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RESEARCH ARTICLE

EVALUATING QUALITY OF LIFE OF PATIENTS WITH VARICOSE VEIN.

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Abstract

Varicose vein (VV) is worldwide problem that can affect both male and female, varicose veins are a common manifestation of venous incompetence in the lower limb. It was classified into trunk, reticular or telangiectasia which is also called spider vein. Most varicose veins are primary while secondary are minority. Untreated VV can increase morbidity and mortality rate, and has bad consequences such as recurrent dermatitis and ulceration, pigmentation and indurations, chronic pain and edema, hemorrhage, deep vein thrombosis, and even malignant transformation, In addition to psychological and financial bad consequences. Epidemiologic studies suggested that up to 15% of men and 25% of women have visible varicose vein. VV are commonly stated to be responsible for a wide range of lower limb nonspecific symptoms such as heaviness, swelling, aching, restless legs, cramps, tingling and itching. VV has a poor impact on quality of life.

The Aberdeen Varicose Vein Questionnaire (AVVQ) was developed and validated by other studies for measuring QOL in patients with varicose veins of the leg, in this study the same Aberdeen Questionnaire will be used to evaluate the quality of life of patients with varicose vein at King Abdul-Aziz Medical city in Riyadh. **The aim** of this study is to evaluate the quality of life of patients with varicose vein. Ethical approval will be taken first.

All patients that have been diagnosed with VV and visit the vascular clinic at King Abdul-Aziz medical city Out Patient clinic will be asked to participate in the study.

The questions and responses will be each coded individually, and manually entered into an excel file and exported into the SPSS program for further analysis of the data. A pilot study was first conducted at KAMC to check if the questionnaire can work here in this area and to calculate the sample size, 15 participants were asked to complete the Arabic version of AVVQ after demographic data questions were added, the result showed that mean quality of life score is 52.4 with SD of 14.4 which is approximately similar to international mean score that showed in published data. This high mean score of quality of life can prove that varicose vein has a negative impact on quality of life.

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Introduction:-

This chapter presents the background of the project, nature of the problem, aim and objectives which will lead to conduct this study.

Background:

Varicose vein is an important disease that has a negative impact on the quality of life, during my work at King Abdul-Aziz medical city I have noticed that an adequate number of patients are suffering from this disease and its bad consequences. Limitation of studies were found about varicose vein and its effect on quality of life in this area; however it has a physical, social, psychological and financial impact on patients. Treatment of varicose vein is of high cost and its financial burden not only at personal level but also governmental. The patients of varicose vein are seeking treatment at public and private hospitals as well. Because quality of life is an important issue, in addition to other reasons that mentioned above a study about evaluating the quality of life of patients with varicose vein need to be conducted; based in this study results a more future studies will be conducted to prevent varicose vein incidence and its complication.

Definition and causes

Varicose vein (VV) is worldwide problems that can affect both male and female, varicose veins are a common manifestation of venous incompetence in the lower limb[i] . VV is of two type primary and secondary; primary when there is a single valve failure or weakness in a significant area, while secondary VV when there is thrombophlebitis that can damage the deep system and the valve[ii]. Primary VV can result in high pressure passes to superficial vein lead to turn it into dilated, elongated, and tortuous, incompetence. Modification of the content of Elastin, Fibronectin, Collagen and Laminin seen in VV, in addition to alteration of tissue remodeling, dysregulations of the synthesis of extracellular matrix proteins of smooth muscle[iii]. Increasing the synthesis of collagen I, and decreasing the synthesis of collagen III and fibronectin, this alteration and dysregulation explain the mechanical change of veins in VV[4].

Untreated VV can increase morbidity and mortality rate, and has bad consequences such as recurrent dermatitis and ulceration, pigmentation and indurations, chronic pain and edema, hemorrhage, deep vein thrombosis, and even malignant transformation[1 2 3]. In addition to its physical impact VV has an impact on psychological status of the patients as it can cause depression with no difference in gender or age[iv]. Also it has financial impact in which treatment is very costly[10 18]. Most varicose veins are primary while secondary are minority. Increase in size of the vein does not indicate abnormality, may be related to high temperature or to hormonal factor in female, sometimes it appear large in thin person while hidden in obese. Varicose vein classified into trunk, reticular or telangiectasia which is also called spider vein[v].

Incidence and prevalence:

Epidemiologic studies suggested that up to 15% of men and 25% of women have visible varicose veins while minor VV effect 50% of women and 45% of men[3]. Some studies resulted in 7-38% of VV in men and 14-51% in women[vi], trunk varicose was 40% in men and 32% in women, and however there are limited studies about incidence of VV[4].

Symptoms:

VV are commonly stated to be responsible for a wide range of lower limb nonspecific symptoms such as heaviness, swelling, aching, restless legs, cramps, tingling and itching[3]. These symptoms are associated with trunk varicose in women but in men only itching is associated with trunk varicose, but there is no association between reticular varicose and lower limb symptoms in both women and men[4].

