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A Study to Determine the Ameliorating Effects of *Vitis Vinifera D1* in the Treatment of Osteoarthritis of the Knee Joint

A Dissertation submitted in partial fulfilment with the requirements for the degree

Masters of Technology

In

Homoeopathy

In The

Faculty of Health Sciences

By

Shekufeh Khayltash

Supervisor: Dr S M power

At the

Technikon Witwatersrand

2000
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2000
DECLARATION

I, Shekufeh Khayltash, declare that this dissertation represents my own work. It is being submitted in partial fulfilment for the degree of Magister Technologiae: Homoeopathy at the Technikon Witwatersrand, Johannesburg. It has never been submitted to another institution for the purpose of obtaining any qualification.

Signed

Date

Shekufeh Khayltash

UNIVERSITY
OF
JOHANNESBURG
DEDICATION

I dedicate this work to my parents and my sister for all their love and support.
ABSTRACT

Osteoarthritis of the knee joint is a disease that is prevalent in the elderly, and causes a great deal of pain and stiffness. The purpose of this study was to determine whether *Vitis vinifera DI,* would have an effect on lowering the pain and stiffness associated with Osteoarthritis of the knee joint, and to compare these effects to a placebo.

Thirty volunteers were selected and were divided into two groups of fifteen each, the first group was given *Vitis vinifera DI,* and the second group was given a placebo. The relevant medication was taken over four weeks, with pain questionnaires and angles of the knee joint measured both before and after the medication was taken.

The data showed that pain levels in the experimental group decreased significantly, \( P=0.00415 \) (refer to Figures 3 and 5). Out of a group of fifteen, five of the volunteers had absolutely no pain at the end of the experiment, compared to the control group, \( P=0.339 \) (refer to Figures 4 and 6), where only one volunteer experienced a significant decrease in pain levels.

The angles of the knee joint when measured, did not show as significant a change as compared to the pain levels the volunteers experienced. In the experimental group \( P=0.206 \) (refer to Figure 7), only four out of fifteen volunteers had significantly increased range of motion of the knee, the angles doubled, but in the control group \( P=0.950 \) (refer to figure 8), only one volunteer had a significant increase in range of motion.
Therefore the conclusion that was reached was that *Vitis vinifera D1* has significant ameliorating effects in the treatment of pain and stiffness associated with Osteoarthritis of the knee joint. It is a cost effective treatment free from side effects, which works gently by draining accumulated toxins in the area affected, in this case, the knee joint.
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GLOSSARY

**Constitutional Remedy** – A specific Homoeopathic remedy chosen for an individual according to his personality, dietary preference and specific symptoms among other things.

*Crepitus* – a grating noise heard on the movement of a joint when there is pathology present, the noise is produced by bone rubbing against bone.

**D1** - a dilution in the first decimal potency, in which one part of the original substance, in this case, grapes, is mixed with nine parts of a solvent, in this case, water, glycerine and 20% alcohol.

**Inclinometer** - an instrument used to measure the angles of the range of motion in all the movable joints in the body.

**Mitosis** – The division of a single cell nucleus that produces two identical daughter cells nuclei; an essential step in cell division.

**Moxa** – a herb that burns at extremely high temperatures, brought close to the skin while burning to stimulate acupuncture points through heat.
Osteoblast - a cell that produces the fibres and matrix of bone.

Osteochondrophyte - also known as an Osteochondroma, a benign tumour consisting of projecting adult bone capped by cartilage.

Proprioception - awareness of the position of bones, joints and muscles.

Proteoglycans - a compound containing a large polysaccharide complex attached to a relatively small protein, for example, hyaluronic acid.

Vitis vinifera - a substance extracted from the leaves and fruit of the grape plant, preserved in alcohol and then diluted to the first decimal potency with the addition of glycerine and water to a D1 potency.
CHAPTER 1. INTRODUCTION

Osteoarthritis of the knee joint is a disease that is extensive in society today, especially amongst the elderly. It is a painful, crippling disease, which reduces the amount of movement in affected joints. It is a disabling condition, which has become one of the most important causes of work-related disability, as well as the main cause of suffering and physical disability in the elderly. It has been present throughout man's history, and affects many other species, including domestic dogs and racehorses. Osteoarthritis is likely to become an even more prominent health problem in the future, owing to two reasons: the first is the increasing average age of the population, the second is the increasing health care expectations with less tolerance of the pain and disability that may accompany aging (George, and Dieppe, 1994).

Osteoarthritis commonly develops in joints that were injured earlier in life, or joints that have been overworked, and mainly affects the weight-bearing joints such as the spine, knees and hips, especially in overweight people (Murtagh, 1995).

Pain is the earliest symptom, and stiffness follows inactivity. As the disease progresses, joint motion becomes diminished, and tenderness and crepitus appear. As the ligaments become lax, the joint has increased instability and deformity is a consequence of loss of cartilage.
*Vitis vinifera D1* is a plant remedy made from the young parts of the grape plant that are rich in plant hormones (Arominnovation, 1999). This plant has strong anti-inflammatory and anti-oxidant properties, and works gently by draining accumulated toxins from the affected area, in this case, the knee joint.

A study involving two groups of subjects was carried out in order to investigate the treatment of Osteoarthritis of the knee joint with *Vitis vinifera D1*. There is inadequate information at present on the various treatment benefits of plant or Gemmo remedies, and thus a scarcity of information on *Vitis Vinifera D1* in the treatment of Osteoarthritis.

It is hypothesised that *Vitis vinifera D1* will have an ameliorating effect on the treatment of the pain and stiffness associated with Osteoarthritis of the knee joint.
CHAPTER 2. LITERATURE REVIEW

2.1. PATHOLOGY OF OSTEOARTHRITIS

Early in this century pathologists and radiologists were able to differentiate between two broad groups of arthritis, the hypertrophic and atrophic forms. The hypertrophic group, which has not been subdivided, further, was characterized by hypertrophy of the marginal bone and soft tissues with accompanying cartilage destruction. This group is now synonymous with Osteoarthritis. Atrophic arthritis is characterized by synovial inflammation with erosion and destruction of cartilage and bone; this group includes rheumatoid arthritis and septic arthritis (George, and Dieppe, 1994).

