



**COMPARISON OF MINIMALLY INVASIVE PROCEDURES WITH
CONVENTIONAL SURGERY FOR TREATMENT OF VARICOSE VEINS OF
LOWER EXTREMITY**

**HEMMATI H^{1*}, MALEKNIA A², KAZEMNEJAD LEILI E³, GOLCHAI B⁴,
ASGARI M R⁵, MOHAMMADI A⁴**

1: Assistant Professor, Department of Surgery, Guilan University of Medical Sciences, Rasht,
Iran

2: Resident of General Surgery, Guilan University of Medical Sciences, Rasht, Iran

3: Assistant Professor of Bio-Statistics, Guilan University of Medical Sciences, Rasht, Iran

4: Medical Student, Guilan University of Medical Sciences, Rasht, Iran

5: Assistant Professor, Thorax Surgeon, Guilan University of Medical Sciences, Rasht, Iran

***Corresponding Author: E Mail: drhossein_hemmati@yahoo.com**

ABSTRACT

Introduction: The lower limbs Varicose of the body is considered as a common costly disabling disease for society and patients. Different modalities ranging from preventive treatments to surgical operations are applied to deal this disease. Selection of modality type is carried out on basis of the conditions and risk factors of patient. This study was conducted to assess life quality of patients and the potential side effects of surgical process involved in two sclerotherapy approaches. **Methods:** This is a cross-sectional study performed on patients hospitalized in two Razi and Poursina Hospitals of Rasht within 2010 to 2014 subjects to surgical stripping of greater saphenous vein and then minimal invasive treatment and conventional surgery of small varicose veins branch. The background information of patients including their age, gender, and family history of varicose, diabetes, and hypertension histories were extracted from patients' record. In addition, life quality of the patients was measured using the specialized questionnaire of varicose patients and Aberdeen Venous Vein Questionnaire (AVVQ). After 6 months, patients were investigated in terms of potential side effects and the obtained data were analyzed using SPSS ver.21 software. **Results:** This

research was conducted on 122 patients including 76 patients undergoing foam sclerotherapy (49 male (64.5%) and 27 female (27%) subjects) and 46 patients under stab avulsion surgery (29 male (63%) and 17 female (37%) subjects). A comparison among gender distribution ($P = 0.87$), age class frequency distribution ($P = 0.45$), and family varicose history distribution ($P = 0.11$) reveals no statistically significant relationship between the patients being treated under these two procedures. However, using the AVVQ instrument indicates a statistically significant difference between the life quality dissatisfaction in varicose patients undergoing both treatment procedures ($P = 0.0001$). **Conclusion:** Both varicose treatment procedures can have positive treatment effects on patients and improvement of their life quality by themselves and the post-treatment side effects of procedures were at normal level. However, considering the obtained results, it is observed that foam sclerotherapy is more cost-effective and safe method with lower side effects and higher efficacy on life quality of the patients.

Keywords: Varicose, Life quality, Foam sclerotherapy, stripping

INTRODUCTION

Venous diseases and, on the top of them, varicose veins of the lower extremities are of the prevalent diseases in different communities. They consist of various symptoms, from the asymptomatic category to chronic wounds in feet. Venous diseases cause devastating illnesses and cost 2% of the national health resources [1]. Many Varicose veins have no notable mark except unpleasant appearance. But in many cases patients complain of pain, cramps, itching, fatigue and swelling [2-5]. Because of the widespread prevalence of disease, the annual cost of healthcare and treating varicose veins are estimated more than billion dollars [6] of which 58% refers to patients going to Cardiology clinic [7]. As well as current varicose veins in 13 to 65

percent of patients happen during treatment and it is a costly problem and, also, debilitating [8]. There is a significant Social and the economic impact on society for Varicose diseases and Around two million working days annually are wasted because of the disease [9, 10]. According to the cases mentioned, the influence of this chronic disease on health , its influences on social and economic factors, and the Chronic Venous Insufficiency of the diseases have considerable influence on people job and life quality .So treating this varicose veins have great Economic and social benefits [11].