Although it has not been studied, an equally large proportion of the adult population may be affected by various lower limb symptoms[viiviiiix]. However, it is now widely recognized that the evaluation of disease burden in chronic conditions such as varicose veins must take into account the impact on quality of life (QOL) in addition to clinical outcomes such as symptoms[xxixiixiiixiv]. VV has a poor impact on quality of life[10.] But some studies showed that there is no difference between patients with VV and normal population[xvxvi].

VV is the most common vascular diseases, and one of the most leading causes of hospitalization[xvii]. VV is one of the most chronic diseases that need surgical intervention[xviii]. So due to high prevalence of VV and its bad outcome on the subjects more studies need to be done. Due to lack of studies about VV in Saudi Arabia; lack of knowledge of

occurrence of this disease and the risk factor is also exist. In this study the impact of VV on quality of life will be evaluated by using Aberdeen questionnaire.

Quality of life

Quality of life (QOL) is concern about all aspects of individual to exist; health related quality of life (HRQOL) is concern about health aspect of an individual[xix].

More recently the concept of health become broader to include social, psychological and physical aspects so that terms like functional ability, social health and positive health have become important in determining health[xx].

Health is a highly valued human asset, every one desired a good health which is difficult to define, and there are two common themes that define health status the first one is based on premature death is undesirable so health is to avoid mortality and health status evaluated in term of mortality or infant mortality rate. The second theme is quality of life is important, life expectancy and quality of life is highly related to disability and diseases in which can make life less desirable, for example a person with heart disease or cancer can cause premature death in addition they can cause disability, can affect person from doing daily activities, work and to participate in social activities. Even minor diseases and disability can make life less desirable such as cold can prevent person from attending the school or concentrate on work for short period of time, but other chronic diseases as arthritis or varicose vein can affect quality of life for long period of time.

Lastly the scientists recognize the importance of measuring the quality of life, major diseases can be evaluated in term of their effect on quality of life and life expectancy, treatment of these diseases also can be evaluated in term of improvement treatment can produce on quality of life[xxi].

The Aberdeen Varicose Vein Questionnaire (AVVQ) was developed and validated by other studies for measuring QOL in patients with varicose veins of the leg (appendix I). It is a disease-specific questionnaire health measures HRQOL for patients with varicose veins[xxiixxiiixxivxxv]. The questionnaire, designed in 1993 by Garratt, consists of 13 questions relating to all aspects of the problem of varicose veins. The questionnaire has a section in which the patients can indicate diagrammatically the distribution of their varicose veins. There are questions relating to the amount of pain experienced, ankle swelling, and use of support stockings, interference with social and domestic activities, and the cosmetic aspects of varicose veins. The questionnaire is scored from zero to 100, where zero represents a patient with no evidence of varicose veins and 100 represents the most severe problems associated with varicose veins[xxvixxviixxviiixxix].

In this study the same questionnaire will be translated to Arabic language, the questionnaire would be translated to Arabic in order to use with the local population. The translation would be conducted by an academic who is fluent in both languages. Demographic details including, age, gender, Place of residence , educational qualification, marital status, history of pregnancy, occupation and family history of VV (which was not included on the AVVQ would be added for use for the proposed study. see appendix II).

Research question

Does VV affect the quality of life of the patients?

Hypothesis

Quality of life of patient with VV is affected by the disease.

Aim and Objectives:-

Aim

To evaluate the quality of life of patients with varicose vein.

Objectives of the study:

Investigate the full range of venous symptoms and signs in patients with varicose vein.
Assess the impact of varicose veins on quality of life.
To provide recommendations to improve quality of life of patients with VV.

Our secondary objective is to assess of the prevalence of all grades of venous diseases on the available sample of patients who visit vascular clinic.

Document Organization:
This project is composed of 4 main chapters:

Chapter 1 is an introduction, which provides a background to the study about varicose vein, nature of the problem, aim and objectives which led to conduct this research and organization of the document were provided. **Chapter 2** is about the literature review, which presents a summary of studies on varicose vein. **Chapter 3** presents the research methods include study design, Sample population, and the main tools used in the conduct of the study.

Chapter 4 it is about the results of the pilot study. Also, it includes conclusion and recommendation.