Although any synovial joint in the body may be affected by Osteoarthritis, certain groups of joints are more usually affected. The knees and hands are the commonest joints involved, followed by the spine, hips, ankles and shoulders. The elbows and wrists are rarely affected. Most commonly between one and four separate joints may be involved (Monash, 1996).

Osteoarthritis can be defined as a disorder of the synovial joint, characterized by focal areas of destruction of the articular cartilage, accompanied by sclerosis of the underlying bone and marginal hypertrophy of both hard and soft tissue. The damage to the joint may be apparent on X-ray and the condition can cause use-related pain and functional problems with the joints (George, and Dieppe, 1994). A membrane called the synovial membrane, which forms a capsule around the heads of the bones involved, surrounds our joints (refer to Figure 1). This membrane secretes a liquid
called the synovial fluid. It has many functions, among these; it serves as a lubricant, a shock absorber and a nutrient carrier. This fluid is characterized by the rare quality of becoming thicker and more viscous when stress is applied to it. Thus, the synovial fluid in the joints assume a very viscous nature at the moment of stress to protect the joints, then it thins out again to normal viscosity instantaneously to resume its lubricating function (Kantata, 2000).

In Osteoarthritis the synovial fluid is more abundant and less viscous, the concentration of hyaluronic acid is decreased as is its chain length and therefore molecular weight. These changes severely decrease the physiological and protective functions of the synovial fluid, shock absorption, traumatic energy dissipation and storage, lubrication and protective coating of the articular cartilage surface and of the inner lining of the synovial membrane (refer to Figure 2), as well as control of the "traffic" between the synovial vessels and cartilage by an exclusion effect on migrating cells and large molecules (George, 1998).

Osteoarthritis is also referred to as "degenerative joint disease". The cause is generally believed to be from the wear and tear that joints are subjected to over time. Some chemical and genetic factors may also play a part in the development of the disease. Risk factors such as being overweight, poor posture, congenital joint or bone deformities and injury may hasten the development of Osteoarthritis in people under 60 years of age. (CRHA, 2000).
Pain is the earliest symptom, sharp pain may be felt when the affected joint is used, especially when it has been inactive for some time (Mayohealth, 2000). The pain is usually exacerbated by exercise, and stiffness follows inactivity. As the disease progresses, joint motion becomes diminished, and tenderness and crepitus appear. As ligaments become lax, the joint has increased instability and deformity is a consequence of loss of cartilage (Berkow, 1999).
Figure 1: A healthy joint

Figure 2: Joint with severe osteoarthritis
All Osteoarthritis joints tend to 'gel' on inactivity, and patients have difficulty initiating movement after rest periods. Features on examination include firm swellings of the joint margins and crepitus on movement. Mild signs of inflammation may be present, especially after excessive use, associated muscle weakness and wasting, loss of balance and changes in the proprioception of the joints. There may be a hard, bony swelling of the joints, and a gritty feeling when the joint is moved (Rhemb, 2000). The classical radiographic features used to define Osteoarthritis, and to assess its severity and progression include narrowing of joint space, osteophytosis, subchondral sclerosis, cyst formation and abnormalities of bony contour, but the radiograph can only detect severe changes (George, and Dieppe, 1994). There are also abnormally high bone mineral density readings in joints affected by Osteoarthritis (Karvonen, et al. 1998).

In Osteoarthritis, the cartilage that covers the ends of the bones becomes irritated and inflamed. The cartilage then becomes soft and wears unevenly. Eventually the cartilage becomes rough and pieces of it will break off and move around within the joint. If enough damage is done to the layer of cartilage, the bone underneath will be left unprotected and outgrowths of new bone (called osteophytes) will form. These new growths of bone often cause pain and reduced movement in the joint. Thickening of the ends of the bone may occur (CRHA, 2000).
Osteoarthritis is primarily a disorder of hyaline cartilage and subchondral bone, though all the tissues in and around the involved joints are hypertrophic. Osteoarthritis is the most common form of all articular disorders, and the onset is earlier in men (Berkow, 1987). Osteoarthritis is not a normal ageing phenomenon, although age is the strongest risk factor for its development (Bird, 1996).

Although the aetiology is unknown, Osteoarthritis appears to be the result of a complex system of interacting mechanical, biologic, biochemical and enzymatic feedback loops. When one or more of these feedback loops fail, the clinical events will follow. The most probable initial event in Osteoarthritis is mitosis of the chondrocyte with increased synthesis of the proteoglycans and Type 2 collagen, the principle structural elements of cartilage. Secondly there is the increased synthesis of bone by osteoblasts in the subchondral bone, presumably by intercellular communication between the chondrocytes and osteoblasts in the subchondral bone cells. With the increased bone formation, the bone becomes stiffer and micro-fractures occur. Thirdly there is metaplasia of the peripheral synovial cells resulting in the formation of osteochondrophytes around the periphery of the joint. Fourthly there is the formation of bony cysts in the marrow below the subchondral bone leading to the extrusion of joint fluid through the hyaline cartilage clefts into the marrow. The gross pathology is that of a roughening or loss of surface of the hyaline cartilage, proceeding to gross ulceration which is at first focal, then diffuse (Berkow, 1987).
The exact causes of Osteoarthritis are unclear, but these five factors increase the risk:

- Age 45 years and older
- Hereditary conditions, including defective cartilage and malformed joints
- Joint injuries caused by physical labour or sports
- Obesity
- Diseases that change the normal structure and function of cartilage

(Mayohealth, 2000).

