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A comparative study between rubber band ligation and local application of herbal caustic compound (*pratisaraneeya kshara*) in management of internal haemorrhoids

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1. Introduction

Haemorrhoid is one of the most common anorectal complaints[1,2] reported in anorectal clinics with estimated prevalence of 4.4% in United States and 13–36% in the United Kingdom.[3] It is one of the oldest ills known to mankind with accounts available in oldest literature like Atharwaveda (1500 BCE)[4] from India and Egyptian Papyrus (1700BCE)[5] from the west. Haemorrhoids are actually the vascular cushions that provide a physiological hermetic seal in the closure mechanism of anal canal and helps in maintenance of continence.[6] Faulty dietary and toilet habits may cause the pathological enlargement of these cushions which create misery to the patient by producing bleeding, discomfort, prolapse and sometimes pain in the anorectal region. A modification in diet, lifestyle and defecation habits can alleviate the symptoms in many patients. For the rest, various surgical methods like haemorrhoidectomy, stapled haemorrhoidopexy etc. and the office procedures like rubber band ligation, sclerotherapy, photocoagulation, cryosurgery etc. are available with each having its own merits and limitations compared to other. Though haemorrhoidectomy is still considered as the 'gold standard' treatment for haemorrhoids,[7] office treatments for symptomatic haemorrhoids are increasing[8] over the last few decades. Rubber Band Ligation (RBL), as advocated by Barron,[9] is one of the safe, simple, cost-effective and the most widely used office procedure by the surgeons which eliminate the pile mass by ischemic necrosis and promote submucosal fibrosis with subsequent fixation of anal epithelium to the underlying sphincter.[10]

In traditional Indian medicine i.e. Ayurveda, the term *arsha* is used to describe an abnormal fleshy growth originating in the anal region due to improper diet, lifestyle and defecation habits.[11] By definition, the term *arsha* may broadly include sentinel tags, hypertrophied papillae, polyps and external as well as internal piles; however, to be very specific, haemorrhoidal disease may be corresponded with *raktarsha* (*rakta* means 'blood' and *arsha* means 'fleshy mass'), a variety of *arsha* described in ancient texts. The management strategies for haemorrhoids include four modalities of treatments viz. medicinal treatment, chemical cauterization, thermal cauterization and surgical excision.[12] While medical management is primarily advocated for uncomplicated haemorrhoids and focusses upon improvement of digestion, easy evacuation and correction of bowel habits; large and complicated piles are advised to be treated with thermal cauterization or excised surgically. Chemical cauterization is a form of parasurgical measure which is employed by local application of a caustic material, *pratisaraneeya kshara* (PK; *pratisaraneeya* means 'to be applied locally', *kshara* means 'alkaline caustics') in internal haemorrhoids. It is prepared from the ashes of medicinal plants by a special technique of preparation with addition of marine shells[13] and, on application, brings about necrosis in the pile mass resulting into an ulcer which heals by fibrosis.[14] Local application of PK, also known as *kshara-karma*, is one of the most widely practiced outpatient treatments

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for internal haemorrhoids by the Ayurveda surgeons in India.

Thus, both RBL and local application of PK have a similar mode of action and are the office procedures of choice for internal haemorrhoids among the modern and Ayurveda surgeons respectively. So, the present study was designed to compare the efficacy of these two techniques in a prospective randomized trial.

2. Materials and methods

Patients of grade I to grade III internal haemorrhoids were randomly selected from the Anorectal OPD of Indian Medicine Wing of Sir Sunder Lal Hospital, Banaras Hindu University, Varanasi, India. Detailed history was taken from all the patients and clinical examination was done. Patients with history of hypertension, diabetes mellitus, liver cirrhosis, cardiac disorders, pregnant women and patients with hemoglobin percentage below 10 gm% were not included in the study. Total 60 patients were selected and randomly allocated into three groups of 20 patients each by lottery method. All patients were advised to avoid straining during defecation and to take 5 gm Ispaghul husk with luke-warm water at bed time only. In addition, haemorrhoids were treated with local application of PK in group B and band ligation in group C. Ethical clearance was obtained from institutional ethical committee and informed consent was taken from all patients.

