to a lack of physical inactivity (Gupta, Goel, Shah & Misra, 2012). Ara, Moreno, Leiva, Gutin & Casajús, (2007) and Graf, Koch, Dordel, Schindler-Marlow, Icks, Bjarnason –Wehrens, Tokarski, Predela, (2004), states that physical activity is strongly associated with increased physical fitness components in children. Thus, through literature we could see there is a strong relationship between physical inactivity and overweight or obesity as well as physical fitness. However, there is still some uncertainty about what the relationship is between overweight or obesity and physical fitness. With regards to the physical fitness components, the boys and girls had a significant relationship between the abdominal muscle endurance and BMI with both having an alpha value of 0.05. The same could not be said for the upper body muscle endurance seeing that there was no significance with increased BMI in the boys. With the girls there was a borderline significance seeing that the girls with an increased BMI struggled with the push-ups. The same was found with flexibility seeing that there was no significant relationship between BMI and flexibility in the boys but there was a borderline significance in the girls. This strongly correlates with what Graf et al. (2004), found previously.

It should be taken into account that this study has some limitations to bear in mind when interpreting this data. One of the greatest limitations is that health related physical fitness components are made up of physical activity as well as non-modifiable factors such as genetics. These factors can greatly influence the results. Another limitation is the sample size that might be too small. With an increased sample size more accurate and significant relationships might have been established. Another limitation might be that the results may only be applicable to the locality of the school and the age group. On the other hand the age of this sample group, 15-17 years, is a beneficial age at which ample efficient strategies and prevention programs could promote health and fitness.

Conclusion

In conclusion, we established that there is a definite increase in the prevalence of overweight and obesity compared to 10 years back with a greater increase in obesity in girls and a greater increase in overweight in boys. We also established that an increased BMI is related to an increase in waist circumference, fat percentage and blood pressure and a decrease in abdominal muscle endurance, upper-body muscle endurance and flexibility. It was found that there is no significant relationship between heart rate and BMI. It is clear that an overweight and obese child has decreased physical fitness components and might not be able to handle the physical activity exercise programs that they are expected to. Thus, these findings are significant to help physical education teachers as well as health promoters to design appropriate health related exercise programs with specific relation to gender and weight class.

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Assessment of complications between two surgical treatments of pelvic organ prolapse: vaginoplasty and mesh implant

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Abstract

Introduction: The aim of this study was to compare two surgical techniques in the treatment of pelvic organ prolapse, and to determine which of these methods have shorter length of hospital stay, less incidence of operative and postoperative complications and less incidence of postoperative stress urinary incontinence.

Methods: It is a prospective study, which included 70 patients who were surgically treated after diagnosed pelvic organ prolapse. The experimental group included 35 patients having pelvic organ prolapse corrected with the Prolift system, while the control group with 35 patients were treated with the classical vaginal surgical method. Following parameters were analised: length of hospital stay, intraoperative complications, early postoperative complications (up to 30 days after surgery) and late postoperative complications (3-6 months after surgery) and the objectification of postoperative urinary incontinence, was performed.

Results: A significant difference between the two groups has been found in the length of hospitalization, frequency of operative and postoperative complications and incidence of stress urinary incontinence after surgery in favour of the minimal invasive method.

Conclusion: The outcome of the treatment of pelvic organ prolapse in women is better after the application of the Sling system.

Key words: Pelvic organ prolapse, sling system, vaginoplasty

Introduction0

Pelvic organ prolapse represents the descent of one or more structures that normally borders with the vaginal vault. The uterine prolapse is a consequence of the lack of support from the sacrouterine and cardinal ligaments, which leads to lowering of the cervix and the uterus itself to the introitus (Swift, 2000).

Pelvic organ prolapse is a condition that leads to 400,000 operations per year in developed health centers. Although mortality is negligible, morbidity caused by prolapse is significant. Previous studies show that an average of 50% of women who gave birth have static disorders that lead to prolapse, while 10-20% of them require medical assistance. Considering only women with second-degree prolapse or more, the prevalence according to the POP-Q test is 51% (Lukanovič, 2004).

Today, there are approximately 260 surgical methods described for the treatment of pelvic floor defects and uterine and vaginal prolapse. The traditional surgery is considered to be the anterior and posterior colporaphy, while the synthetic mashes have started to be used in practice because of the unsatisfactory success of the classical methods (a short duration of surgery success, inadequate surgical techniques, complicated procedures and commercial interests). Of course, we distinguish a large number of different synthetic materials that are used in the form of mashes (polypropylene, polyglycolic acid, polytetrafluoroethylene, polyethylene). It is believed that the advantage of synthetic mashes is their ability to resist infection, the ability to incorporate into the surrounding tissue, histologically good tolerance, minimal size reduction, soft texture and easy use. The synthetic mash allows fast cellular and tissue growth and has a small degree of infectivity, as it does not allow the penetration of bacteria (Lukanovič, 2008).

The most common complications associated with synthetic materials are tape infection, vaginal erosion and vaginal retraction, perforation of the

bladder, perforation of vascular and nerve structures during placement, extrusion of the tape into the vagina, and hematomas are also mentioned (Lukanovič, 2008).

The indication for the use of such a mash is strengthening of the tissue and the long-term stabilization of the facial structures of the pelvic floor. It is considered contraindicated to place a mash in the following cases: pregnant women or women who plan a pregnancy because the tape does not have the possibility of great stretching, acute or latent infections, malignant diseases of the vagina, cervix or uterus (Lukanovič, 2008).

Material and methods

The study was prospective and involved 70 patients who were surgically treated after diagnosed pelvic organ prolapse. A multicenteral study was carried out at the Gynecological Department of the Regional Hospital in Bihać, as well as at the Gynecological Department of the Clinical Center in Ljubljana. The duration of the study was unlimited.

The inclusion criteria was a clinically diagnosed and surgically treated pelvic organ prolapse without prior operative or corrective treatment, and the sample was determined consecutive. Exclusion factors were patients with arteriosclerosis, diabetes, and severe heart, lung, and kidney diseases.

The experimental group consists of 35 patients which were treated with a polypropylene mash-Prolift system, and the control group of 35 patients where the prolapse was corrected with the classical vaginal surgical method. Patients of the experimental group included a front, back or total Prolift kit, while the control group included colporaphy or colporaphy with vaginal hysterectomy.

The following data were analyzed: length of hospitalization, data on intraoperative and early postoperative complications (up to 30 days after surgery), and late postoperative complications (3 to 6 months after surgery).

Statistical analysis

Detailed statistical analysis of the data was carried out during this study. Descriptive statistics was used for the data analysis. To test the statistical significance of differences between samples parametric and non-parametric tests were used. P<0, 05 was considered statistically significant. Statistical analysis was performed with SPSS (Statistical Package for the Social Sciences) software.

Results

The length of hospitalization in both examined groups is shown in Figure 1.

The average length of hospitalization of patients treated with the Prolift system was 5.20 ± 0.901 days, while for the patients treated with the classical method it was slightly higher, 8.28 ± 1.564 days. The shortest hospital stay for the Prolift group was four, and the longest was seven days, while the group treated with the classical method, the minimum number of days was six, and the maximum was 14 days.

The operative and postoperative complications in both groups are shown in Figure 2 and 3.