Osteoarthritis is a disease process that affects all the tissues of a synovial joint. Cartilage (together with the synovial fluid) is the material in our joints that provides the cushioning and the lubrication necessary for healthy, pain-free functioning in the course of ordinary pursuits. It exists in a state of dynamic equilibrium. By its very nature, cartilage, as a slippery, load-bearing covering on the ends of the bones that form joints, is subject to a lot of wear and tear. That is, it is constantly being eroded away by the activities of everyday living (Kantata, 2000).

In Osteoarthritis the articular cartilage is centrally involved, and displays the most prominent changes. Articular cartilage is a remarkable tissue in that it has no nerves, is avascular, and has no lymphatics, few cells and limited capacity for repair (George, and Dieppe, 1994). Articular cartilage is a firm rubbery protein material covering the end of a bone. It acts as a cushion or shock absorber between the bones. When articular cartilage breaks down, this cushion is lost, and the bones will grind together.
This causes the development of symptoms such as pain, swelling, bone spur formation and decreased motion. (Hyalgan, 1999). Some of the earliest changes in the cartilage in Osteoarthritis include, an increase in water, loss of the total proteoglycan content, and a change in the size and structure of the joint. There is significant loss of volume of the cartilage and the surface becomes disrupted and irregular (George, and Dieppe, 1994).

2.2. TREATMENT OF OSTEOARTHRITIS

Conventional treatment for Osteoarthritis of the knee joint includes non-narcotic pain relievers, such as acetaminophen, narcotics for short term pain relief, such as codeine, non-steroidal anti-inflammatory drugs, such as aspirin and ibuprofen, injectable corticosteroids, and topical pain relievers (Healthtoz, 2000).

Surgical treatment may include removal of joint spurs, realigning the joint, and joint replacement (Matsen, F. 2000).

2.2.1. GEMMOTHERAPY

Gemmotherapy is a modern form of drainage using the first decimal dilution of glycerine plant macerates prepared from embryonic plant tissues. This application of drainage known as Gemmotherapy is extremely valuable in that it opens up the possibility of true tissue potentialisation therapy, thereby increasing the drainage possibilities of Homeopathic medication (Natura, 1998).
Gemmotherapeutic remedies are medications produced from plant tissues in the process of active growth and division. The preparations are macerations of embryonic plant tissues derived from buds, shoots, roots and/or bark cortex. They are rich in vitamins, trace elements and specific glucosidal, alkaloidal and hormonal components present in the plant at the pinnacle of its embryonic growth (Natura, 1998).

Gemmotherapeutic remedies have no organic tropism or physiological affinities. They act primarily on excretory systems by stimulating the liberation of toxins from the tissues by a mechanism commonly known as drainage. The term ‘drainage’ reflects the dynamic liberation of toxins by stimulating the centrifugal movement of waste towards the organs, which eliminate them from the body. Gemmotherapeutic remedies are rich in bio-stimulating elements and act on all functioning systems of elimination, not only organs such as the liver, kidneys, intestines, lungs and skin, but also on functional tissue such as blood and lymph. This then applies the fundamental principle of cure by treatment from deep within outwards towards the surface (Natura, 1998).

For Homoeopathic practitioners, Gemmotherapy intervenes as a very specific elimination therapy: highly active and lacking toxicity, offering a perfectly balanced drainage pattern (Natura, 1998).
*Vitis vinifera D1* is a gemmo remedy, which regulates bone metabolism and inhibits proliferative deformities such as osteophytes (Natura, 1998).

### 2.2.2. VITIS VINIFERA

*Vitis vinifera D1* is made from the embryonic tissue of the grape plant. Some of the properties of *Vitis Vinifera D1* are that it is an antioxidant, it gives cardioprotection, thus reducing the risk of atherosclerosis, reduces the risk of cancer and improves vascular strength. Research on Vitis Vinifera D1 has shown that it to be a powerful antioxidant, or free radical scavenger - even more potent than the more commonly used antioxidant vitamins (Enrich, 1998).

Below are listed some of the properties of the grape plant:

The leaves contain a mixture of cane sugar, glucose, tartaric acid, potassium bitartarate, flavonoids, such as quercetine and tannins. The ripe fruit contains sugar, gum, malic acid, potassium bitartarate and inorganic salts. The grape sugar enters the circulation without enzymatic action. The warming and fattening action of the grape sugar acts rapidly in increasing the strength of the body, repairing the damage done by feverish conditions and the seeds and leaves are astringents used to stop bleeding (Grieve, 1980). It can be used extensively in treating anemias, diseases of the respiratory organs and kidneys (Lust, 1962), weight loss, infectious diseases of the liver and gallbladder (Vogel, 1986), systemic infections (Brandt, 1948).
The flavonoids are a large group of naturally occurring phenylchromones found in fruits, vegetables, grains, bark, roots, stems, flowers, tea and wine. A variety of experiments have shown that selected flavonoids possess anti-allergic, anti-inflammatory, anti-cancer, anti-viral and anti-oxidant activities. The remarkable properties exhibited by these compounds make it possible that they should be considered natural dietary biologic response modifiers, i.e., disease preventing, health promoting substances (Manthey, and Buslig, 1998).

The antioxidant activity of certain flavonoids has been recognized for some time. Some of the flavonoids are as potent as, or more potent than, familiar antioxidants such as Vitamin E and Beta Carotene. Certain flavonoids, depending on their structure can inhibit the stimulated release of pro-inflammatory mast cell, basophil, and eosinophil granular constituents that participate in the pathogenesis of diseases, one of the most important ones being quercetine, which has the capacity to inhibit neutrophil activation. Quercetine exhibits both anti-infective and anti-replicative activity against viruses, and causes an abrupt cessation of histamine during an inflammatory process (Manthey, and Buslig, 1998).
2.2.2.1. ACTION OF VITAMINS AS ANTI-OXIDANTS

_Vitis vinifera D1_ contains a number of vitamins and nutritive salts, such as Vitamins A and E, which enable the body to bind cell poisons, and are then eliminated, without putting any strain on the liver. It aids regeneration and healing, and exerts a balancing influence on the pH of blood (Lust, 1962).