Preparation of *Pratisaraneeya Kshara*: PK, the herbal caustic compound, was prepared using the ash of the plant *Achyranthes aspera Linn*. 350 gm of ash was mixed with 3 L distilled water, stirred well and left overnight. Next morning, the solution was filtered with whatmann's filter paper (pore size 610 Å) to obtain a clear, reddish-orange filtrate. The filtrate was evaporated at 120–130 °C to obtain 100 gm of *kshara* powder. 100 gm of *kshara* powder was dissolved in 250 ml of distilled water and the *kshara* solution was put over flame to boil. 45 gm of conch shell was then heated on another flame simultaneously and when red hot, was dipped and macerated finely in the boiling *kshara* solution. This suspension liquid was then evaporated to obtain a thick liquid like compound, PK, which had a pH of 13 when measured on pH paper [Fig. 1(a)].

Procedure: Sodium phosphate enema was administered before the procedure to ensure rectal cleaning in both group B and C. Patient was taken on table in extended lithotomy position. Digital rectal examination and proctoscopy was done to assess site, size and number of pile masses. In multiple piles, one pile mass was treated at one sitting to avoid discomfort to the patient and minimize complications. The largest or the most congested pile mass was selected for the procedure.

In group B, patients were treated with local application of PK. A full slit proctoscope, with 2.5 cm wide lateral slit, was introduced into the anal canal and positioned to project the selected pile mass into the slit of the proctoscope. A gentle traction was applied over the pile mass by holding the anal skin with forceps to help in proper visualization. Size (base diameter) of the pile mass was measured by using the specially designed circular rings of fixed diameter (smallest 0.5 cm, largest 2.5 cm) as shown in Fig. 1(b and c) and the healthy rectal mucosa surrounding the pile mass was gently packed with moist cotton to protect from corrosive action of *kshara*. PK was carefully smeared over the internal pile mass using a shallow scoop, taking care not to spill or touch over the healthy mucosa or the anoderm. Within a few seconds after application, the pile mass started changing its colour from purpulish pink to blackish brown and ultimately became jet black like a ripened blackberry in a span of approximately one minute [Fig. 2(a), (b) & (c)]. After one minute of application, the pile mass was gently washed with dilute lemon juice soaked in a cotton ball to neutralize the caustic action of PK. The proctoscope along with the cotton was taken out and a sterile pad was covered over anus.

In group C, rubber band was applied over the selected pile mass using the Barron's rubber band applicator by traction method after recording the size (base diameter) of the pile mass (as described above).

Patients in both the groups were kept under observation for 1 h to look for any immediate post-operative complaint and advised to go home thereafter. Diclofenac sodium 50 mg tablets were advised to be taken for relieving postoperative pain, if present. 5 gm isphagul husk was prescribed with luke-warm water at bedtime along with warm sitz bath twice daily for five minutes. Patients were evaluated at 1 week, 2 weeks, 1 month and finally at 3 months follow up.

3. Results

The study included 85% males and 15% females with mean age of 39.73 years (range 20–62 years). 55 (91.67%) cases had constipated bowel. 24 (40%) of the total cases had internal piles only while 36