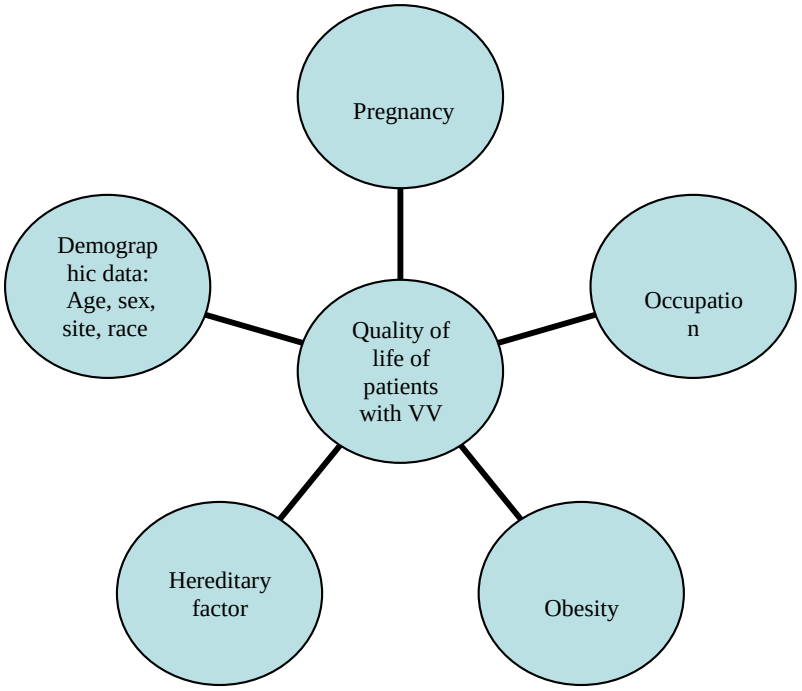
Evaluating quality of life of patients with varicose vein

Chapter 2
Literature Review
Evaluating quality of life of patients with varicose vein

The literature reviews presented in this study will discuss the most common factors which may influence the incidence and the severity of varicose vein and their effect on quality of life, diagnosis and treatment of varicose vein, treatment of complications, some precautions and recurrence of varicose vein. Most of the studies that were done on VV were conducted in developed countries. The studies that focused on evaluating quality of life of VV patients are almost nonexistent in Saudi Arabia.

Conceptual Framework:
This framework was designed based on literature review. A comprehensive literature review was conducted using major databases (e.g. Medline, Pub-med, Science Direct, Google scholar etc.) using the search terms: "varicose vein", "quality life", "prevalence VV" to investigate the most common factors affecting quality of life due to VV. An effort has been made to review related articles, and important information on the different factors that may influence quality of life due to VV was reviewed. **Figure 2.1** summarizes the independent variables that affect VV and quality of life (outcome).

Figure 2.2:-Framework



Independent Variables (risk factors)

Gender

During reviewing articles it is obviously clear that VV is more common in female than male. One article presented that VV is ranged from <1-73% in female and from 2- 56% in male. The author described this difference is may be due to population distribution of risk factor, accuracy of diagnostic test, and availability of diagnostic and treatment resources[xxx]. Another explanation of this gender difference was explained as an action of sex hormones with unknown mechanism[xxxi]. Although a study conducted in 1999 was shown that mild VV prevalence is higher in men than in women[1]. There is a strong relation between trunk varicose and symptoms (such as itching, heaviness or tension, and etching) in female even if they are of limited clinical value, while this relation is low in male except itching[4]. Female prevalence of VV is 2.3 more than male[4.] However some studies showed that there was no relation between gender and varicose vein[xxxii] .

Age

During reviewing the articles all the data suggested that increasing age is a risk factor for VV[1 3 5 10 24 29 33 xxxiiixxxiv]. In spite of an old study (1988) suggested that no clear age difference[xxxv]. The clinical symptoms of VV such as heaviness, itching, and aching, swelling and restless leg are tend to increase with age in both sexes[6]. although another old study suggested that VV increase with age in both sexes except in north America where it is un common in men and women older than 45[xxxvi].

Geographic site

Epidemiological studies suggested that geographic site is a risk factor for VV[53335]. VV is more common in western region[29]. It affected more than 24 million of Americans[xxxvii]. VV related positively with high income and urban areas[xxxviii]. In Japanese VV is less common than Europe and United States but more common than in Africa[xxxix]. Another study showed that the prevalence of VV in female was low in rural area while medium in men in the same area[xl]. The difference may be due to life experience and behavioral pattern of people in different regions[xli]. One old study compared varicose vein in Europe and Egypt and resulted in higher prevalence of VV among European women than Egyptian even though women of both groups had the same working circumstances of working at cotton factory; so this difference of prevalence was explained by environmental factors such as wearing habits, and type of food,

This was largely free of vegetables fibers in western region which lead to constipation, constipation over long period can result in prolapsed colon in which pull on iliac vein lead to venous return and raising intravenous pressure which passes to superficial vein causing varicosities[xlii], however this was a hospital based study and there was limited numbers of bed in developing countries as Egypt so it was not representative of whole population[43].

However some studies showed that VV had no association with geographic site[4].