_Vitis Vinifera D1_ is a good source of Vitamin C, which forms collagen in connective tissue (Griffith, 1988), corrects abnormal capillary fragility and permeability and helps to cure Rheumatic diseases (Rodale, 1976). Vitamin C can also be used to offset the toxic effects resulting from the over consumption of animal foods, which when broken down increases the acidity levels in the body, and could be a cause of Osteoarthritis (Kushi, 1984).

Currently there is much attention directed toward the use of antioxidant vitamins, namely Vitamins A, C and E, as a means of preventing or ameliorating the pain and disability of Osteoarthritis. The attention is driven, in part, by our expanding appreciation of nutritional factors, particularly the vitamins, that contribute to oxidate processes and bone turnover that may be intrinsic to the development and progression of Osteoarthritis (Sowers, and Lachance, 1999).

Vitamins A, C and E are the major antioxidants identified as having a potential for antioxidant activity in the processes associated with Osteoarthritis. There are at least four possible pathways in which these nutrients can influence Osteoarthritis,
protection against oxidative damage, modulation of the inflammatory response, cellular differentiation and biologic actions related to bone and collagen synthesis (Sowers, and Lachance, 1999).

Oxygen radicals have been identified as potent agents in the destruction of cartilage and connective tissue, and are known to cause depolymerization of hyaluronic acid and degradation of proteoglycans and Type 2 cartilage. The production of free radicals also can be the consequence of tissue damage associated with Osteoarthritis (Sowers, and Lachance, 1999).

When Researchers have looked at joint fluid from an inflamed joint, they have noted a significant increase in the number of free radicals. When you look at fluid from a normal joint, there are no free radicals present. There have been studies that have shown a significant increased risk of developing arthritis in those individuals who have low levels of Vitamin E, beta-carotene, and selenium. Other studies have shown low levels of Vitamin D and Vitamin C (Strand, R., 1999).

There are many separate factors, which may be causing the increased oxidative stress within the inflamed joints. These joints have a significant inflammatory response within the joint space. Neutrophils are a predominant cell in this inflammatory response. It has been shown to release a significant amount of free radicals within the joint space. This causes a significant rise in oxidative stress. When we exercise an inflamed joint, there is a lack of oxygen to parts of the joint space. Once we stop
exercising, these tissues again begin receiving oxygen. During this reperfusion phase, studies have shown a significant rise in free radical production. Certain cells from the cartilage called chondrocytes in an inflamed joint have been found to actively generate free radicals. These different sources of increased free radical production within the inflamed joint cause significant oxidative stress. This overloads the antioxidant defence system of the joint space. The synovial fluid (joint fluid), which is usually very thick, becomes thin in this situation. All the components of the cartilage are damaged in this environment. Therefore, the process of joint destruction takes place (Strand, R., 1999).

One study concluded that a high intake of antioxidant micronutrients, especially vitamin C, reduced the risk of cartilage loss and disease progression in people with Osteoarthritis (Strand, R., 1999).

Vitamin A is recognized as a fundamental element of cellular maturation and differentiation. It has an essential role in bone development and maintenance of epithelial tissue. Carotenoids, one of the forms of Vitamin A, are known to scavenge and deactivate free radicals, by trapping them. Vitamin A is necessary for the growth and development of skeletal and soft tissues (Sowers, and Lachance, 1999).
Vitamin C causes less pitting and ulceration in the affected cartilage, and contributes to the increased formation and stability of proteoglycans that successfully counteract the erosion of cartilage during development of Osteoarthritis (Sowers, and Lachance, 1999).

Vitamin C is both an antioxidant in itself and it serves as a co-antioxidant by interacting with Vitamin E (Walter, et al. 1988).

Vitamin C has long been implicated in the synthesis of collagen where it is believed to be involved in the hydroxylation of proline and lysine residues after their incorporation into procollagen polypeptide chains. In Vitamin C deficiency the amount of effective collagen present in connective tissue is reduced due to a reduced rate of hydroxylation. Vitamin C is also important in the formation of collagen fibres outside the cell, the synthesis of the components of the ground substance of connective tissue, synthesis of the mucopolysaccharides and the maturation of fibroblasts, the cells responsible for collagen and mucopolysaccharide production. As Vitamin C is implicated in collagen synthesis, low cellular levels of the vitamin may be connected with microvascular connective tissue changes seen in joints affected by Osteoarthritis (Basu, and Schorah, 1982).

It is well recognized that tissue healing requires synthesis and accumulation of collagen and subsequent cross-linking of the fibres to give new tensile strength to the damaged tissue. Of significance in this context is the fact that Vitamin C has a critical
role in tissue repair and especially in participating as a co-factor in the hydroxylation of specific peptidylproline and peptidyl-lysine residues during collagen biosynthesis. At the site of tissue damage there is rapid utilization of Vitamin C for the synthesis of collagen (Basu, and Schorah, 1982).

Vitamin E helps to control peroxidation of membrane lipids by free radicals. The reactivity of Vitamin E with free radicals is considered as its major biochemical function, and functions as an antioxidant that protects unsaturated tissue lipids from free radical attack, and degradation by free radical chain reactions (Jackson, et al. 1983).

Vitamin E has been described as the only lipid-soluble, chain-breaking antioxidant in human blood plasma and erythrocyte membranes (Walter, et al. 1988).

