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Role of Polidocanol as Sclerosing Agent in Early Haemorrhoids

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Abstract: This study was conducted to evaluate the role of polidocanol as sclerosing agent in internal haemorrhoids. Total 336 cases of 1st and early 2nd degree haemorrhoid cases were treated by polidocanol injection sclerotherapy as an outdoor procedure. The injection was placed in the upper part of the haemorrhoid in submucosal plane. Out of 336 patients, 250 were male and 86 were female, the age ranged from 20-80 years, 141 patients had 1st degree haemorrhoids and 195 had 2nd degree haemorrhoids. Injection sclerotherapy cured 265 patients, improved 60 and it failed in 4 patients. The 15 patients had repeat session and 17 patients had concomitant illness. Complication in the form of complain of pain occurred in 8 patients and local sepsis in 2 patients. All complications were treated successfully. This method is easy, convenient, cheap and effectively practicable at outdoor level.

Key words: Haemorrhoids, sclerotherapy, polidocanol, outdoor procedure, India

INTRODUCTION

Haemorrhoids or piles (haemorrhoids (Gk) = Discharging blood, pila (L) = Ball) are enlarged vascular cushions within the anal canal. Haemorrhoidal disease is a very common disease affecting a large population. The exact incidence of this condition is difficult to estimate. Approximately 5% of the general population and 50% of the individuals over the age of 50 have complaints related to haemorrhoids (Mazid *et al*., 2006).

The anal canal has a triradiate lumen lined by three fibrovascular cushions of submucosal tissue. These anal cushions appear in the right anterior, right posterior and left lateral positions. These cushions are suspended in the canal by a connective tissue framework derived from the internal anal sphincter and longitudinal muscle. Within each cushion is a venous plexus that is fed by arteriovenous communications. Fragmentation of the connective tissue supporting the cushions leads to their descent. Repeated displacement of these cushions results in stretching and eventual prolapse of the cushions.

Goligher classification system describes the haemorrhoids graded by the degree of prolapse and this grading determines the most appropriate methods of treatment. While 1st degree haemorrhoids are merely visible vessels, 2nd degree lesions prolapse with defecation but return spontaneously, 3rd degree lesions prolapse and require manual replacement and 4th degree lesions remain prolapsed out of the anal canal despite attempts to reduce them. The symptoms include bleeding, prolapsing tissue, fullness after defecation and pain.

The treatment choices for haemorrhoids include infrared coagulation, radiofrequency coagulation, direct current coagulation, rubber band ligation, sclerotherapy, cryosurgery, scalpel surgery and laser surgery. Scalpel surgery is generally reserved for advanced 4th degree haemorrhoids. In earlier degrees, conservative management or minimally invasive operations are usually preferred.

Accordingly, injection sclerotherapy has advantages over other modalities of treatment which include that it can be done as an out door procedure with minimal complications. Various sclerosing agents are (Parsons, 2004):

Detergents: Disrupt vein cellular membrane (protein theft denaturation):

- Sodium tetradecyl sulfate
- Polidocanol
- Sodium morrhuate
- Ethanolamine oleate

Osmotic agents: Damage the cell by shifting the water balance through cellular gradient (osmotic) dehydration and cell membrane denaturation:

- Hypertonic sodium chloride solution
- Sodium chloride solution with dextrose

Chemical irritants: Damage the cell wall by direct caustic destruction of endothelium:

- Chromated glycerin
- Polyiodinated iodine

The most commonly used solutions for haemorrhoids are 5% phenol in oil, vegetable oil, quinine and urea hydrochloride or hypertonic salt solution, sodium tetradecyl sulfate.

Polidocanol is a nonester sclerosing agent with local anesthetic properties. It is painless upon injection, does not produce tissue necrosis if extravasated and has a very low incidence of allergic reactions, although few cases of anaphylaxis have been reported. Also in some patients, it may produce hyperpigmentation. Suggested sclerosant concentrations are 0.5-1.0% for reticular veins (2-4 mm) and venulectasias (1-2 mm) and 0.25-0.75% for telengiectasis (<1 mm) (Craig and Feided, 2007). Polidocanol is not commonly used as sclerosant in haemorrhoids. The maximum daily dosage is 2 mg kg^{+} .

This study was performed to assess the effectiveness of polidocanol as sclerosing agent in patients with early degree haemorrhoids as out patient procedure.

MATERIALS AND METHODS

This study was carried out at Surgical Out Patient Department in S.N. Medical College Hospital, Agra from January, 2006 to December, 2010. All Patients with 20-80 years of age presenting with 1st and 2nd degree haemorrhoids with symptoms at surgical out door of the hospital were included in study.

In every case, general systemic examination, proctoscopic and digital per rectal examinations were performed. In all cases, the number, size, situation and degree of piles were noted diagrammatically.