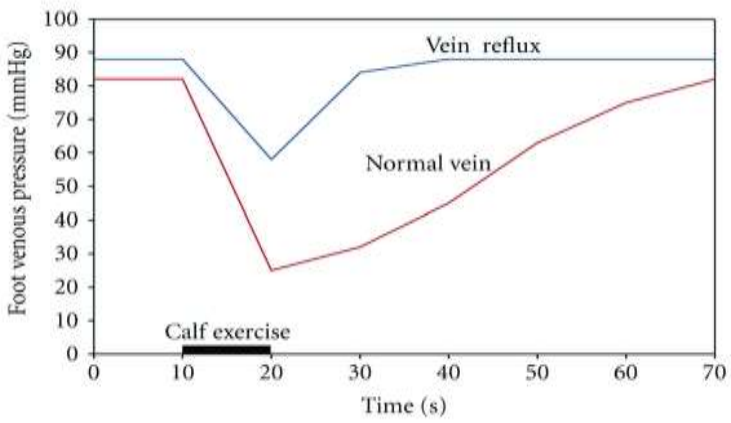
Occupation

Occupational illness is defined by the Occupational health and Safety as "a condition that results from exposure in the workplace to a physical, chemical or biologic agent to the extent that the normal physiologic mechanisms are affected, impairing the health of the worker". There should be a relation ship between the illness and the nature of the work either directly by the characteristic of work or indirectly by the risk from performing that work. Occupations associated with VV are textile workers, heavy lifting, department store employees, prolonged standing at work and sanitary activities for females[16]. Studies found that women who spent 8 hours in sedentary activities had higher incidence of VV than women who spent 4 hours or less[35].

Recent studies suggested that long standing and walking at work is a risk factor of VV[29], other studies showed that setting or standing posture at work is a leading cause of clinical significant VV[xliii]. The biological explanation of increasing VV with long standing is the impeded blood flow and venous stasis due to increased intravenous hydrostatic pressure in the up writing working position, the same mechanism work during walking but to lesser degree due to the muscle pump during walking reduce the venous stasis[35].

This diagram figure 2.2 shows foot venous pressure during exercise in the standing position. Lower curve illustrates normal venous pressure while upper curve shows venous pressure in patients with venous reflux[xliv].

Figure 2.2:



In case of primary VV, during standing and walking position the loss of valvular mechanism in deep venous system forced the blood to flow in abnormal pathway, the muscle pump the blood distally through perforated vein into superficial system. By increasing venous and capillary pressure over time will lead to edema, recurrent inflammation and ulcers which are one of the main causes of hospitalization[16].

Unfortunately, there is no systemic review explained the occupational hazards and varicose vein, the relationship between standing position and prevalence of varicose vein is equivocal, however this may be due to poor quality of the methodology used and no searching of the available literature review[16]. in general, prospective studies is needed to study such relationship this will be more effective in determining that occupation is a risk factor for VV than cross sectional studies[16]. One study suggested that occupation is not a risk factor of VV[5].

Pregnancy

Pregnancy is another risk factor for VV[529], about 15 to 20% of pregnant ladies can develop VV[xlv], this is explained by increase hydrostatic pressure in abdominal vein which drain into leg vein[35], and however an old document suggested that eating unrefined maize can prevent VV even in case of pregnancy[xlvi]. Varicose vein usually appear during the first trimester of pregnancy, involving the venous system around ligaments[xlvii].

The etiological factors of VV during pregnancy was described as hormonal which is considered the most important reason, valvular defects due to congenital or infectious reason, weak wall of veins which is also due to congenital or infectious reason, hereditary, and pressure theory which is not considered an important factor anymore because VV usually appear at the beginning of pregnancy however it may include as a factor if VV occur in the late pregnancy due to intra-abdominal pressure, these etiological factors lead to distortion of normal function of superficial venous system and supporting musculature[xlviii].

Varicose vein during pregnancy should be treated for numbers of reasons: first to reduce the incidence of thrombophlebitis, second to prevent hemorrhage from ruptured vulvar varicosities at time of delivery, third the best result obtained from treatment VV is during pregnancy[45].

Races

Studies suggested that races are a risk factor for varicose vein[5]. The prevalence is high in western and Europe[29], however the prevalence of VV is the same in united states of America for both white and Negro may be due to its diagnosis is difficult in Negro due to the color of black skin while can be seen more clearly with whit skin[37.] While other study showed that Negroes and Caucasian had no difference in varicose vein prevalence and this explained that races was not a risk factor rather it was environmental[43].

Obesity

There is a high association between obesity and VV[1629]. However some studies showed that obesity is not a risk factor for VV[5 33], another suggestion that obesity is a risk factor for female only[4]. Female with varicose vein were

found more obese than female without VV[35]. Controlling bodyweight and practicing physical activities may prevent varicose vein at high risk adult[35].

Hereditary factors

There is a prominent relation between hereditary factor and varicose vein, study showed that 90% of children have the risk of developing VV if both parents had it, 25% of male and 62% of female if one parent was affected, and 20% when neither parent was affected[xlix] . Although some studies suggested that there is no evidence that hereditary factor is a risk factor for VV[4].