Minimally invasive techniques treat saphenous varicose veins. These techniques are as follows: ultrasound guided foam sclera therapy for treatment of varicose veins, radiofrequency ablation,

endogenous laser treatment. In comparison to the conventional surgical techniques (high ligation and stripping) (HL/S) the new results lead to the form of fewer complications, returning to work rapidly, improving the scores quality of life, reducing the costs for patients, and reducing the need to general anesthesia, recurrence rates [12]. According to the clinical evaluation and the patient's condition, comparing and choosing between different treatment modalities are chosen however it was a challenge [13], and in the past, the method of removal vein thoroughly was widespread, but newly, less aggressive Techniques have assigned to themselves a lot of Treatments of varicose veins [14]. In a systematic review that was published an article by Luebke and his colleagues in 2008, the systematic evaluation of the clinical trial, in comparison with the various method of minimally invasive treatment and Surgical in varicose therapy, they concluded the methods of minimally invasive such as: Radio frequency, sclerotherapy with foam and laser endovascular treatment are safer and more affordable than the Current techniques of Surgery and have better clinical outcomes in short-term and mid-term, but, it is necessary to do more widespread researches for comparing the various method of the varicose treatment

with considering the quality improvement of life in the varicose patients and the clinical outcomes of the different modalities [15]. There is an appropriate questionnaire for evaluating the quality of varicose patients' life as other diseases. The first time, in 1993 Garratt et al published an article named to assess the consequences of the varicose disease in the patients that they introduced to measure the quality of varicose patients' life, that in this research was used the questionnaire for measuring the quality of varicose patients' life. This study was planned by 2 conventional methods; surgery and minimally invasive treatment compare the treatment result and the quality of varicose patients' life under treating.

MATERIALS AND METHODS

This study was planned the descriptive analysis on all patients who are treated by the method of saphenous varicose veins between 2010 to 2014 in Razi hospital and Poursina hospital of Rasht and for treating the venous branches they studied foam sclerotherapy technique and stab avulsion of Varicose veins of the lower extremities. All patients' records (All demographic data) were extracted and recorded as; age, gender, family history and medical history of diabetes and blood pressure. The Success treatment was measured by the assessment questionnaire of quality of life.

All patients were followed for 6 months ,and after this period , color Doppler ultrasound was done on the patients, in addition the questionnaire of quality of life AVVQ (Aberdeen Venous Vein Questionnaire) [16] was done by patient.also after 6 months , the patients were investigated for the Possible Complications as; swollen ankle ,itching ,change the color purple, pain after surgery, dull pain in the lower extremities attributed to the previous varicose disease, skin ulcers ,deep vein thrombosis of one or both lower extremity.

Patient Selection

The inclusion criteria is for all patients that treated varicose veins of the lower extremities during 2010 to 2014 and the exclusion criteria is dissatisfaction and inaccessibility to patients to keep track by scholar.

Assessment Tools

Demographic data included of age, gender, family history and medical history of diabetes and hypertension that were used in the scholar's questionnaire .The questionnaire which was used in this research was the same questionnaire of the quality of varicose patient's life AVVQ (Aberdeen Venous Vein Questionnaire) that was considered by Garratt and his associates, the first time, in 1993 .the questionnaire consist of 13 items, the

structure of designed questions is; yes /no, multiple choice and simultaneously was used Lickert. Scores of samples are 0 to 100. It means that higher scores have less success and satisfaction. The first question was about the anatomical location of varicose vein and the some questions were about the health status of both limbs and some questions have been developed separately the involved limb from the right or left. In the year 2009 T.M.A.L. Klem et al evaluated and counted the reliability and validity of the questionnaire, according to their study, Cronbach's alpha was evaluated 0.7, finally they notified that the questionnaire has high reliability and validity [17].

