REVIEW OF LITERATURE
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It is impossible and inexpedient to enumerate and evaluate hundreds of surgical and non-surgical interventions which have been proposed for treating haemorrhoids during a period of more than a thousand years. Frequent post-operative recurrences of the disease, dissatisfaction of both doctors and patients with the results of conservative (non-operative) treatment, and serious complications often developing after surgery, are the factors motivating surgeons to discover the new explanations of the developmental mechanisms of haemorrhoids and new methods of their treatment and management.

Anal canal is one of those few sites in the body, where interest was focused upon by our ancestors quite early because of the accessibility of the area for observations and examination, the sufferings of the afflicted and the readiness with which the area could be observed.

Perhaps, in no other ano-rectal pathology is outpatient treatment of such importance as it is in haemorrhoid. More than two thirds of these numerous patients can begin a complete course of treatment as out-patients. Taking into account that initial stages of many colo-rectal and anal diseases, including tumours, are similar in their clinical manifestations to haemorrhoids. Diagnosing the disease, as well as patients treatment and follow-up at surgery clinics,
is an important link in medical care of population in the country. Also the fact that in the recent years the incidence of the tumours of the large intestine (colonic and rectal) has increased all over the global map, both in absolute and comparative numbers (in comparison with all alimentary tract tumours), and that in most cases rectal cancer arises following malignant transformation of polyps (adenomas), which are similar to haemorrhoids in their clinical signs, assigns significant role to the general clinic surgeon in the early diagnosis and treatment of this disease. The approach to patients with clinically similar ailments including haemorrhoids plays a significant role in the early detection of benign tumours of the large intestine, adequate treatment of patients with those tumours, and determination of optimal follow-up periods which are presently being developed (FEDOROV 1981-83).

Vascular haemorrhoids in which there is extensive dilatation of the terminal superior haemorrhoidal venous plexus. This variety is commonest in younger patients especially males. Secondly mucosal haemorrhoids which occurs more in older persons consists of sliding downward of thickened mucous membrane, which conceals the under lying veins. (GRAHM-STEWARD 1963). Varicosities of the internal haemorrhoidal plexus have been regarded, by most ancient times with few exceptions, as a new theory given by LORD (1968)↑
His theory revolves around his findings of constricting pecten bands in the patients of haemorrhoids.

KARPINSKY (1870) described haemorrhoids as "Vascular blood tumours of the rectum in the form of arterial or venous dilatation or in the form of erectile tissues," and concluding the possibility of arterial haemorrhage in haemorrhoids. In late seventies STELZNEK also described what he called 'Corpus cavernosum recti' in the anal submucosa. Haemorrhoids occur through vascular hyperplasia in the anal canal submucosa, possibly through dysfunction of shunts (THOMSON 1975).

Further more haemorrhoids simply are expression of disruption, to a greater or lesser extent, of anal cushions internal architecture and attachments (THOMSON 1979).

To explain the formation of haemorrhoids a great variety of factors have been implicated. A hereditary predisposition seems to play a role in some individuals. Man's erect posture, the absence of valves in portal venous system, the arrangement of collecting veins in the rectal submucosal space, the veins being liable to compression through the ano-rectal musculature and other biologic and anatomic condition are said to be contributory elements.

More direct causes are all various events that produce transient or constant increased pressure or stasis within the rectal venous plexuses, such as straining at stools.
because of constipation or diarrhoea, tumours or retroversion of uterus, hypertrophy and tumours of prostate, portal hypertension, obesity, use of suppositories or pessaries.

Many predisposing factors have been mentioned, which are thought to be responsible for pathogenesis of haemorrhoids. They include temperature, climate, age, sex, pregnancy, puerperal state and weight lifting.

The exact incidence of the haemorrhoids in general population is not exactly known, but it is higher than what it is realised or estimated generally. BUIE (1960) reported an incidence of 52 percent while GOLIGHER (1976) reported at least 50 percent of people over the age of 50 years. According to HAWLEY (1973), 40 percent of population have symptoms due to haemorrhoids to some extent, to some time or the other in their lives.

For practical purposes the numerous traditional operative methods for haemorrhoids can be divided into three categories according to the principles and character.

1. Various modification for ligating the internal haemorrhoids with separate excision of external skin tags.

ii. Excision of the haemorrhoids with complete closure of the wounds of the anal canal.
iii. Super radical operation of WHITEHEAD;
circular resection of rectal mucosa.

SOLOMON (1888) introduced the operation of haemorrhoidectomy (quoted by ALLINGHAM, 1888). Modification of this operation were subsequently described by MILE'S (1919), MILLIGAN et al. (1937), PARK'S (1956); and FERGUSAN (1959).