In the past the association between hereditary factors and varicose vein in lower extremities was accepted generally but not universally, this was due to limited evidence available to discuss and solve the problems associated with this relationship as mode of inheritance and the weight of genetic factor, also there was few systemic studies of representative samples to study this association. Even twin studies were rare, one study found that 75% of 12 monozygotic pairs to be concordant to varicose vein, and 25% of 25 dizygotic pairs of the same sex, this difference in concordant were not significant, this was come to conduct more accurate studies related to this issue[l]. Anew study showed that there is an association between hereditary factor and the prevalence of VV however this association is less important than the association between women and VV, and less than what usually proposed in literature[li]. Although some studies suggested that VV transmitted by the involvement of hereditary factor, it was agreed by most authors that hereditary factors are the principle cause of VV and the symptoms appear due to environmental factors, decreasing elasticity of the wall of varicose vein due to venous insufficiency and in high risk patients and in children of parents of VV are an evidence that VV has a genetic basis[4].

Diagnosis and treatment

Varicose vein is a medical condition that leads to symptoms and sever complication that require a diagnosis and deserve an intervention.

Varicose vein diagnose by direct history taken from subjects with the disease, and physical examination. Abdominal examination is also required to exclude any secondary causes of varicose vein, the examination of distribution of varicose vein whether long or short saphenous or both is required while patient standing. Any skin change is also examined.

Ideally all patients come to vascular clinic with varicose veins would have color duplex scanning; Patients with recurrent varicose veins should be scanned to determine the precise site of recurrence. Patients with varicose veins in limbs with a history of deep vein thrombosis or thrombophlebitis should be scanned to make sure that the superficial veins are not acting as collaterals in the presence of deep vein obstruction. Scanning is also required for patients with skin changes.

It is controversial to treat such benign disease or leave it due to highly cost treatment options[9]. A clear understanding anatomy of the superficial veins is very important in order to have accurate diagnosis and treatment of varicose vein[lii].

At the beginning the patients should be asked why they seek treatment, because one third of patients come to treat symptoms not related to varicose vein, or because they worried from complications, this type of patients just need reassurance[9].

Treatment should be started as self-care only as raising legs and wearing stocking, but if this option not helps the patients will go for other options.

As discussed before varicose vein mainly due to saphenofemoral and great saphenous vein (GSV) incompetence. So treatment options mostly classified under two main points; surgical or laser[liii].

Conventional surgery such as saphenofemoral ligation, GSV stripping and phlebectomy of residual varicosities; this can be done on one day under general anesthesia and need from two to three recovery period.

Laser such as minimally invasive endovenous techniques called endovenous laser ablation (EVLA) as an alternative to conventional surgery and has the benefits of minimizing post-operative morbidity and shorter recovery period, also can be done under local anesthesia in outpatient clinic. Laser therapy based on thermal ablation of GSV[52].

Residual varicosities can be treated either by delayed injection sclerotherapy or by multiple phlebectomies at the time of initial therapy; multiple phlebectomies should be done in operating theatre under general anesthesia, this technique limits the benefits of EVLA[52].

Another option of treatment is Sclerotherapy which is one common treatment for varicose veins. This technique is based on injection of salt water (saline) or a chemical solution into the varicose vein. The vein will harden and then disappear. Sclerotherapy works best for small spider veins. But sclerotherapy has disadvantages of skin staining and ulceration, and high recurrence rate of VV about 65% within give years[9].

Another technique called radiofrequency ablation which similar to EVLA technique in using heat to treat varicose vein, it depends on ultrasound for guiding the practitioner during treatment when puncturing the vein, then a flexible tube (catheter) threaded through the vein, then special solution is injected to numb the vein, then heat induced through the vein in which it destroyed it until disappear over time; however this procedure is effective in upper thigh only[liv].

Recent study showed that Superoxide production was increased in VV compared with control human saphenous vein so Nicotinamide adenine dinucleotide phosphate (NADPH) oxidases and nitric oxide synthase (NOS) could represent valuable drug targets for pharmacological treatment and prevention of varicose vein disease because their inhibitors greatly attenuated superoxide production in VV[lv]

Varicose vein therapy may be recommended for: Improving the appearance of the leg (a common reason for sclerotherapy), leg pain, Lipodermatosclerosis (fatty tissue under that skin that hardens over time from high blood pressure in a vein), repeated phlebitis of the vein and Ulcers or sores[53]. However, some governments don't provide treatment of varicose vein if the patients want it for cosmetic reasons only, whereas patients with skin changes (eczema, lipodermatosclerosis, and ulceration) are treated[9].In some cases there will be complications but they are less than 1% for serious complications such as deep venous thrombosis, pulmonary embolism, or arterial or nerve injury, but about 17% of patients will have minor complications, most commonly temporary saphenous or sural nerve neuralgia. All patients should be warned of the possibility of having such complications. After surgery, 20-30% of patients will develop recurrent varicose veins within 10 years[9].