RESULTS AND DISCUSION

RESULTS

The study on 122 patients were done in 2010 to 2014 that they wanted to treat varicose veins by the minimally invasive method and surgical method .after evaluating, 76 patients minimally invasive procedure foam sclerotherapy including 49 men (64.5%) and 27 women (35.5%) and 46 patients from the surgical procedure (stab avulsion), including 29 men (63%) and 17 women (37 percent), a statistically significant relationship wasn't seen between gender distribution in the two groups of varicose patients with two procedure, foam sclerotherapy and stab

avulsion ($p=0.87$). statistically significant relationship wasn't seen about the plenty distribution of age groups in the two treatment groups between the distribution of age groups in the two groups ($p= 0.49$). As well as statistically significant relationship wasn't seen plenty distribution of varicose family history, in the two group of the varicose treatment patients ($P= 0.11$).

The percentage dissatisfaction was distinguished after analyzing the quality Questionnaire of life AVVQ (Aberdeen Venous Vein Questionnaire) and the value of the specified rating to each of the questions and the specified total score to each of the questions and the percentage rate for each of the questions in right and left feet separately.

After comparing the percentage of dissatisfaction was revealed, the statistically significant difference was seen by two procedures; Foam sclerotherapy and stab avulsion, in some cases of the quality questionnaire in terms of lower limbs, in two groups of varicose treatment patients. ($P< 0.05$) in other words, was observed in assessment questionnaire of quality of life of terms of lower limb in two groups of varicose patients, the patients in the group foam sclerotherapy were more satisfied than the usual method and was observed statistically significant

differences in some questions of questionnaire.

On the other hand, different results obtain of the two groups of varicose patients by two procedures; Foam sclerotherapy and stab avulsion, in comparing the percentage dissatisfaction of each of the satisfied cases in questionnaire of quality of life in the two groups of the patients. In this case, statistically significant difference in the two treatment procedures of the varicose patients were seen between The average of satisfaction percentage in some cases of the questionnaire of quality of life ($P<0.05$) and only statistics was obtained for using Varis socks that caused Eczema or beech in ankle and also wound related to varicose veins, the average of satisfaction percentage in the two groups weren't seen by the two method ($p>0.05$), as a result, the measuring satisfaction in the patients that were assessed between the two methods the patients treated by the foam sclerotherapy technique were better, and in 75% of questions was obtained better results from the patients that treated with by the foam sclerotherapy technique and Statistically satisfaction difference was observed in comparing the two method.

After evaluating all patients by questionnaire and regardless of the lower limbs were determined that Statistically

satisfaction difference was seen between the percentage dissatisfaction with the quality of life in the two group of varicose patients by two procedures; foam sclerotherapy and stab avulsion ($p=0/0001$). However it is not worthy that the average of percentage dissatisfaction in patients under surgery is 85/8 and in foam sclerotherapy technique 84/4. The records are in an acceptable range and in comparing the two procedures; the satisfaction measure of the foam sclerotherapy technique is more significantly. Comparison the dissatisfaction percentage of quality of life according to sex statistically significant difference between the dissatisfaction percentage of quality of life, in two group of varicose male patients with two treatment procedures was seen ($P=0.0001$) but compare statistically significant difference between the percentage of female dissatisfaction of the quality of life in the two groups of varicose female patients was seen by the two procedures ($P=0.048$).

Comparison the dissatisfaction percentage of quality of life according to sex statistically significant difference in two groups of varicose patients less than 40years old weren't seen by the two methods ($P=0.55$). But in patients with 41-50years ($P=0.012$) and varicose treatment

patients 60 to 51years old with varicose veins treated with two techniques of statistically significant difference was seen ($P= 0.003$). Also in the two groups of varicose treatment patients more than 60 years weren't seen with two treatment techniques.

Plenty distribution in some complications after surgery in two groups of varicose treatment patients with two techniques; stab avulsion and foam sclerotherapy with this form was determined that there are a statistically significant association between the complications of ankle swelling, itching and change the color purple in two groups varicose treatment patients that was seen by the two techniques; stab avulsion and foam sclerotherapy ($P=0.0001$, $P=0.001$, $P=0.0001$).