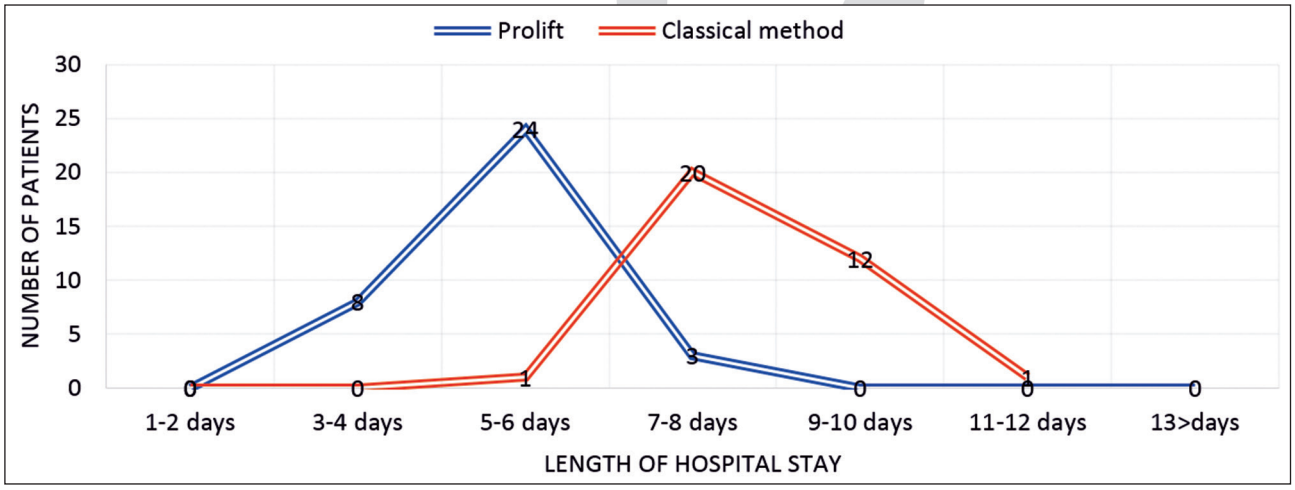

Figure 1. Length of hospitalization

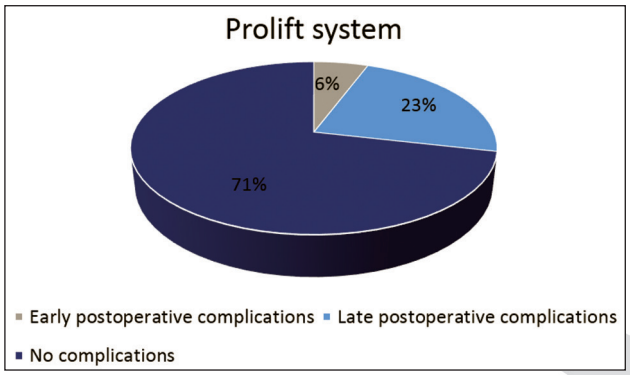

Figure 2. Operative and postoperative complications in the Prolift system

The results showed that 71% of the patients had no complications, 6% of the patients had postoperative complications, while 23% of the patients had late postoperative complications. No surgical complications were reported in this group.

Patients treated with the classical method had three surgical complications, five early postoperative complications and 11 late postoperative complications, while the rest, 46%, were without complications.

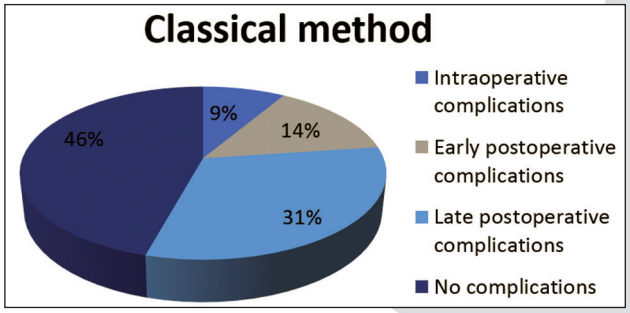

Figure 3. Operational and postoperative complications in the classical method

The description of intraoperative complications in patients of both examined groups are shown in Table 1.

Table 1. Description of intraoperative complications

Intraoperative complications	Prolift method	Classical method
Bladder lesion	0	2
Indury of the urethra	0	0
Intraoperative bleeding	0	1
Vascular lesion	0	0
Indury of the rectum	0	0
Total	**0**	**3**

No intraoperative complications were observed in Prolift-treated patients, while the group of patients treated with the classical method had a total of three intraoperative complications (one intraoperative bleeding, two bladder lesions).

The description of early postoperative complications in both groups is shown in Table 2.

Table 2. Description of early postoperative complications

Early postoperative complications	Prolift method	Classical method
Infection	1	3
Pain	0	0
Hematoma	1	0
Urinal retention	0	1
Erosiones of the vagina	0	0
Bleeding	0	2
Urge incontinence	0	0
SUI	0	0
Total	**2**	**6**

TG: t-test (t = -1.414; dF = 6.0; p = 0.207; ά = 0.05); dF = degrees of freedom; p = error; ά = level of significance, χ 2 = hi-square test (χ 2 = 4,000; dF = 3,0; p = 0,261; ά = 0,05);

A total of two postoperative complications occurred in the Prolift group (one infection and one hematoma), while in the classic method a total of six early postoperative complications were reported (three infections, one retention of urine, and two bleedings).

A description of late postoperative complications in both groups is shown in Table 3.

Table 3. Description of late postoperative complications

Late postoperative complications	Prolift method	Classical method
Apscess	0	0
Late urinary retention	0	0
Mash release	1	0
Sexual dysfunction	0	3
SUI	4	7
Erosion of the vagina	3	0
Total	**8**	**10**

TG: t-test (t = -0.264; dF = 6.0; p = 0.801; ά = 0.05); dF = degrees of freedom; p = error; ά = level of significance, χ 2 = hi-square test (χ 2 = 7.691; dF = 3.0; p = 0.053; ά = 0.05);

The Prolift group recorded a total of eight late postoperative complications (one release of the tape,

Table 4. Postoperative cases of stress urinary incontinence

Postoperative SUI	Prolift system		Classical method		T	χ^2	dF	p
	Nr. of pat.	%	Nr. of pat.	%				
Yes	4	11,0	7	20,0		0,004		
No	31	89,0	28	80,0		0,001		
Total	35	100	35	100	-0,787	0,005	1	0,808
x ± SD	17,5±19,092		17,5±3,849					

x = arithmetic mean; SD = standard deviation; TG: t-test (dF = 2.0; p = 0.514; ά = 0.05); χ 2 = hi-square test; dF = degrees of freedom; p = error

three cases of erosion of the vagina, four cases of stress urinary incontinence). Patients treated with the classical method had a total of 10 late postoperative complications (seven stress urinary incontinences, three patients experienced sexual dysfunction).

The incidence of postoperative stress urinary incontinence in both groups is shown in Table 4.

The incidence of stress urinary incontinence in the Prolift group was lower and amounted 11%, while the incidence of urinary incontinence of patients treated with the classical method was 20%.

Discussion

The risk of surgical intervention due to pelvic organ prolapse in the general female population is 11%, and 29% of women are undergoing reoperations due to the failure of the first operation after five years (Olsen et al., 1997).

An analysis of the length of hospital stay showed that the average length of hospitalization in the Prolift group was on average 5.2 days (ranging from four to eight days), while in patients treated with the classic method, the length of hospitalization was 8.2 days on average (ranging from six to thirteen days).

By analyzing the duration of hospitalization, in the study of Agirović and associates showed that the average duration of hospitalization was 4.5 days (2-14 days) (Argirović et al., 2010).

By analyzing data on operative and postoperative complications, the results showed that 71% of the patients were without complications in the Prolift-treated group of patients, 6% of patients had early postoperative complications, while 23% of patients had late postoperative complications. No surgical complications were reported in this group. In patients treated with the classic method, 46% of the patients were without complications, 9% of patients had operative complications, 14% of patients had early postoperative complications, and 31% of patients had late postoperative complications.

The reported intraoperative complications in the group of patients treated with the classical method were one intraoperative bleeding and two bladder injuries.

As early postoperative complications, a total of two complications in the Prolift-treated group were reported (one infection and one hematoma), while in the classical method six early postoperative complications were reported (three infections, one urinary retention, two bleedings).

A total of eight late postoperative complications have been recorded in the Prolift group (one lumbar discharge, three cases of erosion of the vagina, and four cases of stress urinary incontinence). In the group of patients treated with the classical method, a total of ten late postoperative complications were recorded (seven patients experienced stress urinary incontinence, three patients had sexual disorder).

The incidence of stress urinary incontinence in the Prolift group was recorded in four patients, while in the classical group seven patients had problems with urine incontinence.

Complications of the Prolift-treated patients were resolved conservatively in six cases, while four patients needed a reoperative procedure. The complications of the patients treated with the classical method in 12 cases were resolved with conservative treatments, while in seven cases a reoperative procedure was required.

Hiltunen and associates reported the incidence of de novo urinary incontinence in 14.3% of patients who used a mesh for correction of the cystocele (Hiltunen et al., 2007).

Aungst et al. reported the incidence of de novo urinary incontinence of as much as 24.3%. They had one flatulent incontinence patient after placing a mesh for the last segment in which the problem was resolved spontaneously after six months (Aungst et al., 2009).

Argirović and colleagues received following results: they had a serious intraoperative complication, a bladder injury that was immediately recognized and rehabilitated. They still placed the mesh, but the patient was wearing a catheter for a long time postoperatively. There were no other serious intraoperative complications in their study. Direct postoperative complications were manifested as urinary tract infection in four (4.2%) patients, urinary retention in one (1%) patient, and concave pain in two (2.1%) patients. Late side effects were: erosion of the vagina in nine (9.3%) patients, gland retraction in six (6.2%) patients, de novo incontinence in five (5.2%) patients (Argirović et al., 2010) .

According to literature data, the percentage of mesh exposure in the vagina ranges from 5 to 30%, but there are papers showing that this complication does not occur at all (Migliari et al., 2000).

If the available literature yields a general number of complications related to this type of procedure, the following results are obtained: fecal incontinence with prevalence between 1.9 and 6.9%, sexual dysfunction and coital incontinence with a prevalence of one third to two thirds of women (Lukanović, 2004).