Treatment of complications

Bleeding varicose vein: the feet with bleeding varicose vein should be raised above the level of the heart with compression; the patients should be referred to vascular surgeon to treat the underlying cause of the bleeding, compression hosiery should be weared if the deep veins are incompetence[9].

Thrombophlebitis

the patient with thrombophlebitis should be referred to vascular surgeon to treat the underlying abnormality; high percentage of these patients can develop deep vein thrombosis so duplex scanning is required to exclude it. Bandaging is important to compress vein and reduce propagation of thrombus, analgesia such as non-steroidal anti-inflammatory drug and Low dose aspirin is required but antibiotic is not indicated in such case[9].

Varicose eczema and ulceration:

Patients with varicose eczema require color duplex scanning to define the underlying venous abnormality. If the only abnormality is superficial venous incompetence this should be treated by surgical intervention. If, the deep veins are incompetent, then superficial surgery will not help and the patient should be treated with a topical steroid and wear compression hosiery[9].

Some precautions

If patient has deep vein thrombosis or thrombophlebitis or a family history of such diseases, patient will have high risk of developing deep vein thrombosis after varicose vein surgery, so patient will has one of two options; either not doing VV surgery or do the surgery with preoperative subcutaneous heparin as prophylaxis[9].

If female patient is taking contraceptive bill or hormonal replacement, she is at high risk of developing deep vein thrombosis as well, so should take this under consideration when treat such patient[9].

If patient has any history of skin changes, he will be at high risk of developing skin ulcerations[9].

A study showed that a single dose of preoperative antibiotics before ligation surgery of great saphenous vein can reduce the risk of getting site infection especially high risk groups as diabetes and high body mass index patients[lvi]

Recurrence of varicose vein

The recurrence of varicose vein after surgery considered high, about 20% of cases, this is may be due to inadequate or defective primary surgery, or occurrence of varicose vein due to new site reflux[9]. The recurrence of varicose vein is common irrespective to surgeon method or his experience[lvii]. To eliminate such recurrence an effective primary surgery should be done and a good patient assessment is required.

Varicose vein recurrence has a social and an economic impact, in which surgical treatment of varicose vein has a high cost about 11 million bounds annually[9].

Evaluating quality of life of patients with varicose vein

Research Methods

Evaluating quality of life of patients with varicose vein

This chapter presents the research methods include study design, sample population, the main tools and data management and analysis that will be used in this research.

Research design 3.1

This study will be a cross sectional study that will measure the quality of life of patients with VV using the Varicose Vein Aberdeen questionnaire. All patients that have been diagnosed with VV and visit the vascular clinic at King Abdul-Aziz medical city Out Patient clinic will be asked to participate in the study.

Cross sectional study is an observational study which is mainly used to determine the prevalence of a disease; only one group is used looking for one or multiple outcome of an exposed subject, usually questionnaire is used for data collection. Cross sectional study started by formulating the research question, and choose the sample population, then decide what variables of the study population are relevant to the research question, then method for contacting sample subjects must be devised and then implemented, then the data can be collected and then be analyzed. The most important advantage of cross sectional studies is that in general they are quick and cheap and also when using questionnaire (as is planned in this proposed study), it provides an opportunity to collect data from a big sample in a relatively short time. As there is no follow up, fewer resources are required to conduct the study. , Cross sectional studies are the best way to determine prevalence and are useful at identifying associations that can then be more rigorously studied using a cohort study or randomized controlled study. On other hand, the most important problem with this type of study is differentiating cause and effect from simple association. Another problem is rare conditions which cannot efficiently be studied using cross sectional studies because even in large samples there may be no one with the disease. In this situation it is better to study a cross sectional sample of patients who already have the disease (a case series).

Tools

The translated Aberdeen Varicose Vein Questionnaire (AVVQ) will be used as a tool to collect the data to evaluate quality of life of patients with varicose vein.

A pilot study would first be conducted to check the translated questionnaire. About fifteen participants would be asked to complete the questionnaire as part of the pilot study Full details about the aims and the objectives of this study will be given to the participants and they will be assured anonymity and that the information they provide will remain confidential, (see appendix III).

Setting

This study will be conducted at the King Abdul-Aziz Medical City (KAMC) in Riyadh, outpatient vascular surgery clinic. This clinic scheduled for all vascular disease's patients and not only for VV, twice a week with twenty patients each day not necessarily with VV patients are seen at each clinic.

The KAMC has been selected for the following reasons :- firstly it is the working place of the researchers where it will be easier to conduct such a study., Secondly KAMC is considered as one of the most important national

hospitals in Riyadh which cover the public population in addition to the private sector. As well as people who live in Riyadh, the KAMC also accept referral from all regions in the country in case of emergency and Royal Decrees. Thirdly KAMC is a highly specialized hospital provided by the best specialist in vascular diseases and the latest technologist tools that is used in diagnosis and treatment.