The mineral salts found in grapes restore the function of the liver and joints, cleanse the body, and stimulate the bowels and kidneys to eliminate wastes and toxins (Ledermann, 1989).
2.2.2.2. ANALGESIC AND ANTI-INFLAMMATORY PROPERTIES OF VITAMINS

Highly active analgesic drugs such as aspirin, paracetamol, papaverine metabolites, opiates, as well as very active anti-inflammatory molecules are currently available on the market. These drugs, however, have a purely symptomatic effect and thus risk masking or even aggravating the causal mechanisms. Moreover, they are so potent that they may entail severe side effects or even addiction, especially after prolonged use. Conversely, several vitamins have been found to be the inhibitors of the biosynthesis of prostaglandins, which are responsible for inflammation, and therefore reduce pain levels (Walter, et al. 1988).

The main substances involved in this inhibitory process are Vitamin C, which in large doses is beneficial in alleviating pain in bone disorders, flavonoids, Vitamin E and carotenoids, a precursor to Vitamin A (Walter, et al. 1988).

2.2.3. THE HOMOEOPATHIC APPROACH TO THE TREATMENT OF OSTEOARTHRITIS

Homoeopathy deals with the individual and his sufferings rather than with a collection of symptoms grouped under a diagnostic title. The treatment of a patient is based on finding a simillimum, a Homoeopathic remedy which best matches the unique symptoms of the individual. Homoeopathic remedies can be helpful during painful flare-ups, or a constitutional remedy, chosen by an experienced practitioner to closely fit the individual, may help on deeper levels (Healthatoz, 2000).
Plant or gemmo remedies are also given to complement the action of the similimum. Gemmo remedies act by draining the affected areas of toxins that may have accumulated during the disease period on a cellular level (Mothernature, 2000).

Disease is defined as a morbid dynamical disturbance of the vital force caused by some morbific agent actually or relatively external to the organism. From this point of view all diseases may be regarded as intoxications, and all bacterial disease is primarily intoxication or toxaemia. Pathologists agree that all pathogenic microorganisms produce their effects in the living body by means of the specific poisons, which they secrete while living, or generate after death. If all diseases are the result of some form or degree of poisoning, then in the last analysis all curative treatment is antidotal treatment (Gaier, H.C., 1991).

2.2.4. ALTERNATIVE FORMS OF TREATMENT FOR OSTEOARTHRITIS

Relaxation techniques from yoga to psychotherapy will allow the patient to reduce stress and muscle tension, thus relieving pain. Lifestyle changes, such as a better diet, more exercise and increased socialization should be part of any pain management programme (Healthtoz, 2000).
One strategy for obtaining short-term pain relief is to apply heat or cold to the aching joint. The decision to use either heat or cold for arthritis depends on which factors are causing the pain and the response to this method. Applying heat relaxes the muscles and helps alleviate aches due in part to muscle tension. It also stimulates blood circulation, which helps irritated tissues heal. In contrast cold applications numb the area, reducing the pain (Health toz, 2000).

Pain, stiffness and fatigue are symptoms of Osteoarthritis, which often cause the sufferers to avoid exercise, but inactivity can actually increase arthritis problems. There are three major types of exercise; aerobic fitness, muscle strengthening and stretching, and each play an important role in improving general health and reducing the disabling symptoms associated with arthritis. Daily flexibility exercises help to maintain and even improve range of motion and reduce type of stretching should be done slowly, gently and at a very low intensity. Improving flexibility not only reduces the pain associated with arthritis, but it also improves the individual’s ability to perform daily activities. Muscle conditioning increases the strength of the muscle around a joint and, as a result helps to decrease the pain associated with that joint, and protect it from injury. Aerobic exercise improves heart, lung and muscle function (Agenet, 1999).
2.3. CHRONIC PAIN

Pain specialists consider chronic pain to be the most costly health problem today. In terms of medical expenses, lost income, and lost productivity the total cost is exorbitant. The impact on the patient is even more overwhelming. It can keep him from being active, from enjoying family and friends, from sleeping and from eating. It can make him depressed, anxious and irritable. Getting help early on can make the pain more manageable. More important, chronic pain has a life of its own and is truly a disease in its own right (Healthatoz, 2000).

Because pain is a private, unique experience, it is subjective. There are no blood tests or objective means to measure pain. Doctors rely on the patient's description of pain to help determine treatment. They may ask you to locate your pain on a picture of a body and select words, like burning, aching, throbbing or stabbing that best describe it. Or they may have you rate your pain on a numerical scale from 1 to 10, a verbal scale from no pain to the worst possible pain or even a visual scale using smiling and frowning faces (Healthatoz, 2000).

2.3.1. MCGILL PAIN QUESTIONNAIRE

Since its introduction in 1975, the Pain Questionnaire has been used in over 100 studies of acute, chronic and laboratory produced pains. Because pain is a private, personal experience, it is impossible for us to know precisely what someone else's pain feels like. No man can possibly know what it is like to have menstrual cramps or
labour pain. Nor can a psychologically healthy person know what a psychotic patient is feeling when he says he has excruciating pain. But the Pain Questionnaire provides us with an insight into the qualities that are experienced. Recent studies indicate that each kind of pain is characterized by a distinctive constellation of words. There is a remarkable consistency in the choice of words by patients suffering the same or similar pain syndromes. (Wall and Melzack, 1994)
CHAPTER 3. MATERIALS AND METHODS

3.1. SUBJECT SELECTION

Advertising in local newspapers distributed by Caxton Publishers and Health shops, were used in the recruitment of thirty subjects pre-diagnosed with Osteoarthritis of the knee joint. The volunteers were required to bring X-rays and reports stating that they were diagnosed with Osteoarthritis of the knee joint. All subjects were informed about the purpose of the study as well as what was expected of them, before being included in the study. Subjects gave their written consent in order to participate.

3.2. PROCEDURE OF RESEARCH PROJECT

Once the subject selection took place, all subjects were notified by telephone, as well as in writing. All procedures were explained, and patients were required to sign the consent form and complete a personal questionnaire. All information was treated confidentially. The questionnaire gathered demographic data such as diet, hobbies, and levels of exercise.