Conclusions

Based on the results obtained, we concluded the following:

- The length of the hospitalization was considerably shorter in the Prolift group than in the classical group, which showed a statistically significant difference
- The Prolift method compared to classical vaginoplasty has a much easier operative course, it carries a far smaller number of early and late postoperative complications. During the placement of the Prolift network there were no intraoperative complications because we strictly followed the prescribed surgical techniques. Prolift method proved to have statistically significantly lower number of operative and postoperative complications compared to the classical method.
- Stress urinary incontinence was postoperatively less present in patients treated with the Prolift method compared to patients treated with the classical method.
- In order to resolve postoperative complications in, a reoperative procedure was less frequently required in the Prolift group compared with the classical method.

It is evident that the prolapse of the pelvic organs represents a significant health problem and special curiosity is given to different therapeutic approaches. With the development of medicine and technology, almost all materials used in the production of support mashes have been developed to perfection. It is believed that precisely the minimum invasiveness, minimal tissue damage, and a short absence from the workplace after the operation with mashes lead to a better benefit for the patient.

The conducted research confirmed the benefit of the Prolift system in prolapse correction in relation to the classical method, shorter hospitalization, a lower number of early and late postoperative complications which allows patients greater comfort and easier resolution of their problem. A smaller number of de novo incontinence has been shown in the Prolift system in relation to the classic surgical method.

The conducted research concluded that the problem of resolving pelvic organ prolapse consists in selecting a method that will be best for the patient, as well as most economical for the health institution. Some of the criteria are that surgical intervention should be minimally invasive, short, postoperatively achieve minimal morbidity and complications which implies minimal tissue damage, short hospitalization and absence from the workplace which significantly affects economic cost-effectiveness and, above all, the highest possible rate of treatment success with a minimum number of recurrences, and the complete restoration of the quality of life that the patient had before the illness. The fulfillment of these criteria in our research was demonstrated by using the Prolift method.

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Prospective single-center clinical study of GelcoPEP, a new multifunctional hydrolyzed collagen type I

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Abstract

Introduction: The present prospective single-center clinical study investigated the safety and efficacy of GelcoPEP, a new multifunctional hydrolyzed collagen type I.

Methods and materials: Safety and clinical efficacy of the new multifunctional hydrolyzed collagen type I were determined. A total of eight parameters were investigated at the beginning (D0) and after 30 ± 2, 60 ± 4 and 90 ± 4 days by a questionnaire. Firmness and elasticity were assessed by cutometry, and wrinkles, by Reveal Imager.

Results: The results indicated that administration of 10 g/day of GelcoPEP for 90 days improved important essential symptoms in individuals, considering skin and joint. No adverse effects were detected during the observation period.

Conclusion: The obtained data support the view that GelcoPEP, a new multifunctional hydrolyzed collagen type I, is safe and efficacious and may be ingested worldwide as a nutritional supplement by healthy people.

Keywords: Collagen, GelcoPEP, joint, skin, type I.

Introduction

GelcoPEP, a new multifunctional hydrolyzed collagen type I, is a dietary supplement that may be beneficial for the improvement of skin and cartilage tissues. Its use in the supplementation has increasingly gained support in the medical and nutraceutical community, and among consumers [(1)].

It has been verified, in preclinical studies, that orally administered hydrolyzed collagen type I is thoroughly absorbed by the intestine and circulated in the blood stream in peptides form[(2)], accumulating in skin for up to 96h[(3)]. It was also revealed that collagen bioactive peptides have the ability of exerting remarkable antioxidant effects in different biological systems [(4)].

Hydrolyzed collagen type I is one of the main structural element that confers resistance to skin and cartilage tissues. It is known that, in addition to the support function, it participates in cell differentiation, adhesion, migration and proliferation [(5,6)].

The composition and complex structural organization between collagen and proteoglycans ensures the inherent tissue properties, such as strength, elasticity and compressibility, necessary to dissipate and cushion the forces, as well as reduce friction, without much energy expenditure. Therefore, the integrity of the components is essential to ensure normal tissues function [(6)].

Additionally, hydrolyzed collagen type I has been reported to have beneficial therapeutically functions in skin. Studies have shown that collagen peptides stimulate the growth of mouse skin fibroblasts [(7)] and are chemotactic attracted for human skin fibroblasts [(8)]. The effects of hydrolyzed collagen ingestion on fibroblast and collagen densities were also investigated and the results showed that density and diameter of fibroblasts and density of collagen fibrils were significantly larger in the collagen group than in the control group [(9)].

Although, from the preclinical perspective, there is convincing evidence that collagen ingestion may improve skin conditions, and, based on the findings that collagen is absorbed in its molecular form, accumulating in skin, it might be reasonable to investigate a new multifunctional hydrolyzed collagen type I as a nutritional supplement. Thus, the aim of this single-center investigation is to extend these earlier findings with GelcoPEP.

Methods and materials

Participants' selection

In accordance with the ethical standards of the Ethics Committee on human experimentation and with the Helsinki Declaration of 1975, as revised in 2000 and 2008, this prospective single-center clinical observational study was approved by its responsible committee and managed in its Department of Clinical Medicine.

According to study schedule, the consent form was discussed, signed, and a complete physical examination was executed at screening. Activity level, diet history, medication/supplement use and medical history were recorded. A total of 68 subjects were recruited using the inclusion and exclusion criteria outlined in Table 1.

Test product application

The participants used the products during 90 ± 4 days in their residence and in accordance with the instructions supplied. The participants were divided in two study groups: one group used the control product (placebo group) and the other used the collagen (treated group). The participants' distribution among the groups was randomized and performed

Table 1. Inclusion and non-inclusion/exclusion criteria

Inclusion criteria
Age: 40 to 65 years old
Gender: female
Healthy participants (assessed by the dermatologist)
Phototypes: I to IV (according to Fitzpatrick classification);
Intact skin in the study region (face, eyes, cheeks, wrinkles);
Having been clarified and signed the Informed Consent Term (ICT);
Participants that want to participate in the study without financial profit. They will only be reimbursed for expenses such as transportation and food;
Participants that accept not using products from the same category on the test region during the research;
Participants that have not taken part of similar studies at least 2 months before the research;
Occasional user of cosmetic products similar to the investigational product;
Participants that declare not to expose to pregnancy risk during the research.
Non-inclusion/exclusion criteria
Allergy to the test product category;
Pregnant or lactating women;
Immunodeficiency;
Active atopic dermatitis;
Participants that had their kidney, heart or liver transplanted;
Use of the following the drugs: immunosuppressive, antihistamines, non-hormonal anti-inflammatories and steroids;
Any condition not mentioned above that, in the opinion of the investigator, might compromise the assessment of the study;
History of noncompliance or unwillingness to adhere to study protocol.

Table 2. Participants randomization in the clinical study

Participant #	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17
Treatment	P	T	T	P	P	P	T	P	T	T	P	T	P	P	P	T	T
Participant #	**18**	**19**	**20**	**21**	**22**	**23**	**24**	**25**	**26**	**27**	**28**	**29**	**30**	**31**	**32**	**33**	**34**
Treatment	T	P	T	P	T	P	P	P	T	T	P	T	T	T	P	T	P
Participant #	**35**	**36**	**37**	**38**	**39**	**40**	**41**	**42**	**43**	**44**	**45**	**46**	**47**	**48**	**49**	**50**	**51**
Treatment	T	P	P	T	T	P	P	P	T	P	T	T	P	T	P	P	P
Participant #	**52**	**53**	**54**	**55**	**56**	**57**	**58**	**59**	**60**	**61**	**62**	**63**	**64**	**65**	**66**	**67**	**68**
Treatment	T	T	T	P	P	P	T	P	P	P	T	T	P	T	T	T	P

P = placebo (no active); T = treated (with hydrolyzed collagen).

in accordance with Table 2. The study was simple-blind, which means that the participants were unaware of the product they received (collagen or placebo) during the whole study.

Medical assessment of the clinical signs and discomfort sensations

The initial medical assessment was performed in the participants' moment of inclusion to verify the absence of clinical signs incompatible with the inclusion criteria. After 30 ± 2, 60 ± 4, 90 ± 4 days of product use, the participants returned to the Institution for the final medical assessment of the clinical signs presented and questioning of the discomfort sensations felt.

The data of the medical assessment were registered in the investigation brochure. The dermatologist was available during the whole study in case of adverse reactions.

The results were evaluated as follows:

- Discomfort sensations: the participants were questioned about the discomfort sensations felt during the clinical exam. The reported discomfort sensations were described (example: blazing, stinging, pruritus, cooling, burning, etc.) and were classified according to: intensity (slight, moderate or intense); localization and duration.
- Clinical signs: if applicable, the signs were evaluated as erythema, soap effect, edema, papules, coloring (hyperchromia), pustules, bulla, nodules, desquamation/dryness, crust or vesicle and were classified according to: intensity (slight, moderate or intense); appearance and number. The attributability of the reactions to the test product was investigated.

Anti-wrinkle subjective efficacy assessment

In order to determine the clinical efficacy of this product, the dermatologist assessed the following parameters at the beginning (D0) and after 30 ± 2, 60 ± 4 and 90 ± 4 days of product use:

Cosmetic appreciability assessment (participants' opinion)

The participants were instructed to answer a questionnaire containing the questions and possible answers described below after 30 ± 2, 60 ± 4 and 90 ± 4 days of investigational product use.