Participants First approval from the head of the vascular surgery clinic was taken to allow us collect the data from the patients, and then the questionnaire will be distributed to all patients who come to KAMC for varicose vein problem in the waiting area.

Inclusion criteria:
All patients that are referred to the vascular surgery clinic for varicose vein diagnosis and treatment will be included in this study. Also all patients booked for surgery of varicose vein with obvious clinical VV will be included.

Exclusion criteria:
Patients with venous ulcers, or deep venous disease and Patients with previous venous surgery or recurrent varicose veins will be excluded from this study.

Sample size
A pilot study was conducted of around 15 patients with varicose vein at KAMC to evaluate their quality of life. The calculation from this study showed that the mean score of quality of life is 52.4 with a standard deviation of 14.4(see table 4.1). To estimate the mean score of quality of life to within 2 (i.e. a maximum likely error of 2) with 95% confidence we used the formula ($n= 4* SD^2/e^2$) (see essential medical statistics book)[lviii]. The sample size needed for this study will therefore be equal to 207 patients with varicose vein. As there are two vascular clinics per week with approximately 4 patients with VV in each clinic so to recruit up to this sample size (207 subjects) will require about 13 months.

All patients from all ages and sex who attend vascular clinic with obvious clinical VV or booked for surgery of VV but without venous ulcer or deep venous disease will be approached to participate in this study.

Data Collection methods, instruments used, measurements
The Aberdeen Questionnaire (appendix II) will be used as the instrument for data collection. One member of the investigation team will complete the questionnaire by direct interview of patients, to make sure that all questions will be answered and clear to the patients.

The Aberdeen Varicose Vein Questionnaire (AVVQ) was developed and validated by other studies for measuring QOL in patients with varicose veins of the leg (appendix I)[25]. It is a disease-specific questionnaire health measures HRQOL for patients with varicose veins. The questionnaire, designed in 1993 by Garratt, consists of 13 items relating to all aspects of the problem of varicose veins. The questionnaire has two sections. In section 1 the participants indicate diagrammatically the distribution of their varicose veins. There are also questions relating to the amount of pain experienced, ankle swelling, and use of support stockings, interference with social and domestic activities, and the cosmetic aspects of varicose veins.

In the second section, there are questions about patient symptoms and concerns where they have to answer questions about specific symptoms associated with VV, if they have the problem and its degree, (see appendix I).

The questionnaire would be translated to Arabic in order to use with the local population. The translation would be conducted by an academic who is fluent in both languages. Demographic details including, age, gender, Place of residence , educational qualification, marital status, history of pregnancy, occupation and family history of VV (which was not included on the AVVQ would be added for use for the proposed study. see appendix II).

Calculation of quality score
The total score will be calculated as described by Garratte[25]. Briefly, responses to all questions (see appendix I) regarding severity of vein will be added to make the total score. The total score will then be rescaled to ensure that patients can score between zero and 100, where zero represents a patient with no evidence of varicose veins and 100 represents the most severe problems associated with varicose veins. For each question there is minimum and maximum values (for example 1-3 where 1 represents no pain and 3 represents the severe pain), then the maximum

value for each question will be added and their total will be used as the denominator to express the total score for each patient as a percentage of 100 by dividing the total score for each patient by the denominator and multiplying by 100. Thus the score of quality of life will be from zero to 100. If a question is omitted for a patient the total score is calculated after removing the value for that question from the denominator.

Ethical issue
Permission to carry out the study will be requested for the hospital administration. Application for ethical approval will also be sought from the KMAC ethical committee. The confidentially of the information provided by the participants will be assured that it would not be accessed except by the main researcher and only for the purpose of this project. Anonymity of participants will be assured as well. The participant's responses will be reported and analyzed in such a manner that they cannot be linked or traced to any individual.

After ethical approval complete, another approval will be sought from the head of vascular surgery department to allow us to conduct the study at KAMC clinic. The questionnaire will be distributed in the waiting area to the patients who come for varicose vein problem; a direct interview with the patients will be done to fill the questionnaire to make sure that the patients understand all the questions and to reduce the possibility of not returning the questionnaire back after filling it.

Data Management and Analysis Plan
The questions and responses will be each coded individually, and manually entered into an excel file and exported into the SPSS program for further analysis of the data.

My dependent variables in this study is a total score of quality of life, we will check if the total score is normally distributed by using Kolmogorov-Smirnov test, (. If data is normally distributed the comparison between groups will be done by using t test in case of two category of the same variable such as gender or by using one way ANOVA in case of three or more categories of the same variable as occupation or by using regression test in case of comparison two or more variables. On the other hand if the data is not normally distributed we will use non parametric methods for example Mann Whitney or Kruskall Wallis test as appropriate.

Evaluating quality of life of patients with varicose vein

Pilot Study
Evaluating quality of life of patients with varicose vein

This chapter presented lesson learned from pilot study, analytic plan

Lessons learned from pilot study
Pilot study was conducted of around 15 patients of varicose vein, direct interview with the patients were conducted to complete the questionnaire, about 4 patients every week were asked to fill the questionnaire.