3.2.1. MCGILL PAIN QUESTIONNAIRE

The levels of pain experienced by the volunteers were measured both before and after the medication was taken, using the McGill Pain Questionnaire. This questionnaire was divided into two sections, namely the present pain intensity (PPI) and the pain-rating index (PRI).
The PPI was recorded as a number from 1-5, in which each number was associated with the following words:

1 mild;
2 discomforting;
3 distressing;
4 horrible;
5 excruciating.

The mean scale values of these words, which were chosen from the evaluative category, were approximately equally far apart so that they represented equal scale intervals and thereby provided 'anchors' for the specification of the overall pain intensity. The PRI was based on the rank values of the words. In this scoring system, the word in each subclass implying the least pain was given a value of 1, the next word was given a value of 2, etc. The rank values of the words chosen by a patient were summed up to obtain a score (Wall and Melzack, 1994).

The most important requirement of a measure is that it be valid, reliable, consistent and above all, useful. The McGill Pain Questionnaire appeared to meet all of these requirements and provided a relatively rapid way of measuring subjective pain experience. When administered to a patient by reading each sub-class, it could be completed in about 5 minutes. The patient could also fill it out in a more leisurely way as a paper and pencil test, though the scores would be somewhat different (Wall, and Melzack, 1994).
3.2.2. MEASUREMENT OF THE ANGLE OF THE KNEE USING AN INCLINOMETER

Musculoskeletal tests were conducted on each subject by the Researcher, under the supervision of a qualified Supervisor, measuring the angles of range of motion using an Inclinometer.

The instructions on how to use an Inclinometer are as follows:

1. To turn the inclinometer on or off, press and release the "On/Off" button.
2. The inclinometer face must be held in the vertical plane to operate properly.
3. When the inclinometer is turned on, the read-out displays zero when the Long Base is in the horizontal position. In most of the applications, the inclinometer's Short Base will be placed against the body, or inserted into the attachments. You may select any position to be used as the zero position. To zero the inclinometer to a new zero position, press and release the "Alt Zero" wording next to the display. This indicates that the angle displayed is relative to the position to which you have zeroed the inclinometer.
4. All numbers shown in the digital display are in degrees. The reading display is always relative to the zero position.
5. To hold the reading shown in the digital display, press the "Hold" button. To release the reading shown, press the "Hold" button again. The reading will change to show the inclinometer's actual position (Saunders, 1998).
3.2.3. MEDICATION ADMINISTERED

The subjects were divided into two groups, and both groups had fifteen subjects.

**Group 1:** took *Vitis Vinifera D1* for a period of four weeks.

**Group 2:** took placebos containing equal quantities of glycerine, water and 20% alcohol for a period of four weeks.

The study occurred on a double blind basis, and an external, independent person monitored what medication was given to each subject.

After the medication was taken, a subsequent musculoskeletal examination was conducted, again measuring the angles of the range of motion of the knee, using an Inclinometer.

At the beginning of the four-week period, each subject was issued with his medication, after the questionnaires had been completed. The dosage of the medication was twenty-five drops three times a day. The duration of the study was four weeks. Subjects were telephonically reminded at the appropriate times.

At the end of the study, after all the data was collected, the numerical values of the McGill Pain Questionnaire were entered in Microsoft Excel in a tabular form. The values were then entered into the Mann-Whitney Rank Sum Test to assess the statistical viability of the values. The statistical programs used were Jandel Scientific SigmaStat and SigmaPlot, version 2.02.
Graphs were created using the numerical values of the McGill Pain Questionnaire on Microsoft Excel, and were pasted into Microsoft Word 97, which was used to type the dissertation.
CHAPTER 4. RESULTS

The results of the effect of *Vitis vinifera D1* on the treatment of pain and stiffness associated with Osteoarthritis of the knee joint are as follows.

- **PRI** – Pain rating index, based on rank values of words used to describe the intensity of the pain experienced at present. The word implying the least pain in each subclass is given a value of 1, the next word implying pain of a slightly increased intensity is given a value of 2, etc.

- **PPI** – Present pain intensity, recorded as a number from 1-5, in which each number is associated with the following words:
  - 1 - mild
  - 2 - discomforting
  - 3 - distressing
  - 4 - horrible
  - 5 - excruciating

- **ANGLE** – the angle measuring the range of motion of the knee joint, measured both before and after the medication was taken.
<table>
<thead>
<tr>
<th></th>
<th>P VALUES</th>
<th>AVERAGE</th>
</tr>
</thead>
<tbody>
<tr>
<td>PRI EXP. GROUP</td>
<td>P=0.00511</td>
<td>BEFORE – 19  AFTER – 11</td>
</tr>
<tr>
<td>PRI CONTROL GROUP</td>
<td>P=0.206</td>
<td>BEFORE – 25  AFTER – 16</td>
</tr>
<tr>
<td>PPI EXP. GROUP</td>
<td>P=0.00415</td>
<td>BEFORE – 3  AFTER – 2</td>
</tr>
<tr>
<td>PPI CONTROL GROUP</td>
<td>P=0.339</td>
<td>BEFORE – 2  AFTER – 2</td>
</tr>
<tr>
<td>ANGLE EXP. GROUP</td>
<td>P=0.206</td>
<td>BEFORE – 56  AFTER – 74</td>
</tr>
<tr>
<td>ANGLE CONTROL GROUP</td>
<td>P=0.950</td>
<td>BEFORE – 81  AFTER – 71</td>
</tr>
</tbody>
</table>

**Table 1 – The P values and the average values of results**

The P values for the McGill PRI and PPI groups are statistically significant, but the P values for the angle of the knee joint are not statistically significant, therefore the majority of the amelioration was in the reduction of the pain levels, and not in the increase of range of motion of the knee.
4.1. MCGILL (PRI) EXPERIMENTAL GROUP

This graph depicts the group of volunteers that was given *Vitis vinifera D1*, and shows the results of the questionnaire that measured pain intensity, before and after the medication was taken.