At the first visit, selected subjects, properly informed by the Consent Term approved by the Scientific Committee of the Institute, were assigned to receive 10 g of GelcoPEP (Gelco International, Inc., Pedreira, SP) daily. At the second and the final visit, subjects were required to come to the

Table 3. Parameters for anti-wrinkle subjective efficacy assessment

Eye wrinkles	Determined in accordance with the atlas [10].
Nasolabial folds	
Forehead wrinkles	Determined in accordance with the photographic scale for the assessment of human facial wrinkles [11].
Elasticity	Determined as: 1 = very hydrated/firm/elastic; 2 = hydrated/firm/elastic; 3 = little hydrated/firm/elastic; 4 = very little hydrated/firm/elastic.
Firmness	
Hydration	

Table 4. Cosmetic appreciability assessment questionnaire

After ingesting the product, did you think that:
1. Was the product effective to reduce wrinkles?
2. Did the product improve skin hydration?
3. Did the product improve skin elasticity?
4. Did you notice improvement considering skin general aspect?
5. Did the product reduce joint pain?
6. Did the product improve nail hardness?
7. Did the product reduce "hunger" sensation?
8. Did the product improve the general aspect of hair (volume and strength)?

clinical division for clinical assessment. A subject treatment diary was completed by each patient throughout the study period to determine product compliance, side effects, and supplementation use.

Firmness and elasticity assessment by cutometry

The participants were instructed to interrupt the use of products (creams, oils, lotions and similar) on the face 24 hours before the beginning of the study.

The participants came to the Institution for the initial medical assessment and verification of the accomplishment of the inclusion and non-inclusion criteria. Then, they were submitted to an acclimatization period of 30 minutes at 20 ± 2°C and 50 ± 5% relative humidity before the beginning of the measurements.

After this time, the baseline cutometry measurements (D0) were performed to assess skin firmness and elasticity using the Cutometer® MPA 580 probe coupled to the equipment *Multi Probe Adapter*, MPA 580, (CK eletronics, Germany). The measurements were performed on the face (malar region).

Then, the participants used the product at home according to the how to use instructions supplied by the Sponsor during 90 ± 4 days. On D30, D60 and D90 (respectively after 30, 60 and 90 days of product use), the participants returned to the Institution for another cutometry reading after performed after a 30 min acclimatization period at 20 ± 2°C and 50 ± 5% relative humidity.

Firmness and elasticity[12]:

Firmness assessment:

R0 (Uf): total skin deformation after suction, encompassing elastic and plastic deformation. The lower the R0 value, bigger the firmness (less extensible skin and therefore firmer).

Elasticity assessment:

R5 (Ur/Ue): corresponds to the ratio of the "immediate retraction" to the "immediate distention". This parameter refers to the elastic part of the skin, disregarding viscous deformation. The higher the value, bigger the skin elasticity.

R7 (Ur/Uf): corresponds to the biologic elasticity. The higher the R7 value, bigger the skin elasticity.

The following softwares were applied to analyze the data:

- Software for measurement acquisition - *MPA for Windows® NT/XP.*
- Software for data analysis - *Microsoft® Office Excel 2007*
- Software for statistical analysis - *SPSS Statistics 22.0.*

Instrumental efficacy assessment (wrinkles)

The equipment Reveal Imager® (Canfield) was used to capture images from the face of the participants to quantitatively determine wrinkle improvement. Therefore, the following capture positions were used: front, right side and left side.

The images were captured at the following experimental times: D0 (baseline) and D90 (after 90 days of product use).

Results and discussion

Dermatological acceptability

No participant referred discomfort sensations and no clinical signs were detected after 90 ± 4 days of product use.

Subjective dermatological efficacy (wrinkle)

The subjective dermatological efficacy results are summarized in figures below:

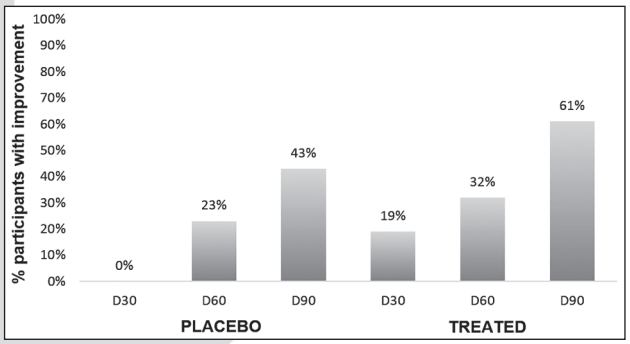

Figure 1. Eye wrinkles efficacy results

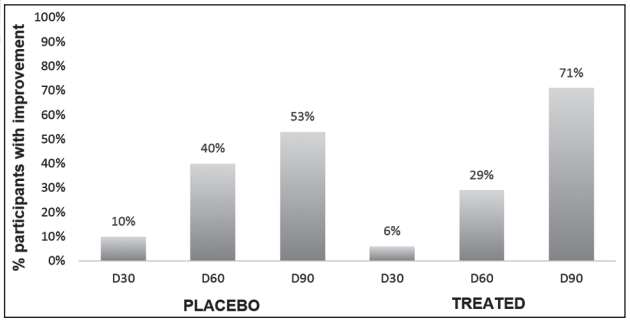

Figure 2. Forehead wrinkles efficacy results

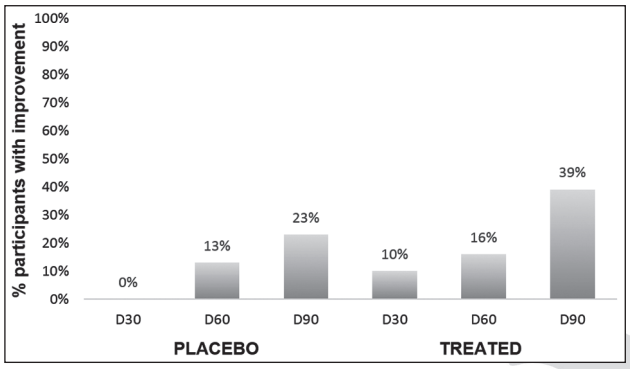

Figure 3. Elasticity efficacy results

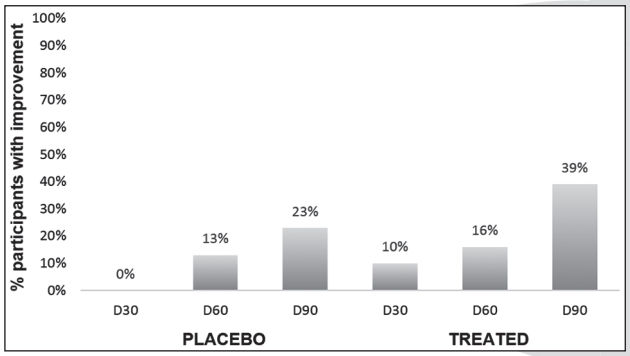

Figure 4. Firmness efficacy results

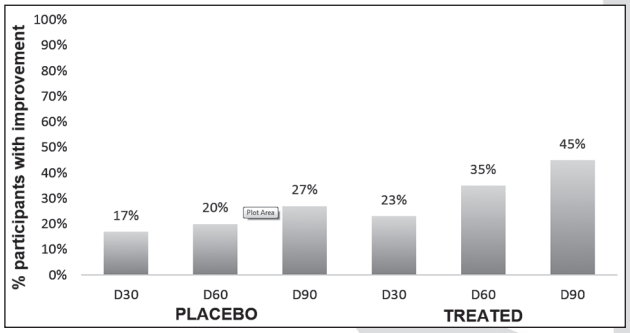

Figure 5. Hydration efficacy results

Among the parameters assessed by the dermatologist, those, where the investigational product presented a better performance compared to placebo, were eye wrinkles (on D30, D60 and D90); forehead wrinkles (on D90); elasticity (on D30, D60 and D90); firmness (on D30, D60 and D90); and hydration (on D30, D60 and D90).

Cosmetic appreciability assessment (participants' opinion)

In the cosmetic appreciability assessment (participants' opinion), the investigational product presented a better performance compared to the placebo for the following parameters:

- Efficacy in wrinkle reduction on D30, D60 and D90;
- Efficacy in articulation pain reduction on D30, D60 and D90;
- Efficacy in nail hardness improvement on D30, D60 e D90;
- Hunger sensation reduction on D30, D60 and D90.

Firmness and elasticity assessment by cutometry

The firmness (R0) and elasticity data (R5 and7) obtained with the Cutometer® probe were statistically analyzed by variance analysis (ANOVA) comparing the baseline condition with the other experimental times per treatment. Besides, the cutometry data were also compared between treatments for each experimental time by variance analysis (ANOVA) with Dunnett post-test. These analysis were performed with the software SPSS Statistics 22.0.