The reluctance of many patients to undergo rectal surgery is responsible for attempts to develop other forms of treatment. The operative treatment is always associated with pain, post operative morbidity and loss of time from work and expensive hospitalisation.

So keeping the above views in the mind various non-operative treatment were invented and practised at out-patients basis with their merits and demerits.
HAEMORRHOIDECTOMY

The surgical treatment of haemorrhoids was one of the earliest exercises in operative surgery and was practised even in ancient Greek and Rome. Operation for this condition are clearly mentioned in the writings of HIPPOCRATES, CELSUS, and GALEN and methods recomended comprised excision, ligation and the use of the cautery.

In 1882 WHITEHEAD devised, circular excision of the whole of the pile bearing area of the anal canal with suture of the mucosa, above to the skin margin.

The credit for development of the present day concepts is given by SALMON: (ALLINGHAM 1888). He dissected the haemorrhoids above the tissue innervated sonatically and the pedicle containing the superior haemorrhoidal vessels were ligated without causing much pain. Later MILES (1919) and MILIGAN et. al. (1939) both described modifications of SOLMON operation in which low ligation of the pedicle was associated with excision of skin tags and internal haemorrhoids.

MITCHELL (1903) introduced his clamp and excision operation with oversewing of the wounds.

In 1931 FOMSLEER performed closed method of haemorrhoidectomy carried out through the proctoscope. FERGUSON and HEATSON (1959) modified above method by using Sim's
speculum and patients in left lateral position.

Since HIPPOCRATES, the ligation has been applied as method of treatment (HOLLEY 1946). BLAISDELL (1958) described the post-haemorrhoidectomy haemorrhage. He compared the methods of haemorrhoidectomies in relation to formation of slough. In one group of patients, he applied only single ligature to the undissected tissue, in other with the help of Beebe forceps, several mattress sutures were placed as close as possible to produce a small amount of slough. It was discovered on analysing that in second group of the study the incidence of secondary haemorrhage was significantly reduced.

The most satisfactory of the newer procedures of operations is the submucous resection of PARK'S (1956) and more recently that of EISENHAMMER (1969). These methods conserve the mucosa, so that it can be closed without any tension and thus preserve the lining of the anal canal.

**LORD'S PROCEDURE (MANNUAL DILATATION OF ANAL CANAL)**

In 1968 LORD suggested safe one day procedure for treatment of all patients with symptoms of haemorrhoids. This was developed empirically and later a theory of presence of constricting bands or pecten bands was explained to rationalize the treatment.
This procedure consists of eight fingers dilatation of anal canal and rectum to break all pecten bands under general anaesthesia, followed by insertion of a moistened Polyvinyl sponge, which is removed after an hour. Patients are then sent home with instructions to use Lord's anal dilator daily for two weeks, further twice a week for two weeks and then once a week for another two weeks and lastly once a month for six months.

The main disadvantage of this procedure is, the requirement of the general anaesthesia to carry out the procedure, expensive hospitalization, formation of perianal haematoma and use of anal dilators for such a long time. Some times in older patients it aggravates the symptoms of prolapse (McINTYRE AND HALFOUR).

GEHAMY et al. (1974) found no constant relationship between severity of haemorrhoids symptoms and the size of haemorrhoids seen at proctoscopic examination. Treatment of haemorrhoids is therefore directed towards elimination of the symptoms complex caused by them.

RUBBER BAND LIGATION METHOD

Surgeons had for many years been searching for a simple, effective but quick method of ligating haemorrhoids without the need for general anaesthesia.

BLAISDELL (1954) used silk as a ligature material but later on he used rubber rings to give constant haemo-
static pressure. He finally succeeded in the search. He made his technique almost painless by ligating only internal haemorrhoids. The covering mucosa, of which is wholly insensitive. By using elastic rubber bands, he removed the possibility of secondary haemorrhage.

The first demonstration of his technique in the scientific exhibition of American Medical Association at San Francisco in 1954. Blaisdell's instrument consisted of ligating drums with long handle and screw device to slip the rubber bands over the haemorrhoids from ligating drum. BARRON (1963) modified the instrument innovated by Blaisdell. He modified the original apparatus by giving the instrument the pistol handle grip and making it interchangeable. For loading the drum he also added Gravee-umbilical cord ligator in his instrument.

BARRON performed rubber band ligation in about 200 patients using his modified rubber band ligator. All patients felt persistent ache after ligation. The pain was often so much, that the patients required analgesics to relieve the pain. Rubber band ligation also caused constipation leading to complications like tenderness and nervousness, prolapse of untreated haemorrhoids and thrombosis of the external haemorrhoids due to straining.
CRYOSURGERY

The concept of using freezing for medical therapeutic purpose is not very new. Cryosurgery was introduced to the medical sciences by CAMPBELL WHITE in New-York in 1898. At that time cryosurgery was exclusively used by WHITE and others in treatment of skin lesions.