However, most complications related to the change purple in the lower extremities by stab avulsion were observed (69.6%). Finally, plenty distribution in some complications after surgery, in two groups of varicose treatment patients by two method; stab avulsion and foam sclerotherapy were seen statistically significant relationship between the number of complications in the two groups of varicose treatment patients with two treatment techniques ($P=0.0001$).

DISCUSSION

Varicose veins are included 10-20% of the adult population in western countries. Varicose veins presents are from a range of asymptomatic to symptomatic and in case of symptomatic shows the complications such; stasis dermatitis, edema, spontaneous bleeding, superficial thrombophlebitis, frequent cellulite is, lipoderma to sclerosis and limbs edema. A lot of patients have symptoms such as pain, cramping, fatigue, restless legs, feeling of fullness and heaviness or tingling in the legs [18].

Varicose veins can be due to; hereditary, primary venous reflux, secondary venous reflux. The attaining blood to veins is the final conclusion of the cases which increase blood pressure. Having strong family predisposition for varicose veins has been reported. The annual incidence of varicose veins is estimated in the Framingham study, 6.2 %among women and 9.1% among men [19]. Varicose vein is a common disease, so its treatment has major economic and social effects [7]. We study to compare the quality of life of varicose patients undergoing treatment by two techniques; surgical treatment and less invasive approaches. As mentioned, statistical significant relation isn't seen between gender distribution in the two groups of varicose patients undergoing treating by the either method. Plenty

distribution of age groups in the two treatment groups ($P=0.49$), and plenty distribution of family history of varicose veins in them ($P=0.11$), weren't observed statistical significant differences in these two variables, as observed. unlike The findings of this study that weren't seen a statistical significant relation between gender and age of the participants , in the study that Jawien did in 2003 , he studied prevalence and risk factors for varicose veins and concluded prevalence of varicose veins and CVI (Chronic Venous Insufficiency) is similar what is observed in developed countries , that is more common in women but female isn't considered important factor and the risk factors relevant to CVI, age, family history of varicose veins and constipation. Fatness and lack of physical activity connect significantly with higher prevalence of CVI in women than men. The number of pregnancies (more than twice) between women with and without CVI was famous, and was seen less relation in female, previous injury leg DVT and staying in the position of standing for long time [16].

After analyzing the data of the questionnaire of varicose patients, the percentage of dissatisfaction was determined on the basis of quality of life AVVQ (Aberdeen Venous Vein Questionnaire) and the value of the

specified rating to each of the questions on the basis of the total score and calculate the percentage for each of the questions the left and right leg separately.

The statistical significant difference between the percentage of dissatisfaction were seen in some cases, in the questionnaire of the quality of life, in terms of lower limbs in two groups of varicose patients under treating by foam sclerotherapy and stab avulsion ($p < 0.05$). According to the data, we can say both of method have adequate efficient generally; however, we pay to detail of outbreak of complications, foam sclerotherapy method was more successful than surgery. As well as satisfaction rate and the quality of life of the patients significantly in foam sclerotherapy method are higher, it is noteworthy that the average percentage of patient's dissatisfaction under surgery 85.8 and foam sclerotherapy 84.4 respectively. As mentioned previously, the patients' dissatisfaction of these two methods have been reported acceptable and reasonable, but in comparing these two methods, the satisfaction rate of Foam sclerotherapy method is higher significantly. After evaluating the questionnaires, whether to study and compare or calculates scores of the questionnaire in the two treatment methods (under the Protocol questionnaire), the results of this study is

linked with many results of previous studies [15, 20, 21].

According to this case that any surgical procedure can cause short or long complications, the method of the varicose veins therapy isn't excluded in this rule. As mentioned, each of the 4 main method of varicose therapy has complications, in the questionnaire of the quality of life, 1/3 questions has been allocated to the complication after surgery. In this study, after analyzing the data was observed plenty distribution in some complications after surgery in the varicose patients under treating by stab avulsion and foam sclerotherapy have a significant link between complications of ankle swelling, itching, change purple in two groups of varicose patients under treating ($P = 0.0001$, $P = 0.01$, $P = 0.0001$). However, most complications related to the change purple in the lower extremities in the method of stab avulsion (69.6%). Finally, plenty distribution of some complications after surgery in the two groups of patients by foam sclerotherapy and stab avulsion, statistical significant relation were seen between the number of patient's complications by the two methods; foam sclerotherapy and stab avulsion ($P = 0.0001$).