According to the obtained results, there was no statistically significant difference in the firmness (R0) and elasticity values (R5 and R7), neither between experimental times, nor between treatments for each time. However, the investigational product presented a tendency to promote improvement in skin firmness (R0) of 11% after 60 days of use (D60) and of 10% after 90 days of use (D90). The placebo did not present any tendency to improve firmness. Table 5 and Figure 6 contain the means of the firmness and elasticity values obtained per treatment per experimental time.

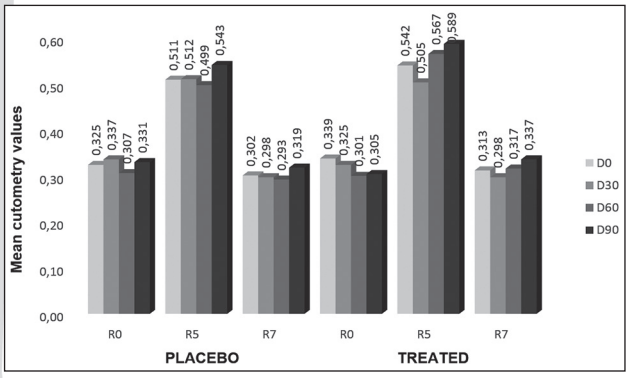

Figure 6. Mean cutometry values per time and treatment

Instrumental efficacy assessment

The mean wrinkle data obtained (mean of participants) per treatment (treated and placebo) per angle of capture (right, left and front) per time (D0 and D90) for the quantitative analysis with the

equipment Reveal® Imager (Canfield) are summarized in Figure 7 below.

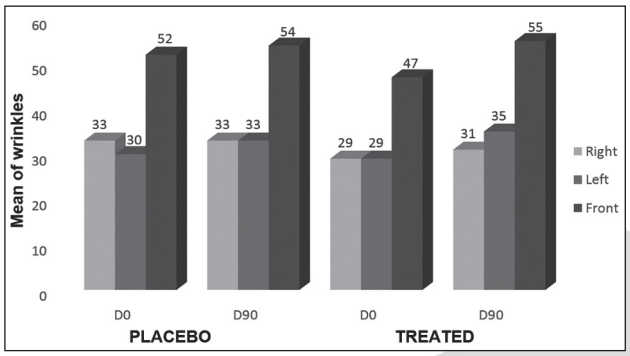

Figure 7. Mean of data obtained with the equipment Reveal Imager (Canfied)

According to the obtained results, there was no statistically significant difference in the wrinkle values by Reveal (right, left and front) between the experimental times, nor between treatments for each time ($p > 0.05$);

However, the investigational product (hydrolyzed collagen type I) presented a higher tendency to improve wrinkles when compared with the placebo. After 90 days of use, the collagen product promoted an improvement of the wrinkles of 7% for the right side; of 20% for the left side; and of 16% for the frontal angle.

Conclusion

The purpose of this study was to define whether administration of 10 g of GelcoPEP daily would improve skin and cartilage tissues in healthy volunteers. The design of the observational study was appropriate to reveal that hydrolyzed collagen type I as a nutritional supplement ingested over 90 days was safe and efficacious in improving skin and cartilage tissues. The results of the study provide data supporting the view that GelcoPEP may be administered to healthy patients as a potential. Further research will elucidate additional benefits from this multifunctional source.

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The effect of dyspnea on quality of life in patients with chronic opstructive lung disease Prospective control study

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Abstract

Introduction: Chronic obstructive pulmonary disease (HOPB) is one of the leading causes of disease and the fourth most common cause of adult mortality in the world. Very significant outcome of chronic obstructive pulmonary disease is worsening that leads to dyspnea and deterioration of life quality.

The aim of research: the evaluation of dyspnea level influence and the six-minute walk test on psychological condition, control model and disease adaptation, working capability and general life activity in time of complications and clinical stabilisation of HOPB after 6 weeks.

Respondendts and methods: The prospective control study included 50 respondents treated from March, 1st 2010 to March, 1st 2011 in Tuzla county clinic for pulmonary diseases. Evaluation unit for Dyspnea was evaluated on base of dyspnea scale of medical research council (MRC). The test of ergometric load – six minutes walk test, was conducted and used for diagnosing of dyspnea level. Health status was evaluated with St. George's Respiratory Questionnaire SGRQ. Statistical evaluation of data was conducted with statistical package for social researches (SPSS) version 10.0.

Results: In our sample, the most commonly ill with HOPB were men older than >70 years. Statistically significant is the fact that men were more frequently ill than women (39/11% v.s. 78/22%). The difference of trend increase of average estimated activities through SGRQ for 2.66 (interval of trust 95% CI = 0.10 to 5.23) was significant (p=0.04) and in accordance to result 6MTH. Values of total score SGRQ questionnaire in time of AEHOPB and clinical stabilization were compared. The average difference of trend increase for 1.49 in values of total SGRQ score (interval of trust %95 CI= 0.87 do 3.86 of trust %95 CI=-0.87 do 3.86;), statistically wasn't significant (t=1.27; df=49; p=0.21). In time of clinical stabilization, 18% of respondents have had clinically significant improvement, score fail SGRQ > 4 units. Values of 6MTH in stabile phase were significantly different in comparing to time of acute exacerbation (ANOVA for repeated measurements; P=0.014).

Values of MRC scale for dyspnea measured in t1 and t2 were compared. Both measurements confirmed that the degree of MRC scale of dyspnea is significant predictor of SGRQ level score (B=6.20; %95CI=2.52-9.8; p=0.001). Scale of dyspnea and values of 6-minutes test in time AE and stabilization of illness were significant value predictors of total SGRQ score in exacerbation.

Conclusion: In Tuzla county, the most frequent cases with HOPB were men (78%) in age 40-86. There were evident statistically significant higher values of 6 MTH in stabile phase of HOPB in comparing to time AE. During stabile phase of HOPB, the trend of value increase of estimated activities through SGRQ score was evident what is statistically significant and the result correlated with 6MTH results. In clinical stabilization, HOPB degree of dyspnea according to MRC scale show itself as excellent predictor of total SGRQ score values.

Key words: dyspnea, health status, chronic opstructive lung disease

Introduction

Chronic opstructive lung disease (HOPB) is clinical entity characterised by progressive opstruction of airways which is not completely reversible according to global initative for HOPB

(1). Due to increase of prevalence, assumptions are that HOPB will become one out of four lesding death causes in world by 2020.Accute exacerbations (AEHOPB) present worsening of typical symptoms of stabile disease such as: increased and frequent caugh, increased amount and purulence of cough, progression of dyspnea and increased deterioration of general condition (2).

Patients with frequent AEHOPB have more pronounced loss of lung function and life quality, frequent hospitalization what is related to increased risk of lethal outcome (3).

The primary symptom of HOPB is dyspnea. The aim of this research is to evaluate the level of dyspnea and 6MTH on psychological condition, control model and disease adaptation, working capability and general life activity in time of complication and clinical stabilization HOPB after 6 weeks.

Respondents and methods: prospective control study included 50 patients treated from March, 1st 2010 till March, 1st 2011 in pulmonary diseases clinic, university and clinical centre (UKC) Tuzla. Research was divided into 3 time intervals: t0-6 MTH and scale of dyspnea were determined previously in stabile phase of disease, t1-6MTH, scale of dyspnea and SGRQ were determined on first and second day of hospitalization in all respondents which were experimental group in time AE and and t2 – 6MTH, scale of dyspnea and SGRQ were conducted in time of stabilization of HOPB, six weeks after all AE signs were in control. Ergometrical load test was also conducted and used in diagnosing of dyspnea level according to MRC scale from 0 to 4. Six minutes walk is simple load test. Patient with HPB should walk more than 350 metres in 6 minutes. With shorter walking length without signs of dyspnea, the evaluation of disease is worse (4). Point for dyspnea was evaluated on basis of scale of medical research council as shown in table 1 (5).

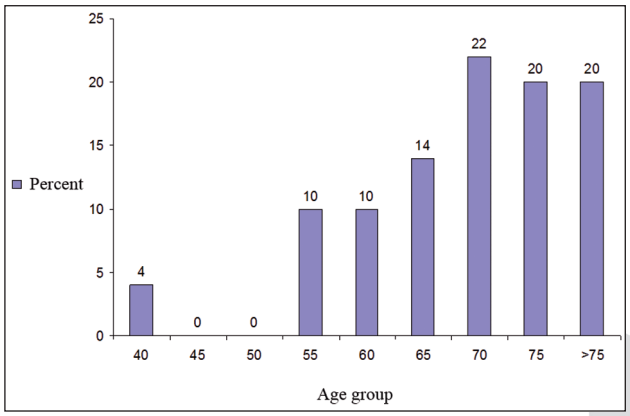
Health status was evaluated by usage of specific, widely used in world, standardized questionnaire on respiratory diseases (engl. St. George's Respiratory Questionnaire SGRQ (6), which was translated in Bosnian in two intervals in AEHOPB and 6 weeks later in stabile clinical HOPB condition. Score values of SGRQ questionnaire in stabile HOPB were <100. High score revealed bad health status-outcomes. Decreasing of SGRQ score for 4 units represented clinically significant improvement. Statistical data processing: standard statistical package for social researches (SPSS) was used for analysis, version 10.0. In statistical processing of results, standard methods of descriptive statistic were implemented. For testing of statistically significance in difference of chosen variables χ2-test and t-test was used. In order to test relation between dyspnea level according to MRC scale and significant segments and scores of SGRQ, nonparametrical Sperman correlation was used (regarding the fact that MRC is scale of ordinal type). In order to test relation between level ofdyspnea according to 6MTH significant segments and scores, Parsons correlatrion was used. For multivariant correlations analysis, univarient and multivariant analysis of variance with linear and logistic regressive analysis - ANOVA was used.