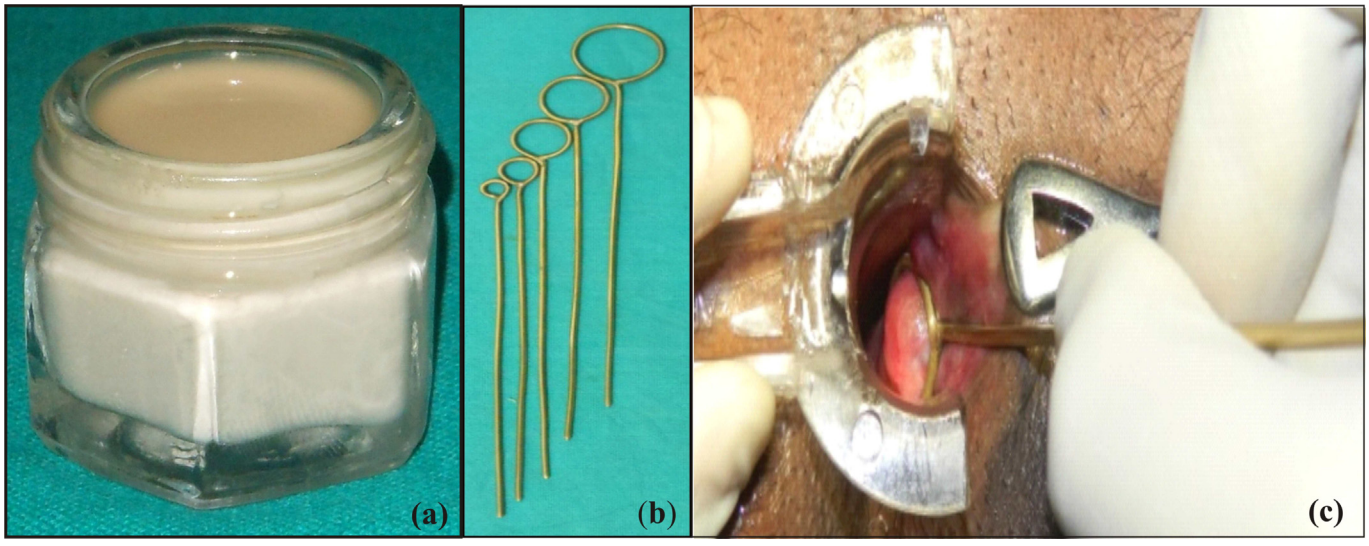


Fig. 1. (a) *Pratisaraneeya kshara,* (b) Specially designed circular rings, (c) measuring the size of pile mass using the rings.

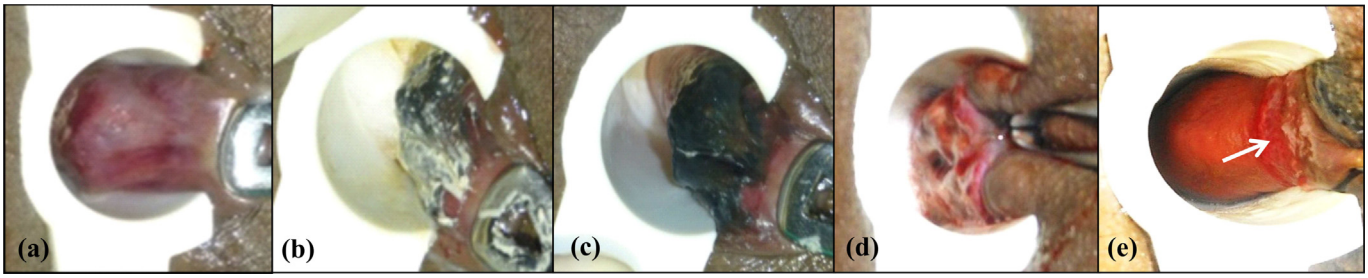


Fig. 2. Effect of local application of *pratisaraneeya kshara* over 3 o' clock internal pile mass (a) before *kshara* application (b) during *kshara* application (c) after washing with dilute lemon juice after one minute (d) ulceration with slough at the site of application after one week (e) healed scar (arrow) with no residual stump at 1 month follow up.

(60%) had external component too. 16 (26.67%) subjects had piles at all three quadrants, 23 (38.33%) at two quadrants while 21 (35%) cases had piles at single quadrant only. Total 9 (15%), 34 (56.67%) and 17 (28.33%) cases had piles of 1^0, 2^0 and 3^0 respectively [Table 1]. Patients were assessed before therapy and at different follow ups for bleeding and size of pile mass as per the scoring pattern described in Table 2.

After the procedure, 4 patients had to take oral analgesics till 3rd postoperative day in group B while 9 other had only mild, bearable pain which subsided with hot sitz bath only. In group C, 5 patients had to take oral analgesics till 5th postoperative day while 4 others had mild pain and didn't require any analgesic. Rest of the patients in both groups (7 in group B and 11 in group C) did not complaint of any postoperative pain. Proctoscopy performed in group B showed the presence of ulcer with slough at 1st week [Fig. 2(d)], clean healthy wound at 2nd week and a healthy scar at 1 month and 3 months follow up [Fig. 2(e)] at the site of PK application. In group C, a clean healing ulcer was visible at the site of banding at 1st week which was replaced with a healthy scar at further follow ups.