![McGill PRI Experimental Group](image)

**Figure 3. McGill PRI Score in Experimental group**

The above graph shows that the pain levels in the experimental group after the medication was taken was decreased in this group of volunteers, therefore signifying that *Vitis vinifera D1* has a significant effect on lowering pain levels associated with Osteoarthritis of the knee joint. (P=0.00511)
4.2 MCGILL (PRI) CONTROL GROUP

This graph depicts the group of volunteers that were given the placebo, containing 20% alcohol, glycerine and water. The questionnaire measured pain levels by using words of increasing intensity as chosen by the volunteers.

**Figure 4. McGill PRI Score in Control Group**

The above graph does not show a significant change in the pain levels of the volunteers that were given the placebo. \( P=0.206 \)
4.3 MCGILL (PPI) EXPERIMENTAL GROUP

This graph depicts the group of volunteers that were given *Vitis vinifera D1*, and completed the section of the McGill Pain Questionnaire marked, Present Pain Intensity, and choosing one out of five words to describe the level of pain each volunteer was experiencing.

![McGill (PPI) Experimental Group Graph](image)

**Figure 5. McGill PPI Score in Experimental Group**

The above graph shows that the PPI readings after the medication was taken are significantly lower than the readings before the medication was taken, therefore showing that *Vitis vinifera D1* is effective in reducing the pain associated with Osteoarthritis of the knee joint. (*P=0.00415*)
4.4 MCGILL (PPI) CONTROL GROUP

The following graph depicts the group of volunteers that was given the placebo, and who completed the Present Pain Intensity section of the McGill Pain Questionnaire.

Figure 6. McGill PPI Score in Control Group

The above graph does not show a significant change in the pain levels experienced after the placebo was taken. (P=0.339)
4.5 ANGLE OF THE KNEE JOINT IN THE EXPERIMENTAL GROUP

The following graph depicts the angles of the knee joints of the volunteers in the group that was given *Vitis vinifera D1*.

![Angle of Knee Joint - Experimental Group](image)

**Figure 7. Angle of Knee Joint in Experimental Group**

The above graph shows an increase in the angle of the range of motion of the knee joint, after the medication was taken, thereby showing that *Vitis vinifera D1* has an effect on enabling the volunteer to have a greater range of motion of the knee joint, but not enough of an effect to make it statistically viable. *(P=0.206)*
4.6 ANGLE OF THE KNEE JOINT IN THE CONTROL GROUP

The graph below depicts the angles of the knee joint of the group that was given the placebo.

![Angle of Knee Joint - Control Group](image)

**Figure 8. Angle of Knee Joint in Control Group**

The above graph does not show a significant change in the range of motion of the knee joint, after the placebo was taken. ($P=0.950$)
CHAPTER 5: DISCUSSION

This Research Project was undertaken to determine whether *Vitis Vinifera D1* has an effect on reducing the pain and stiffness associated with Osteoarthritis of the knee joint, in a Research group consisting of men aged between forty and seventy years.

The results showed that there was a beneficial effect in the volunteers that were administered *Vitis Vinifera D1*, as compared to the volunteers in the control group. *Vitis Vinifera D1* did indeed reduce the levels of pain that the volunteers were suffering from, and to an extent, increased the range of motion of the affected knee joint.

The exact action of *Vitis Vinifera D1* on the affected knee joint cannot be discussed at this point, as intensive research will have to be done on this topic, using X-rays, blood tests, and internal investigations. These investigations are very costly and have not been included in this Research project.

This Research topic had a relatively uncomplicated model. One volunteer, who had been suffering from joint pains, especially knee pain for a period of forty years, was placed in the control group and administered the placebo. Initially there was very little improvement, but towards the end of the trial period, he dramatically improved and claimed to be free from all joint pain. This incident points to the fact that there is a psychological factor that plays a large role in disease and the subjective reporting
that he was given the actual medication. A marked example of the placebo effect.

Another factor that could be attributable to this case is that when medical care is given in this country, owing to the large numbers of patients that a general hospital would tend to in a day, there is little time for individual attention. In Research projects, a lot more time and attention is spent on the patient. The Researcher helps the patient complete the relevant questionnaires, the symptoms of the disease are noted, taking the patient’s perspective of his symptoms very seriously, and follow-up phone calls are made weekly to see how the patient is faring. The attention and care that a patient receives during a Research project could be attributable to amelioration of symptoms, even though the patient has been given the placebo.

In the light of these observations, the positive outcomes in terms of the subjective data should be viewed with a certain degree of scepticism, however they should not be rejected entirely. This is because it is seen that the volunteers in the experimental group all improved, although some more dramatically than others, and most of the volunteers in the control group had no change in the intensity of pain or range of motion.

One of the problems experienced during this Research Project was that there was no way of determining if the volunteers were complying with instructions pertaining to their diet, to the dosage of the medication and whether they took the medication or
not. This will bring in the aspect of trust between the volunteer and the Researcher. The volunteer and the Researcher both sign the consent form, the volunteer giving consent to participate in the Research, and to comply with the regulations, the Researcher to place the volunteer in a group at random and to maintain the anonymity of the volunteer, as well as to conduct the Research in a professional manner. I think that this matter should be left to trust and respect, which will ultimately promote the relationship between the volunteer and the Researcher.

A way to make this Research more complete would have been to have a follow-up appointment three months after the medication was finished, in order to see the longer term ameliorating effects of *Vitis vinifera DI* on the pain and stiffness associated with Osteoarthritis of the knee joint. The Pain questionnaire would again be completed for the third time and the angle of the knee joint would be measured to again determine the range of motion. It would be interesting to note whether the amelioration lasted in those who were given *Vitis vinifera DI*, or whether it diminished, and whether the amelioration came about more forcefully a few months later, after the medication would have had time to act on the pathology in the knee. It would have also been interesting to note how long the complete amelioration lasted in the volunteer who was on the placebo and experienced a total amelioration of his symptoms.