In 1905 PUSEY a dermatologist introduced the use of DRY SNOW (carbon-di-oxide) as a source of low temperature for cryosurgery. This was followed by introduction of the liquid Nitrogen as a cooling agent.

In July 1936, TEMPLE FAY attempted successful palliation of symptoms of stage IV carcinoma of cervix by circulating the ice-cold water around the tissue.

In 1960 CAHAN started treating tumours of many organs including cervix and uterus fundus by freezing the tissues at -80 degree centigrades or lower.

LEWIS et. al. (1969) first introduced cryosurgery for the treatment of haemorrhoids. Cellular destruction, the aim of modern cryosurgery is accomplished by rapid freezing followed by rapid thawing, which destroy the cellular membrane.

This method is simple, absolutely painless, not requiring any anaesthetic agent administration or expensive hospitalization. The main disadvantage of this method is
that the cost of apparatus is quite expensive and there is considerable post-treatment perianal oedema and profuse watery discharge. Which remains for two to three weeks duration. It requires wearing of sanitary pads for the same duration. While healing is complete in four to six weeks duration.

BARRON adopted this cryosurgical technique in his band ligation method. The haemorrhoidal banding interrupts the blood supply and allows freezing to take place more certainly and the area of tissue frozen is precisely confined to banded area. In turn less production of watery discharge, quicker healing of wound occur (BARRON 1973). RUDD 1977.)
INJECTION TREATMENT METHOD.

"The treatment of haemorrhoids by injection of certain substances, chief of which is carbolic acid, may now, I believe, be accepted as a surgical procedure of certain definitive value, and one worthy of a place among the recognised means of cure at our command. Originating as it did among the quacks, it has been looked upon with suspicion followed by the accidents which generally attended a new remedy before its applicability is fully understood; but this does not mean to diminish its real value."

In these words KELSEY (1884) introduced the subject of injection treatment, and we of the present day may well admire Kelsey's grasp of the method and note his decision that the weaker solution of carbolic acid, 5 to 7½% in glycerine and water, were better than the stronger solution, and were attended by less risk of sloughing.

In spite of being dramatically effective in suitable cases, this method was encountered with very strong opposition. When it was first introduced in the profession.

The opposition was not because of fear that some inevitable may happen to the patients on whom this procedure will be performed. But it was based upon the fact that injection treatment was originally in the hands of quacks and only after a period of 30 to 40 years, was it finally adopted by legitimate medical professionals.
Many early historical facts of great interest in the regard to injection treatment were collected and outlined by GRAEME ANDERSON (1924). Apparently the first person to practice the injection treatment method, was MORGAN OF DUBLIN who used a solution of per sulphate of iron, for the treatment of patients suffering from haemorrhoids, to inject the solution locally at site of haemorrhoids. This idea had been borrowed and based on much older injection treatment for cure of naevi. This method was used also, by well known DUBLIN surgeon, COLLES, in 1874, but did not find popular favour in BRITAIN, and was allowed to lapse till it was re-introduced from AMERICA some years later.

The use of carbolic acid for injection treatment for the haemorrhoids is ascribed to MITCHELL OF CLINTON, ILLINOIS, U.S.A. CLINTON was pioneer in that country, and starting in 1871, treated many hundreds of cases of piles by injecting a solution composed of 1 part of carbolic acid in two parts of olive oil, with very good results. Unfortunately MITCHELL kept his method of treatment as a secret and before his death, he sold the technique to a large numbers of quacks, who roamed around the United states of America and treating the patients suffering from haemorrhoids. These quacks were known as "Travelling pile doctors". For the most part they used carbolic acid solutions of different strengths ranging from 27 to 95% for injections. Eventually ANDREWS of CHICAGO discovered the secret from one of these
quacks and gave it to the medical science in 1879. At first most surgeons spurned the method, but due to firm advocacy of ANDREWS (1892) himself, KELSEY (1883) and MARTIN (1904) injection treatment was slowly adopted in America.

When the method became generally and universally known, much discussion and experimentation took place as to find out the best solution strength without having untowards reactions of the carbolic acid on human beings, and KELSEY'S opinion has just been quoted. One of the first favourable report of the method was given by SWINFORD-EDWARDS (1888), who used 10% solution (occasionally 20%) of carbolic acid in glycerine and water. For many years this remained the favourite preparation for injecting haemorrhoids in England. In England the revival of method was strongly opposed by Allingham's seniors.