Results: the largest number of treated patients with AEHOPB in Clinic for Pulmonary diseases are in age > 70 years (n=31). The number of respondents is significant > 55 years (n=34).

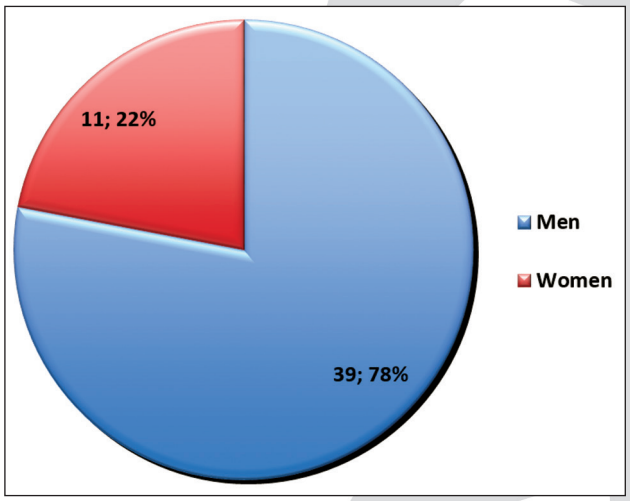
There are signifficant differences for values: 6MTH, functional parameters of breathing according to GOLD in repeated measures (t0, t1, t2).

Table 1. Dyspnea scale of MRC

Level of dyspnea	MRC dyspnea scale
0	Lack of air only in extreme efforts
1	Short periods of air loss in hurry or running or climbing up the hill
2	Loss of air during slower walk in comparing with other people of your age
3	Air loss during walking less than 100 m or couple of minutes that requires rest
4	Stays indoors for suffication feeling, lack of air during dressing

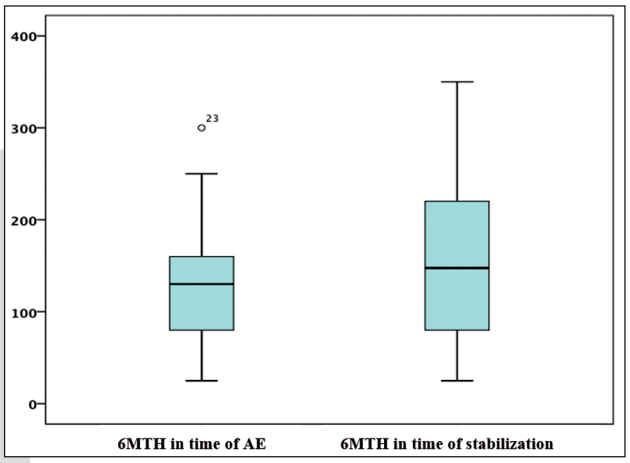


Picture 1. Distribution of all respondents (n=50) in total sample according to age subgroups. Men were ill more frequently39 (78%)



Picture 2. Structure of respondents according to gender

Values of 6 MTH in t2 time interval in comparing to t1 were with average difference of 33,5 m (interval of trust %95 CI=17.88 do 49.12) which was significant (t=4.31; df=49; p<0.0001)



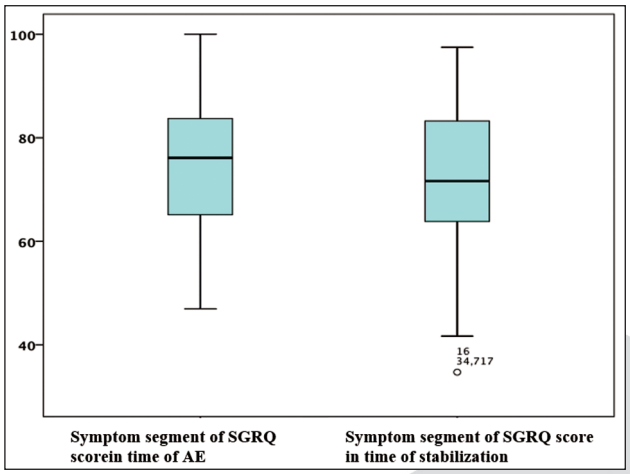
Picture 3. Box plot: correlation 6MTH in time of AE ad stabilization of HOPB

There was an average difference, trend of decrease in illness stabilization for 2.69 SGRQ score in segment of symptoms (interval of trust %95 CI=-0.90 do 6.09), what statistically wasn't significant (t=1.49; df=49; p=0.14).

Table 2. Evaluation dyspnea level according to HOPB markers in previously stabile time, time of AE-HOPB and time stabilization

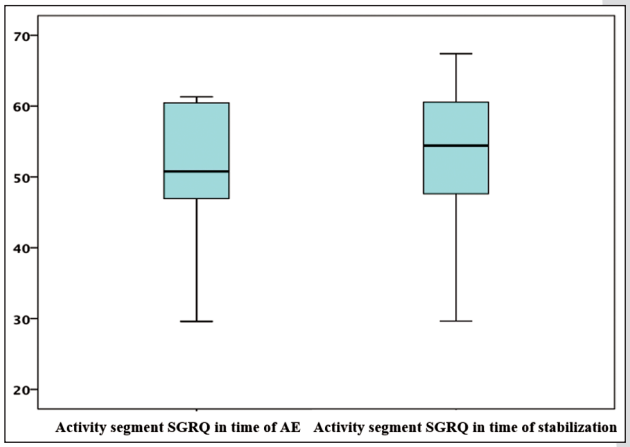
Markers	Time of measurement	Maximum of values	Minimum of values	Medijan (int. span) AS±SD*	p-value**
6-minuts walking test	t0	30.00	375.00	180.18±86.42	0.014
	t1	25.00	300.00	125.38±60.32	
	t2	25.00	350.00	158.38±90.62	
GOLD[1]	t0	1	4	3 (3-4)	0.002
	t1	2	4	3 (3-4)	
	t2	2	4	3 (3-3)	
MRC dyspnea scale	t1	2	5	4 (3-5)	0.330
	t2	2	5	4 (3-4)	

**SD-standard deviation*
***ANOVA for repeated measurements*
t0- stabile phase; t1- egzacerbation; t2- after egzacerbation
[1]spirometrical clasiffication according to GOLD: categories from 1 to 4 match the stadium I to IV ² z= 1.95



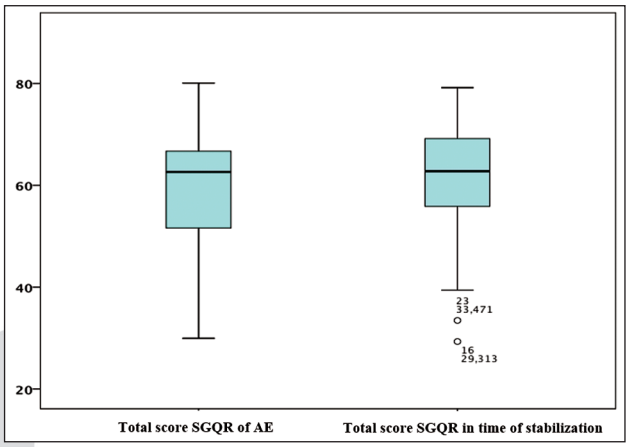
Picture 4. Box plot: correlation of symptom segment of SGRQ score in time of AE and stabilization HOPB.

Average difference was evident, in comparing to AE, increase trend for 2.66 in values of estimated activities through SGRQ – score in time of stabilization (t2) interval of trust (t=2.09; df=49; p=0.04), which was significant in statistics. This result is in accordance with result 6MTH.



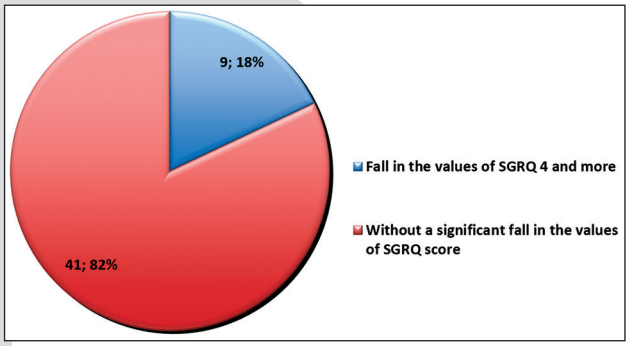
Picture 5. Box plot: correlation of activity segment SGRQ – questionnaire in time of AE and stabilization of HOPB

There was average difference – increase trend for 1.49 in values of total SGRQ score in time of AE in relation with stabilization (interval of trust %95 CI=-0.87 do 3.86), and what wasn't statistically significant (t=1.27; df=49; p=0.21).