The above findings in this study are aligned with some previous studies. Xia et

al concluded the average of important unwanted complications include of pulmonary embolism and venous thrombosis, their depth were lesser than 1%. In a systematic review, the effectiveness of foam sclerotherapy method for varicose vein therapy was investigated in 2007 in 69 patients. 166 patients were investigated and injected foam sclerotherapy for pain (81%) itching (41%), inflammation (17%), ulcers (17%), thrombophlebitis (14%), ruptured in varicose vein (3%). At 215 feet (99%) after an injection, varicose vein was blocked. 93% active ulcers improved or were reduced their size. There were unwanted complications of pain. Thrombocytopenia, hematoma, skin necrosis, and neurological complications were rare. At the end, foam sclerotherapy is mentioned a safe and effective slippers treatment in symptomatic veins [22].

It is noteworthy, complications that were expressed in the other studies such as skinny wounds, deep vein thrombosis weren't observed in any participating patients in the study. On the other hand, in multiple analysis of the effect of treatment methods (stab avulsion against foam sclerotherapy) used multiple linear regression model (Multiple linear Regression) for the percentage of quality of life by controlling the effects of

demographic variables (age, sex, history of varicose veins). Results show the dissatisfaction percentage of the quality of patient's life with stab avulsion against foam sclerotherapy is significant, statistically. On average 1.1 ± 7.3 percent have the dissatisfaction of the quality of higher life ($P=0.001$). Also in the final model of multiple regression, age as affecting factor of the dissatisfaction percent of the quality of patient's life was considered ($P=0.025$) as with increasing every 10 years, 49.0 ± 12.1 will increase on dissatisfaction percentage of quality of life .

Finally, the two treatment methods; minimally invasive treatment (foam sclerotherapy), and conventional surgery (stab avulsion) have favorable effects in therapeutic efficacy, the quality of patient's life and also possible complications ;and caused to improve the quality of the patients' life , generally the amount and type of complications after surgery was in acceptable level. But in comparing the two approaches, according to the results of this study can be said that foam sclerotherapy is a more economical, safer, with less complications after surgery and also has the most effectiveness on the quality of patients' life.

Although many of investigated variables and cases in this study has been in line in

different countries, but there are limits in this method that we pay them briefly, questionnaires were completed by the patient, and some questions are not comprehensible and it doesn't seem to be unlikely the possibility of human error, also according to scheduling of follow-up patients after surgery and the need to memorialize their disease status by themselves, the human error is doubled. Sometimes, defects in patient records, access to some of them was impossible. It is offered to do studies in this area as much as possible not to be like this research retrospectively and also it seems desirable results are achieved retrospectively the study for 10-year-old in comparing different therapeutic approaches including non-invasive (conservative), minimally invasive and surgery on a broader population of patients and this questionnaire is used at different time until is calculated the long-term and medium-term complications in different method of surgery and also The rate of relapse and treatment failure in a longer period of time. And also we can use several different questionnaire for more careful in evaluating the quality of the patients' life that each of questionnaires show the different aspects of the relation of the quality of life and health, Examples of the questionnaires that can be offered to

short form of quality of life (SF36) or global quality of life questionnaire (GHQ) that can use them along with the quality of patients' life (AVVQ).

In addition, according to all modalities were used for patients by indication and Clinical evaluation, is suggested that may be it becomes more logical that in future studies are compared in minimally invasive techniques and surgical procedures with each other.

Ethic and conflicts of interest

In this study, the patients complete the form of consent questionnaire after researcher's explanations. In this study, patients have liberty in any part that exit of the study, the patients' information was retained except generally wasn't published.

Conflicts of interests

Researchers did not have any conflict of interest.

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