In other countries, many other solutions such as 5% Quinine and Urea hydrochloride in water were used as sclerosing agents (TERRELL 1917). 70 percent alcohol solution (BOAS 1922) or 5 percent Sodium morrhuate in Benzyl alcohol (DOBSON 1940) etc. were tried in the injection treatment of haemorrhoids with varying success. The only one of these which has been at all widely adopted and accepted, is Quinine and Urea hydrochloride solution which has been used by many American surgeons.
In other countries like Russia, similar studies were conducted with good results. One study performed on 410 patients, produced very encouraging results regarding injection treatment. Many reports on sclerosing injection for haemorrhoids have been published. (AMINEV 1971; GELLER 1971; TIMOKHIN 1979) etc.

The modern practice carrying out injection for haemorrhoids, is to use the ALBRIGHT'S technique of placing a sclerosing solution in a fairly good amount above the haemorrhoids, so as to form a dense barrier of fibrous tissue in the submucosa about the level of anorectal ring, and to have a good vascularizing effect than injecting into the submucosa of the piles themselves, was described by BLANCHAND (1928). In England this method was introduced by MORLEY (1928).

While treating the haemorrhoids by injection treatment GABRIEL described the two main objective for which the method is performed:

(i) to stop bleeding by obliteration of vascular capillary and venous spaces.

(ii) to produce a submucous scleroses which will draw up and fix loose mucous membrane to the underlying tissue.

For some time after introduction of 5 percent solution of phenol in oil, there was a considerable phase
of enthusiasm for it and a large proportion of haemorrhoids cases were treated by injection. For instance in a communication to the Subsection of Proctology, Gabriel (1931) presented one analysis of 800 new cases of haemorrhoids seen by him of which 75 percent were treated by injection. But subsequently the proportion of cases treated by injection has been reduced by reason of disappointment with the results of injecting third degree haemorrhoids, especially when prominent skin tag developed in the same quadrant as the haemorrhoid.

Injections are the most suitable treatment for tuberculosis patients troubled by internal haemorrhoids. In a series of ten cases of anal tuberculosis analysed by GuiE and Renkin (1941), previous anorectal surgical treatment had been carried out in six cases of which five had been a haemorrhoidectomy. It appear from this that in subjects with active phthisis there is a risk of tuberculous infection of operation wound from swallowed sputum and it is clearly preferable in such cases to offer palliation by injection rather than to incur the risk of a secondary tuberculosis ulceration of the anus.

The very aged and feeble old patients, who refuse operation or whose general condition or mental status renders operation inadvisable even if performed under local anaesthesia.
Recently, doctors from Kupriyanov, along with commonly used conservative treatments of haemorrhoids have been firmly advocating injection treatment, using different sclerosing solutions. AMINEV and TIMOKHIN think that sclerotherapy can and should replace surgery in the early and later stages of haemorrhoids. Their data, good and satisfactory results in more than 70 percent and stable long term effect in 90 percent of patients followed up, deserve attention. However this is true that no single kind of treatment of haemorrhoids can become a panacea. When patients are selected properly and carefully for sclerotherapy, can and must give excellent results.

Frequent post injection recurrence of the disease dissatisfaction of both doctors and patients with the result of treatment, and complications developing after using some of the sclerosants, are the factors motivating surgeons and researchers to look after new, effective, safe and simple sclerosing agent which is yet to be found.

DUKE (1924) and PRUITT (1931) administered 10 to 20% phenol in glycerine and water into the submucous areolar tissue of internal haemorrhoids and noted marked oedema and perivenous tissue infiltration by WBC and RBC in 24 hours. They also observed proliferation of fibroblasts which increased during succeeding days.
GRAHAM-STEWARD (1962) used oily solutions, 5% phenol in almond oil and they even tried the injection of pure almond oil, surprisingly he observed identical reactions in all cases injected with different sclerosants. However CLARK, GILLS and GULICHER (1967) did not relied upon the injections of almond oil they recomended the 5% phenol in almond oil.

On experimental and therapeutic basis many more substances has been tried Brooks (1984), For example, 66% glucose solution; BOURGEOIS (1984), Ethanolamine oleate; KITANO S. (1987), Absolute alcohol; ATMAKURI (1958), Sodium tetra decyl sulphate; but non proved to be of satisfactory value. Recently a new sclerosing substance, Hydroxypolyethoxydodecan (Polidocanol) has been introduced as a sclerosing agent for the treatment of oesophageal varices (IMPERIALI G. 1986). KITANO S. (1987) conducted a perspective randomized study comparing the Ethanolamine oleate and polidocanol for the sclerotherapy of oesophageal varices.

The present study has been undertaken to evaluate the effectiveness of Polidocanol as a sclerosing agent for the injection treatment in the patients suffering from internal haemorrhoids.