Picture 6. Box plot: correlation of total score SGQR – questionnaire in time of AE and stabilization of HOPB

It is determined that 9 out of 50 (18%) of respondents have had clinically significant improvement (score fall SGRQ > 4 units) in time of clinical stabilization.



Picture 7. Distribution of respondents according to improvement of clinical condition of HOPB i.e. fall decrease of total score SGQR value – for at least 4 units in time of stabilization

Univariable linear regressive analysis, level MRC scale in AE, predictor of height SGRQ score (B=6.77; %95CI=3.93-9.61; p<0.001) is significant. Analogical analisys was conducted only for measurement in phase of clinical stabilization. Also, in this case, MRC scale level turned out to be excellent predictor of value in total SGRQ score (B=6.20; %95CI=2.52-9.8; p=0.001).

Statistically significant correlation in all analysis was evident instead in segment of symptoms SGRQ in stabilization (weak point of questionnaire). It is similar in MRC scale. It is proved that this parameter is also excellent predictor of total SGRQ score (B=-0.046; %95CI=-0,079-0.012; p=0.009).

Table 3. Correlation display of MRC degree in t1 and t2 and SGRQ in repeated measurements (t1-t2)

Marker		SGRQ symptoms t1	SGRQ activity t1	SGRQ influence AEt1	SGRQ score t1	SGRQ symptoms t2	SGRQ activity t2	SGRQ Influence AE t2	SGRQ Score t2
MRC t1	ɗ	0.308	0.345	0.558	0.533	0.456	0.729	0.504	0.686
	pt	0.030	0.014	0.001	0.001	0.001	0.001	0.001	0.001
MRC t2	ɗ	0.519	0.720	0.522	0.522	0.334	0.608	0.396	0.527
	p	0.0001	0.001	0.001	0.001	0.018	0.001	0.004	0.001

p - p- value
ɗ - correlation coefficient

Table 4. Display of 6MTH level correlation in t1 and t2 and SGRQ in repeated measurements (t1-t2)

Marker		SGRQ symptoms t1	SGRQ activityt t1	SGRQ Influence AE t1	SGRQ score t1	SGRQ simptoms t2	SGRQ activity t2	SGRQ Influence AE t2	SGRQ score t2
6MTH t1	ɗ	-0.363	-0.544	0.427	-0.504	-0.251	-0.475	-0.405	-0.449
	pt	0.010	0.001	0.002	0.001	0.079	0.001	0.004	0.001
6MTH t2	ɗ	-0.353	-0.467	-0.386	-0.453	-0.233	-0.312	-0.351	-0.367
	p	0.012	0.001	0.006	0.001	0.103	0.027	0.013	0.009

ɗ - correlation coefficient
p - p- value

Table 5. Multivariant analysis of dyspnea level according to MRC scale associated with 6 MTH (independent variables) in time of AE and after stabilization with SGRQ (dependent variable)

Markers	β	%95 interval of trust	p-value
6-minutes test, t1	-0.063	-0.112 do -0.013	0.014
Dyspnea level according to MRC scale t1	5.14	2.157 do 8.123	0.001
6-minutes test, t2	-0.023	0.061 do 0.016	0.246
Dyspnea level according to MRC scale t2	4.801	0.417 do 9.185	0.330

Multivariate stepwise regression analysis and MRC and 6 MTH values in both measurements were significant pfredictors of total SGRQ score values in AEHOPB. However, 6MTH values measured in phase of clinical stabilization, in multivariant analysis, were not shown as significant predictor of SGRQ test values. Instead, the dyspnea level evaluated according to MRC scale remained the only significant predictor in this phase.

Discussion

HOPB nowdays presents global health problem with large degree of morbidity and mortality. Consequences of HOPB include: symptoms, muscular disfunction, intolerance on effort, worsenings of health status and usage of health resources and lethal outcome. Result of our research indicate that HOPB u Tuzla county affect mostly men older than>70 godina. Men were in statistical signifficance with this condition in comparing to men (39/11% v.s. 78/22%). Even though, there are more evidences that women react differently on enviroment polution and perhaps are more sensitive than men (7). Values of 6MTH in our research in stabile phase were statistically in signifficant difference in comparing to relation on time of AE (ANOVA for measurement improvement P=0.014). It is proven that sceleton and muscular disfunction are the most signifficant reason for development of intolerance on effort as consequence on decontamination of organism. Less lenght of walking without dyspnea is with worse illnes prognosis (4). In our research there was an average difference of 6MTH in t1 and t2 interval of 33.5 m which was signifficant (t=4.31; df=49; p<0.0001). Results of MTH in our respondents are statistically signifficant because they show

high values of dyspnea according to MRC scale and have bad illness prognosis. Disturbed pulmonary function affects symptoms and activities in patients with HOPB in a way that valorisation of life quality is conducted in area of symptoms and activity. Symptoms which are valorised are dyspnea, whisleing sound in chest are, cough and coughing out (8). Health status in our research is evaluated with usage of SGRQ questionaire. When speaking about score of SGRQ questionaire on symptoms in our sample in AE gtime and clinical stabilisation, there was a average difference, trend of decreasing 2.69 SGRQ score which was not signifficant statistically (t=1.49; df=49; p=0.14). Many studies were conducted in world whith aim to measure quality of life during pulmonal function damadge progression in HOPB and are related to dyspnea, decreasing of physical activity, depression, anxiety, muscular weakness and invalidity. Limited physical activity is with consequence, muscular weakness and invalidity which combined can affect social and emotional patients health (9). In our results the difference of increasing trend of evaluated activities average score is confirmed through SGRQ for 2.66 (interval of trust 95% CI=0.10 do 5.23) and was significant (p=0.04). This result was in accordance with result of 6 minutes walk test. Values of total score SGRQ of questionaire in time of AEHOPB and clinical stabilisation were compared. Average difference of increase trend for 1.49 in values of total score (interval of trust %95 CI=-0.87 do 3.86;) statistically was not signifficant (t=1.27; df=49; p=0.21). Therefore, the values of total score in SGQR questionare in our research are directly dependable on segment of SGRQ symptoms score in time of AE in HOPB stabilisation, and dependability on segment of SGRQ score activity questionaire was not statistically signifficant.

It is determined that totaly 9 out of 50 (18%) respondents were with clinically signifficant improvement (SGRQ score decrease> 4 units) in time of clinical stabilisation. Score increase trend of physical activities in stabile phase, as well as improvement of clinical condition can be assigned to: quiting of smoking, desopstructive therapy treatment and results of rehabilitation which led to improvement of pulmonal function and effort tolerance. At the moment, many studies are trying to identify biomarkers which relate to level of dyspnea or HOPB prognosis (10). In one such study conducted on 322 respondents, the new method of identification of HOPB fenotypes was introduced, which is grounded on multiple clinical variables among which dyspnea, measured by MRC scale, is extremely signifficant (11). We compared values of MRC scale for dyspnea measured in t1 and t2, and difference testged by Wilcoxon test was not signifficantly important for statistics (Z=-0.198; p=0.843). Signifficant difference for dyspnea categories for repeated measures was not evident, which is different in some way than other studies having in mind age and degree of education of our respondents during description of dyspnea level. Frequency and level of agzacerebation ledas to: dyspnea worsening, malnutrition and reducing of life quality (12). In our research, level of MRC scale in exacerbation is signifficant predictor of level of SGRQ score (B=6.77; %95CI=3.93-9.61; p<0.001). Analogously, in clinical stabilisation of HOPB, level of dyspnea according to MRC scale turned out to be excellent predictor of value of total SGRQ score (B=6.20; %95CI=2.52-9.8; p=0.001). It is evident that symptoms of SGRQ as parameter are excellent predictor of total SGRQ score (p=0.009), except in stabilisation phase. Therefore, values of 6MTH don't have influence only on values of SGRQ in stabilisation.

Conclusion: Men were frequently ill from HOPB (78%) in Tuzla county, with age of 40 to 86 years. In stabile phase of HOPB, there were statistically signifficant higher values of 6MTH regarding the time of AE. 6 MTH results of our respondents were statistically signifficantly higher becouse they show high values of dyspnea according to MRC scale and have bad illness prognosis. During stabile phase of HOPB, there is a trend of increasment of values in estimated activities through SGRQ score, what was statistically signifficant, result corelated with results of 6MTH. In clinical stabilisation of HOPB, level of dyspnea according to MTRC scale turned out to be an excellent predictor of total SGRQ score values.

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Superior mesenteric artery syndrome: Case Report

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Abstract

Objetive: To report the case of a patient with thesuperior mesenteric artery syndrome.