The results of friedman's test shows statistically significant reduction in bleeding and size of pile mass in all groups [Tables 3 and 4] but the changes were more conspicuous in group B & C. In group B, 50% cases had base diameter of more than 2 cm and 30% of 1.5 cm as measured preoperatively but after PK application, 80% cases had no remaining stump at the end of three months. 60% of patients had some amount of blood mixed discharge during the first week from the necrotizing pile mass which also reduced significantly to 10% by the next week but none of the patients had any complaint of bleeding after three months, although a small residual stump of about 0.5 cm and 1 cm base diameter was remaining in 2 cases each, all of which had piles of >2 cm diameter initially.

While in group C, out of 11 (55%) cases with pile mass >1.5 cm diameter (3 of which had piles of > 2 cm diameter), 6 patients (30%) still remained with a residual mass of about 0.5–1 cm diameter though only one third of them (10%) again developed congested cushions in the remaining stump with reappearance of bleeding per rectum by the end of three months follow up. In group A, wherein only bulk laxative was given along with an advice to avoid straining during defecation, size of the pile mass and the complaints of bleeding also decreased gradually in three months duration with statistically significant changes (Friedman's test) but the reduction was not much when compared to other groups (graph 1 & 2). The Kruskal-Wallis test showed significant statistical heterogeneity among the results of all the three groups.

4. Discussion

To choose and recommend any single modality as the most optimal treatment for haemorrhoids is a matter of controversy as choice of modality may vary according to the grades of symptoms, patient compliance, economic affairs as well as the availability of equipment and facilities. Of all the outpatient procedures, RBL has been recommended as the primary mode of therapy for grade I to III haemorrhoids[15] with success rates ranging from 69 to 97%[16] in different studies. Pain and bleeding are two of the most commonly occurring complications of RBL.[17] As stated earlier, band ligation

Table 2
Scoring criteria for different symptoms.

Score	Bleeding	Size of Pile Mass
0	No Bleeding	<0.5 cm
1	Occasionally	0.5–1 cm
2	Once in a Week	1–1.5 cm
3	2-3 times in a Week	1.5–2 cm
4	Once Daily	>2 cm

Note: Scores were counted for bleeding and size of piles separately.

Table 1
Demographic characteristics of the patients.

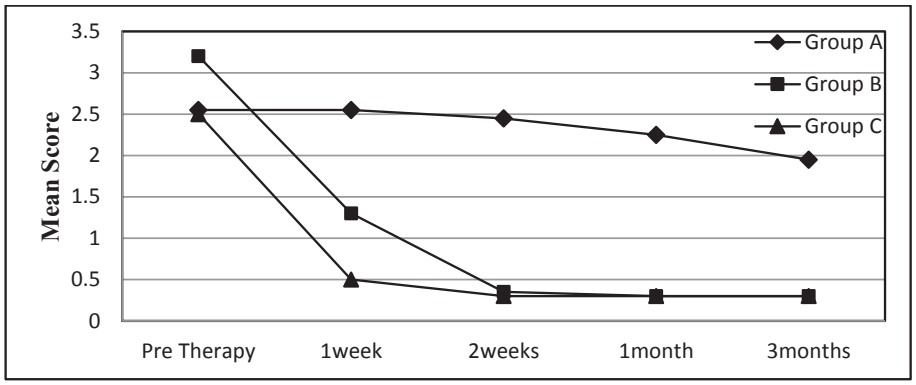
Variable		Group A (n = 20)	Group B (n = 20)	Group C (n = 20)	Total (n = 60)
Age (years)	Mean (Range)	41.45 (23–60)	41.1 (20–62)	36.65 (26–57)	39.73 (20–62)
Sex	Male	13	20	18	51
	Female	7	0	2	9
Bowel Habits	Regular	1	1	3	5
	Constipated	19	19	17	55
Nature of Piles	Internal only	6	8	10	24
	Externointernal	14	12	10	36
Degree of Piles[3]	1°	3	2	4	9
	2°	13	8	13	34
	3°	4	10	3	17
No. of Piles	Single quadrant only	4	9	8	21
	Two quadrants	10	7	6	23
	All quadrants	6	4	6	16

Table 3
Comparative effect of therapies on size of pile mass.