In advertising for volunteers, it was extremely ineffective to place advertisements in the Health and Beauty section of local newspapers, the only effective method was placing an article in the Editorial column, explaining the nature of the Research
Project, the background of the medication being researched, where the Research is taking place, and the requirements of the volunteers. Many people phoned, but it seemed the fact that it was a Homoeopathic Research Project discouraged the callers, who seemed to know nothing about the science of Homoeopathy. If the general awareness of Homoeopathy was increased, people might be more willing to take part in such Research Projects.

The volunteers that participated in the Research Project all seemed to come from an affluent social group, this might have been because that social group could have been more exposed and would know more about Homoeopathy than other social groups.

In their youth, most of the volunteers had participated in a vigorous sports program, the most common being tennis, and most of them had sustained injuries to the knee, which could have pre-disposed them to getting Osteoarthritis in their later years.

Osteoarthritis is a very broad topic and so is Gemmotherapy, and a great many research projects could stem from either topic, which would greatly benefit the science of Homoeopathy. In such way, more light could be shed on treating using Gemmotherapeutics, and new methods of treatment could be found for Osteoarthritis sufferers.
CHAPTER 6: CONCLUSION AND RECOMMENDATIONS

According to the results of this study, it has shown that *Vitis vinifera D1* is effective in the amelioration of the pain and stiffness associated with Osteoarthritis of the knee joint, although it has shown that this remedy is more effective in reducing pain levels, (refer to Figure 3 and Figure 5) as compared to its action in increasing the range of motion of the knee joint (refer to Figure 7).

Other Research topics stemming from this source could be doing the same experiment using *Vitis vinifera D1* in treating Osteoarthritis of other joints, such as the hip and shoulder, using *Vitis vinifera D1* in treating other ailments such as Rheumatoid arthritis, Gout or Osteoporosis.

There could be a lot of changes made in the sample group, for example performing the study on a group of women, on a specific racial or social group, or increasing the size of the group, changing the quantities of *Vitis vinifera D1* administered, and also the duration during which *Vitis vinifera D1* is administered, using X-rays to see the effect that *Vitis vinifera D1* has on the pathology of the joint and using blood tests to measure the levels of oxidative agents in the blood.

It was decided to perform the study on a group of men, because there is a much lower risk of there being other diseases such as Osteoporosis complicating the picture, which is known to be common in women in the age group chosen for the study. The
testing process for Osteoporosis, i.e. the bone scans would have been far too expensive to perform on all the volunteers, but if the study was to be performed on a group of women, methods of eliminating such risks would have to be found. The risk could be greatly reduced by performing the study on pre-menopausal women, or the study could be performed to determine the ameliorating action of *Vitis vinifera D1* on Osteoporosis, instead of Osteoarthritis.

In the study performed, all racial and social groups were invited to volunteer to partake in the Research. There did not seem to be a difference in the results of volunteers from different social or racial groups, but I think the Research would be a lot more conclusive if a particular racial or social group was chosen. Advertising would have to be done in a way to prevent a certain racial or social group from becoming offended, for example, if the Research was to be done on a population of people that earn under R1000 a month, instead of placing advertisements in the paper and putting up posters, shelters could be contacted, or Institutions such as the Red Cross, and the anonymity of the volunteers should be upheld at all times.

There are a lot of differences in social and racial groups that would have an effect on pain and stiffness experienced with Osteoarthritis. The diet would play a big part, especially levels of alcohol consumed, intake of fizzy drinks such as Coke, eating acidic or spicy foods and amount of meat consumed. A Research group could be chosen that would include only volunteers in different dietary groups, for example,
vegetarians, vegans, people who eat more seafood and white meat, and people who eat red meat.

The occupation would also make a big difference in the symptom picture, for example, an office executive that sits behind a desk all day long, would have a great deal more pain and stiffness than a milkman, who is always walking and exercising the affected joints. Levels of exercise also have an effect on the symptom picture, people who play high contact sports such as Soccer or Rugby injure their joints frequently, and repeatedly, and many of them have surgery to remove either all or pieces of cartilage, which greatly increases the risk of Osteoarthritis forming in their joints.

Access to medication and supplementation is also an important factor. If patients can afford to take anti-inflammatories, painkillers, and supplements such as chondroitin sulphate, or herbal preparations that reduce inflammation and ease pain and stiffness, the case presented may not be a serious one, and the effects of the remedy being tested may not be accurate.

Increasing the sample size of the research group will also serve to get more definite results, especially if the results of different groups of people could be compared, as mentioned above, for example, people in a specific racial, social, dietary and gender group.
Increasing the amount of medication ingested may have an effect on the speed of the amelioration, and also on how long the amelioration will last. Increasing the time during which *Vitis vinifera D1* is administered could also have an effect on the long-term amelioration of the pain and stiffness associated with Osteoarthritis of the knee joint.

X-rays could be used to visually monitor the effect that *Vitis vinifera D1* has on the affected joint, whether the inflammation has died down, whether osteophytes are decreasing in size or structure, and the general health of the joint can be monitored. Although this is a costly procedure, a lot of information can be gained on the action of *Vitis vinifera D1* in the treatment of Osteoarthritis.

Blood tests could be used to measure the levels of oxidative agents in the blood, and the values can be compared by performing the test before, during and after the medication is taken. The main action of *Vitis vinifera D1*, according to the literature researched, is through its anti-oxidant qualities, and this can be verified through blood tests.

This was a very simple and rewarding Research project, and it is hoped more Research will be conducted in this field and in turn more people may benefit from the results obtained.
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