The results of first part of questionnaire:
Because it is just a pilot study no statistics would be reported here, only the results will generally list below.

It was found that most of the patients of varicose vein were female in a ratio of 13 female to 1 male only.
The most affected group is the older age.

No relation was noticed between overweight and varicose vein.

Most of patients with varicose vein have family history of the same disease especially mother or a grandmother.
Also most of them have more than three pregnancies.

There is no relation between working and non-working patients; however most of the working patients are work at hospital and school or college.

Half of patients are experienced pain and pain killer while half of them are not.

Most of them have swelling with different stages, but they are not wearing stocking, also most of them have no itching, skin rash, and ulcer, but most of them are concern about appearance.

The results of second part of questionnaire:
Most of the patients have no itching, skin rash and phlebitis but few numbers who has it considered it as a highly important problem.

But most of them have swelling, concern about appearance, aching, pain, discoloration and anxiety with different stages of importance ranging from 1 to 5. About half of the patients have cramps, and varicose vein affected their daily activities as house work and walking but it does not affect studying.

Also, half of patients their varicose vein affected leisure activities as practicing sports and hobbies but has no effect on their social life.

Most of the patients are not worried of getting ulcers, and about half of them the appearance of their varicose vein affecting their clothing and experienced pain during rest.

Another thing was noticed is that all female patients being not pregnant at the time of collecting data, this is because it was difficult to collect data in the waiting area or in the clinic so all the cases were completed the questionnaires who have appointment for duplex x-ray which are already diagnosed as varicose vein patients and referred for x-ray and they should be not pregnant in order to do such x-ray.

So to solve this problem the patients who diagnosed as varicose vein patients will be asked to set in an empty clinic or office for completing the questionnaire.

These results of pilot study may be different if having more representative sample of 500 patients or more.
It was found that all questions in the questionnaire are understandable to the patients and can measure their quality of life in appropriate manner.
The pilot study resulted in a mean score quality of life equal to 52.4 and SD of 14.4 which is approximately similar to international published values, it was found that mean score quality of life was 52 and SD of 13[11].

The results of pilot study are summarized in table:
Table 4.1:-presented the quality of life of patients with VV Statistics

Statistics		
Quality score		
N	Valid	15
	Missing	0
Mean	52.4309	
Median	51.9651	
Mode	45.85	
Std. Deviation	14.39957	
Minimum	31.88	
Maximum	91.27	
Percentiles	25	44.1048
	50	51.9651
	75	58.5153

Analytic plan:
The results will be summarized in the following tables:

Table 4.2: -will represent the association between total score of quality of life and the demographic variables.

Table 4.2 quality of life score				
	N	Mean (SD)	T test	p-value
Gender Male Female				

Age * 18-30 31-43 44-56 57-69				
City Riyadh Out Riyadh				
Marital status Married Not married				
Pregnancy Yes No				
Number of pregnancy * 1-3 4-6 7-10				
Over weight Yes No				
Working Yes No				
Nature of working * House wife School, college Hospital student				
Family history Yes No				
* one-way ANOVA				

Table 4.3:-will represent the joint effect of all independent variables on quality of life by using multiple linear regressions.

Table 4.3: multiple regression				
	regression coefficient B	SE(B)	t- test	p-value
Gender Male Female				
Age 18-30 (reference) 31-43 44-56 57-69				
City Riyadh Out Riyadh				

Marital status Married Not married				
Pregnancy Yes No				
Number of pregnancy 1-3 (reference) 4-6 7-10				
Over weight Yes No				
Working Yes No				
Nature of working Housewife (reference) School, college Hospital student				
Family history Yes No				

Evaluating quality of life of patients with varicose vein

Conclusion & Recommendation:-

Evaluating quality of life of patients with varicose vein

Conclusion and Recommendations

It seems that varicose vein is a major worldwide problem that has a negative impact on quality of life. The result of pilot study showed that the severity of the problem locally is the same as what it showed internationally with a mean score quality of life equal to 52.4 which is consider a high value; and this will encourage us to continue the study with representative sample. This study also focused on most risk factors that can affect quality of life of patients with varicose vein.

The findings of this study could help in understanding the seriousness of the problem in order to develop and implement strategies to reduce and prevent risk factors that lead to varicose vein and its effect on quality of life.
Based on this more studies is needed in this area to extract the prevalence of varicose vein, bad consequences and risk factors. Also focus on prevention and treatment methods is required.

Implementation of education programs for the population about this disease and its outcome so patients will be educated enough to go and seek treatment when they have the symptoms of varicose vein before reaching advanced stages.

Education programs are also needed for health workers in order to be able to diagnose the disease in its early stage for example at gynecologist clinic where most risk groups are found (pregnant female); in order to treat them in early stage or prevent the incidence of varicose vein by prescribing stocking to all pregnant women.
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