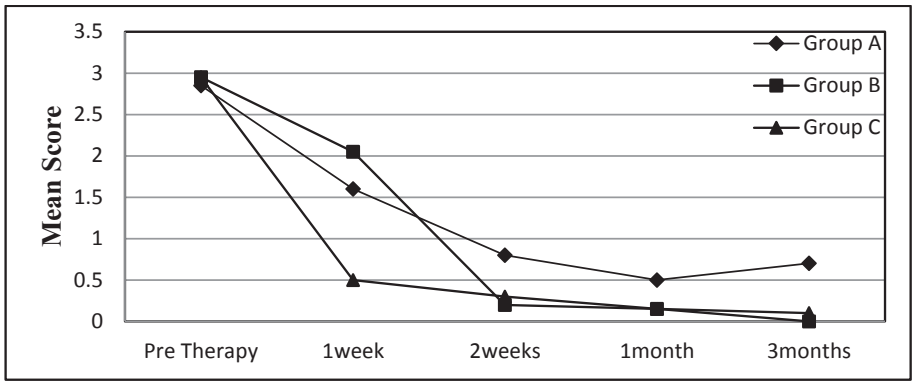
Groups		Mean ± SD Score					Friedman's Test
		Pre Therapy	1week	2weeks	1month	3months	
Group A		2.55 ± 0.999	2.55 ± 0.999	2.45 ± 0.945	2.25 ± 0.910	1.95 ± 0.887	$\chi^2 = 47.200$ **p < 0.001**
Group B		3.20 ± 1.005	1.30 ± 0.979	0.35 ± 0.671	0.30 ± 0.657	0.30 ± 0.657	$\chi^2 = 91.910$ **p < 0.001**
Group C		2.50 ± 1.00	0.50 ± 0.688	0.30 ± 0.470	0.30 ± 0.470	0.30 ± 0.470	$\chi^2 = 90.588$ **p < 0.001**
K W Test	χ^2 p	**6.324 = 0.042**	**28.750 < 0.001**	**39.059 < 0.001**	**38.526 < 0.001**	**35.283 < 0.001**	

Table 4
Comparative effect of therapies on bleeding.

Groups		Mean ± SD Score					Friedman's Test
		Pre Therapy	1week	2weeks	1month	3months	
Group A		2.85 ± 1.268	1.60 ± 1.273	0.80 ± 1.005	0.60 ± 0.883	0.70 ± 0.733	$\chi 2 = 36.548$ **p < 0.001**
Group B		2.95 ± 1.317	2.05 ± 1.146	0.20 ± 0.616	0.00 ± 0.00	0.00 ± 0.00	$\chi 2 = 82.389$ **p < 0.001**
Group C		2.95 ± 1.050	0.50 ± 0.889	0.30 ± 0.733	0.10 ± 0.308	0.10 ± 0.308	$\chi 2 = 85.411$ **p < 0.001**
K W Test	**χ^2 p**	**0.167 = 0.920**	**15.924 = 0.001**	**5.987 = 0.050**	**12.613 = 0.002**	**20.204 < 0.001**	



Graph 1. Comparative effect of therapy on size of pile mass.



Graph 2. Comparative effect of therapy on bleeding.

causes an ischemic necrosis at the base of pile mass which fell off in a few days leaving an ulcerated area at the plane of cleavage with vascular granulation tissue that can cause bleeding. Severe bleeding may occur if a small arteriole lies at the plane of cleavage. Various studies comparing rubber band ligation with other modalities for management of haemorrhoids, have shown incidence of postoperative bleeding. While Arizi et al.[18] reported minor bleeding in 36% cases within 48 h postoperatively, Bat et al.[19] reported only 3 (0.6%) out of 512 cases with minor bleeding and 6 (1.2%) cases with delayed massive bleeding. In this study, 5 patients from RBL group experienced minor bleeding within the first week and 3 still had a single incidence of minor bleed in the 2nd week. However, all these had a history of passing hard stool on the day of bleeding which might have caused friction of the remaining ulcer at the site of banding. Proctoscopy also revealed some residual haemorrhoidal tissue of size 0.5–1 cm in 6 cases, all of whom had pre therapy pile mass of size more than 1.5 cm which shows that the conventionally available Barron's band applicator with 1 cm cylinder diameter is not effective in large, broad based piles. 2 of these 6 patients again developed congested cushions and the complaint of bleeding

persisted. Also, 9 (45%) patients experienced postoperative pain, 5 (25%) of whom had to take oral analgesics. Ideally, RBL should be a painless procedure but pain may occur when the band is placed close to the dentate line with chances of involving the anoderm. Other studies have also reported incidences of varying degree of pain after band ligation.[16,19] In the study conducted by Watson et al.[20] where RBL was performed by all grades of surgeons, 90% of patients experienced some degree of pain after RBL with 65% requiring oral analgesia during the first 24 h, 20% for 3 or more days while 10% still required analgesia after 7days. These results show that there is a lot of variability in the incidence of postoperative pain after band ligation and the operator dependent factor should also be taken into consideration.