Case presentation: A 59-year-old male patient was admitted with sensation of postprandial abdominal bloating associated with solid dysphagia, which evolved to liquid dysphagia. He reported the sensation started in the last few days and progressed 2 to the present episodes of emesis of food content in great amount, besides remarkable weight loss. These symptoms worsened when he was in the supine position, but he had a slight improvement when he raised. The thoracoabdominal tomography presented hepatic parenchymatous hypodensity area in the mesial portion of the IV segment of the left hepatic lobe measuring 3. 4cm, without significant enhancement of contrast. Also reduction of the superior mesenteric artery space that could predispose to pinching of thethird part of the duodenum (superior mesenteric artery pinching) was observed. Patient underwent duodenojejunostomy without complications.

Conclusions: The superior mesenteric artery is an uncommon cause of duodenal obstruction, but it should besuspected forexclusion of other more frequent causes.

Key words: Superior mesenteric artery syndrome; Intestinal obstruction; General surgery; Case report.

Background

Wilkie's syndrome, or superior mesenteric artery syndrome, is an uncommon obstructive intestinal pathology that occurs due to the compression of the third part of the duodenum, when it passes between the superior mesenteric artery and the abdominal aorta (1), secondary to acondition that decreases the angle between these two arteries(2).

This condition results in acute or chronic obstruction of the duodenal segment. The diagnosis of certainty is sometimes difficult, because the symptoms are alike those of several digestive tract diseases (3). The conservative treatment, including psychiatric and nutritional management, is recommended as initial therapy. If the conservative 3 treatment fails, surgery is many times necessary. Nowadays, the traditional bypass open surgery has been replaced by the laparoscopic duodenojejunostomy as a curative surgical approach [4], after the first approach through this technique in 1998 (5).

Considering the rarity of the case and its importance to the academic community, we aimed to present a patient with superior mesenteric artery syndrome attended in a surgical clinic from a hospital in Barbalha (CE), Brazil.

Case presentation

F. G. S, 59-year-old male patient, farmer, from Quixadá, Ceará State countryside, was admitted in the service with sensation of postprandial abdominal bloating associated with solid dysphagia, which evolved to liquid dysphagia. He reported the sensation started in the last few days and progressed to the present episodes of emesis of food content in great amount, besides remarkable weight loss. These symptoms worsened when he was in the supine position, but when he raised, he felt a slight improvement. At 30 years old, he underwent appendectomy, and he also irregularly used paracetamol and Revange® for thoracic and lower back pains.

At physical examination, we noticed enhanced weight loss without further findings. We performed laboratorial exams with the following results: TSH 1. 9; free T4 0. 72; hemoglobin 14. 1; hematocrit 42. 5; leukocytes 5, 450, without deviation to the left; platelets: 358. 00; AST 40; ALT 45; GGT 37; alkaline phosphatase 59; amylase 81; lipase 38;

bilirubins 0. 78; and indirect bilirubins 0. 18. Upper digestive endoscopy showed enhanced enanthematous pangastritis. Duodenitis was moderate, and ureases test positive.

Thoracoabdominal tomography presented hepatic parenchymatous hypodensity area in the mesial portion of the IV segment of the left hepatic lobe, measuring 3. 4cm, without significant enhancement of contrast. A reduction of the superior mesenteric artery space that could predispose to pinching of the third part of the duodenum (superior mesenteric artery pinching) was noted (Figures 1 and 2). Pelvic tomography did not show alterations.

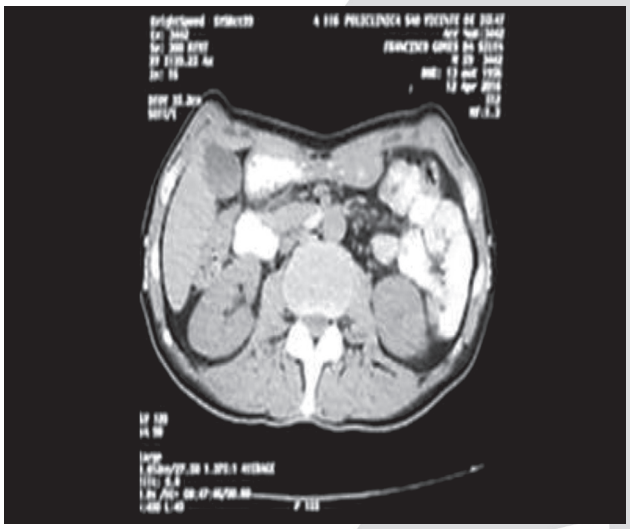

Figure 1. Computed tomography with oral contrast showing reduction in the superior mesenteric artery space and pinching of the third part of the duodenum

Figure 2. Contrasted computed tomography presenting a sharp decrease of the duodenal light in its passage through the superior mesenteric artery space

The patient underwent duodenojejunostomy without complications. During follow-up in the general surgery hospital outpatient clinic, he reported weight gain of 2kg in 15 days.

Discussion

Firstly described by Rokitansky, in 1861, the superior mesenteric artery syndrome consists of the compression of the third part of the duodenum due to low angulation between the abdominal aorta and the superior mesenteric artery (6). However, only in 1921, Wilkie published a series of 75 cases of open surgery and it was named after him (7, 8).

We have seen an incidence of around 0. 1 to 0. 3% in studies that used barium contrast, and the syndrome is more common among women aged between 10 and 40 years (9, 10). The present report is about a 59-year-old male patient.

Our patient's clinical condition corroborates literature, even though it is unspecific (11). Among the patients presenting the syndrome, 59% had abdominal pains; 40%, nausea; 50%, vomits; 32%, early fullness; and 18%, anorexia (12). All these symptoms worsen in the supine position, crouching position and after meals. Patients with such signals and symptoms should have other hypotheses verified, such as paralytic ileum, side effect of drugs, hydroelectrolytic disorders, and intestinal constipation. In the other hand, dehydration, malnutrition and repeated vomiting could result in aspiration and pneumonias (10, 13).

Due the unspecific signals and symptoms, additional exams are necessary. The golden standard in cases with higher diagnosis sensitivity is the abdominal computed tomography. In the past, the standard was to perform esophagus, stomach, and duodenum seriography checking dilation of the first and second duodenal parts with compression of the third part (14). The computed tomography with contrast or angiography through magnetic resonance enable the visualization of the duodenal vascular compression and the accurate measurement of the superior mesenteric artery angle and its distances. The endoscopic examination can visualize an extrinsic pulsatile compression that suggests such condition (6). In this case, the classic reduction of the superior mesenteric artery space was noted in the computed tomography –

this scenario, associated to the clinical condition, increased the diagnostic suspicion.

Treatment is usually conservative and includes fluid and electrolyte replacement, feeding through nasojejunal tube and mobilization of the patient to the left or lateral decubitus. Subsequently, the conservative treatment focuses on nutritional support directed to restoration of the retroperitoneal fat and weight gain (9). However, if the conservative treatment fails, the proposed surgical interventions will include Strong's procedure, gastrojejunostomy or duodenojejunostomy. Strong's procedure maintains the gastrointestinal tract integrity, but its failure rate is of 25%. Gastrojejunostomy enables gastric decompression, but it does not relieve duodenal compression in a way that digestive symptoms may persist and lead to the appearance of a blind loop syndrome or to recurrent peptic ulcers. Duodenojejunostomy is the procedure of choice with a success rate of more than 90% (14).

Conclusions

The superior mesenteric artery is an uncommon cause of duodenal obstruction, which should be suspected for the exclusion of other more frequent causes. Diagnosis is made through clinical images, and early intervention is a support to provide better therapeutic results.

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Abstract

In this paper the instructions for preparing camera ready paper for the Journal are given. The recommended, but not limited text processor is Microsoft Word. Insert an abstract of 50-100 words, giving a brief account of the most relevant aspects of the paper. It is recommended to use up to 5 key words.

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Table 1. Page layout description

Paper size	A4
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Regular paper may be divided in a number of sections. Section titles (including references and acknowledgement) should be typed using 12 pt fonts with **bold** option. For numbering use Times New Roman number. Sections can be split in subsection, which should be typed 12 pt *Italic* option. Figures should be one column wide. If it is impossible to place figure in one column, two column wide figures is allowed. Each figure must have a caption under the figure. Figures must be a resolution of 300 DPI, saved in TIFF format, width 10 cm min. For the figure captions 12 pt *Italic* font should be used. (1)

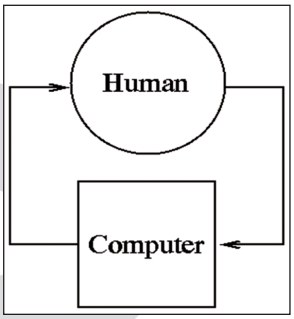

Figure 1. Text here

Conclusion

Be brief and give most important conclusion from your paper. Do not use equations and figures here.

Acknowledgements (If any)

These and the Reference headings are in bold but have no numbers.

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