Injection sclerotherapy is performed using 3 mL disposable syringe. After locating the haemorrhoid with help of proctoscope, the needle is introduced into the center mass of veins, through the mucous membrane. It is important that the injection be made into submucosa at the base of the haemorrhoidal tissue and not into the haemorrhoids themselves; taking care not to enter the lumen of the vein or traverse to the sensitive margin of the dentate line. To ensure the needle is not in the lumen, plunger is draw back before injecting. No antiseptic is necessary. The injection was placed in the upper part of the haemorrhoid, injecting 0.5-1 mL at each site to a maximum of 3 mL. Correct sitting must be verified by a trial injection of a small amount which should be seen to raise and pale the overlying mucosa and be crossed by blood vessels, the so called striation sign. If no mucosal swelling occurs immediately with a trial injection, the needle must be withdrawn further. A very great care must be taken to prevent mislocation to avoid disastrous consequences. Treatment sessions for the same anatomic locations were carried out at intervals of 2 weeks, if required. After the procedure, the patients were given a standardized treatment of metronidazole 400 mg thrice daily and levofloxacin 500 mg daily for 3 days along with the advice to increased vegetable intake in diet. All the patients were called for regular followup. Patients who did not turn-up for follow-up, bleeding diathesis and not willing for injection sclerotherapy were excluded.

Assessment proforma was designed for each case by taking history including symptom severity and proctoscopic examination and overall satisfaction. Symptom severity score findings were noted as follows:

No effect: There is no effect or slight decrease (0-25%) in bleeding per rectum, no shrinkage of pile core on proctoscopy.

Reduced bleeding: There was noticeable reduction in bleeding per rectum (25-90%) and the pile cores were shrunken on proctoscopy.

Fully cured: Bleeding per rectum was fully stopped and the pile cores were sclerosed.

Also, overall satisfaction score was measured. In the patient had to mark his level of overall satisfaction with 0 meaning not satisfied, 1 meaning moderate satisfaction and 2 meaning highly satisfied from the procedure.

RESULTS

There were 336 patients out of them 250 were male and 86 were female, the age ranged from 20-80 years with mean age 40 years. About 141 patients had 1st degree haemorrhoids and 195 had 2nd degree haemorrhoids. Majority of patients (200 in number) had symptoms of bleeding for the last 1-3 months with a range from few days to 6 months.

Injection sclerotherapy cured 265 patients, improved 60 and it failed in 4 patients. Total 15 patients had repeat session. While 17 patients had concomitant illness like diabetes mellitus, ischemic heart disease and hypertension. Complication in the form of complain of pain occurred in 8 patients while 2 patients developed local small ulcer. All complications were treated successfully.

DISCUSSION

Hsemorrhoids is a very common problem of the society and patients are reluctant to undergo surgery because of shyness to show their anal region, fear of pain

of operation (haemorrhoidectomy) and hospitalization. So, non-operative modalities of treatment are now being tried which include rubber band ligation and injection sclerotherapy.

Injection sclerotherapy is very effective and a less tedious procedure. The commonly used compound, 5% phenol in almond oil has a list of complications which can be serious sometimes. Common complications include reactive and secondary hemorrhage, retention of urine, peri-anal abscess and peri-anal fistula.

Rare complications reported were liver abscess, life threatening retroperitoneal sepsis from UK and necrotizing fasciitis of the perineal region from India. Phenol induced chemical hepatitis from injection sclerotherapy has been reported by Suppiah and Perry (2005).

Complications in this study occurs in only 10 patients and were limited to pain and local ulcer. Pain means sclerosant is injected close to dentate line and it is usually relieved by giving analgesics, ulcer occurs due to injecting the drug superficially.

In this study, sclerosing therapy is found to be very useful in haemorrhoids with portal hypertension, pregnancy and in patients not fit for surgery.

The recurrence rate in 5% phenol in almond oil sclerotherapy is 11.9% after 2 years follow-up as reported by Komorozos, 27% at 1 year follow-up by Walker *et al.* (1990), 23% after 5 years follow-up by Savioz *et al.* (1998). Recurrence rate is more unless the patient alter their dietary habits. Mattana *et al.* (1989) have reported a low recurrence of 9% in patients with normal bowel habits when compared with constipated patients whose symptoms recurred in 85% case.

In this study, 15 patients required two sessions and there is no recurrence reported till the completion of study.

Many studies have been done comparing rubber band ligation with haemorrhoidectomy, sclerotherapy, cryotherapy and infrared coagulation. A prospective clinical trial by Murie *et al.* (1982) has shown that sclerosing therapy abolished or improved prolapse and bleeding as effectively as haemorrhoidectomy.

CONCLUSION

The aim of outpatient management of haemorrhoids is to provide a convenient, safe, effective and economical method of treating haemorrhoids. This study shows that polidocanol as sclerosing agent in patients of 1st and 2nd degree haemorrhoids fullfils most of these criteria and recommend that polidocanol may be used as sclerosing agent for the patients of 1st and 2nd degree haemorrhoids as treatment of choice.

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