Local application of alkaline caustics (*kshara*) for the treatment of haemorrhoids has been in practice in traditional Indian medicine since ancient times. PK used in this study was prepared from the ash of *Achyranthes aspera* which mainly contains carbonates, sulphates, chlorides and nitrates of alkali elements like sodium and potassium[21] and the conch shell which is made up of calcium carbonates. While making a concentrated solution of the alkaline ash with marine shells, alkaline hydroxides of calcium, sodium and potassium are produced[22] and it becomes a strong alkaline paste. Like other strong alkalis, PK also causes liquefaction necrosis. It causes saponification of fats, dissolution of proteins by alkaline proteinates formation and extracts considerable water from cells due to its hygroscopic nature leading to cell death.[23] Alkalis also promote thrombosis in blood vessels by base absorption.[24] Thus, local application of PK eradicates the bleeding haemorrhoidal cushions by liquefaction necrosis and vascular thrombosis. Thrombosis may lead to breakdown of hemoglobin, the products of which may be responsible for blackish discolouration of the pile mass on application of PK. Also, the short duration of contact (1 min only) of the drug also prevents its penetration beyond the submucosal layer. Due to this necrosis and sloughing, most of the patients had blood mixed pus like discharge during the first week but no frank haemorrhage occurred in any patient. 90% of the patients got relieved of bleeding by the 2nd week. Though a small residual stump was observed in four patients, no subsequent haemorrhoidal development occurred due to healing by fibrosis and a complete relief was observed from bleeding at subsequent follow ups. In a similar study comparing the outcome of PK application with infrared coagulation in haemorrhoids, PK application proved superior in terms of complete relief in bleeding per rectum at 1 month follow up than only 62.5% in case of infrared coagulation.[25] Though, 4 patients had to take analgesics for relieving pain in our study but not for more than 3 days. Pain after PK application may be caused by spilling of *kshara* over the sensitive anoderm area which may be minimized with careful application. Application of PK at all pile masses in one sitting may result in painful inflammatory edema around the anus and should preferably be avoided which has also been recommended by Sushruta, the ancient Indian surgeon.[12] In addition to this, duration of contact longer than the recommended time may cause damage to the deeper layers and may result in complications like stricture. A secondary bleeding may also be possible due to sloughing of pile mass. However, none of these complications was recorded in this study.

Apart from taking care of local manifestations of the disease, systemic components also play an important role in the management of haemorrhoidal disease. Role of diet, lifestyle and improvement in defecation habits has been advocated both in the modern as well as ancient literature. In Ayurveda also, diets and drugs which improve digestion and facilitate easy evacuation of faeces have been advised as a part of medical management.[26] In this study too, all patients were given a fiber supplement (isphagula husk) and advised to avoid straining during defection. In group A, where only isphagula husk was given to patients, mean score for bleeding reduced initially but a slight increase was observed again at 3 months as the local pathology was not treated unlike PK and RBL group. However, a reduction was observed in overall mean score for the size of pile mass as fiber facilitates easy evacuation of faeces and so, does not induce straining. Earlier studies have also demonstrated beneficial effects of fiber supplements in reducing bleeding and prolapse in patients of haemorrhoids.[27,28] Hence, a symptomatic relief was also observed in group A but the results were much better in group B and C where the local treatment was also done in the form of PK and RBL respectively.

5. Conclusion

Conservative management with an advice regarding improvement in diet and defecation habits may provide symptomatic relief in haemorrhoids, but local management is also required for effective management. Efficacy of local application of PK is comparable to RBL in the management of haemorrhoids though PK is better than RBL in eradication of large, broad based piles and can be employed as an office procedure in anorectal settings.

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Conflicts of interest

None.

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