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An Innovative Clinical Study of Anal Stricture and its Management with PCA Therapy

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Abstract

Background: The anal stricture is a fibrotic narrow way to anal canal, can be also called as anal stenosis, Due to stenosis of the stool passage, there is difficulty and strain defecation leads to painful bowel movements sometimes with bleeding or mucopus in chronicity which is correlated with Sannirudhaguda in Ayurveda. Usually it happens after anorectal surgery in about 90% of Haemorroidectomy and while treating malignant lesions of the pelvis under irradiation with radiation therapy, stenosis may result in 20%. The unsuccessful treatments inspired to find out result oriented method. It is an innovative study. The Ksharasutra under PCA therapy has been proved successful in treatment of Piles, fistula, pilonidal, sinus and KSS method in anal fissure *Aim:* To evaluate the effect of PCA therapy consisting of Ksharasutra suturing (KSS) and Kshara Malahar (KM) in anal stricture. *Materials and Methods:* Total 76 patients of anal stricture were selected and randomly divided into group A- (24) group-B (20) and group-C(32).In group- A, the patients were treated with KSS where as in group-B, KM and in group-C , both KSS and KM were carried out. Under spinal anesthesia A& C group patients were treated while the B group from the beginning and group- A, patients and after 7 days by removal of KS were KM applied continuously for one week under local anesthesia, The anal wound was treated for 04 weeks and the result was assessed on the basis of gradation. *Results:* The assessment of result in the group- C was 98.7% success and in the group- B it was 68.8% while in group –A the result was assessed 84%.The group C treated with the KSS procedure and KM showed the maximum benefit to the patients due to both procedures had continuous action to remove the stricture lesions from the anal area. Totally 89% cases were cured while 6.5% cases of group B marked improvement after 1st week of treatment and 2.6% cases of group A had moderately improved. *Conclusion*: The group –C patients, treated with KSS and followed with KM procedure were cured early in time as compared to other - A group (KSS treatment alone), and B group (KM treatment only)
Keywords: Anal Stricture; Hemarroidectomy; Anastomosis; Sannirudhaguda Colostomy; PCA Therapy KS; KSS; KM.

Introduction

A fibrotic narrowing of the anal canal is known as Anal Stricture (AS). It is non-malignant in nature. As a result of stenosis, there is difficulty and strain during defecation leading to painful bowel movements. This anal stricture can also be called as anal stenosis. Though it is a medical problem but not common. Usually it happens after anorectal surgery in about 90% of hemorroidectomy, in which the surgery in the area of the rectum and anus; leads to hard or painful bowel movements. This is simulated with Sannirudha Guda (SG) owing to the similar features. The major etiological factors, which are responsible for anal-stricture, can be specified like in the congenital the stricture remains at the level of the anal valves due to incomplete obliteration of the proctodeal membrane.

The etiology of anal stricture are specified that the ano-rectal surgery mainly owing to the operation for imperforate anus in infancy and hemorrhoidectomy while the spasmodic causes by the spasm of anal

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sphincter due to anal fissure, and abuse of laxative drugs for long time .The senile anal stenosis also occurs for chronic internal sphincter contraction and while treating malignant lesions of the pelvis under irradiation with radiation therapy, stenosis may result in 20%. The lymphogranuloma inguinal which is more common in women due to the infection and endometriosis of recto-vaginal septum produces Proctitis and stenosis, and also due to the inflammatory bowel disease like ulcerative colitis and Crohn's disease stricture may be formed .

The stricture is presented with mainly pipe stem or ribbon shape of stool passing, painful defecation with or without bleeding and requiring more laxatives. Under digital examination the stricture is confirmed by a sharp defined shelf-like interruption of the. Biopsy of the stricture lesion is done to exclusion of carcinoma.

The conservative treatment is stool softener with fiber type of foods. Besides this the sphincterotomy, the Anoplasty, Colostomy and Rectal excision and colonel anastomosis are the existing procedures to correct the problem. These methods can be done according to the condition of the stricture; but these are quite invasive and everywhere cannot be possible to undertake the surgery while the recurrence rate is more. The treatment is not affordable and acceptable by all the categories of people due to high cost and apprehension of recurrence.

As per the surveillance study of Indian proctology society about 5-7% of anal stricture cases are found out of which 3-5% has reported and built confidence to receive the treatment. Moreover, surprisingly to note, it has been observed from the version and belief of the victimized patients; once they have been returned with negative result from the medical prevailing surgical treatments; have closed the door of treatment in their mind and taken to lead their life with that curse of disease, because, the qualitative treatments of other medical science like in Ayurveda surgery has not taken such place par in the society with that science due to lack of Government patronization and awareness creation by all medias towards the popularity.

The unsatisfactory results from surgical treatments made us encourage to finding out the solution. The successful result of piles, fistula, and fissure under taken by the PCA therapy are quite significant and now established as one of the best modality of treatment. Keeping in view, the innovative clinical study for the treatment of anal stricture with the PCA therapy was planned and clinically assessed the result from different treatment places.

Aim of the Study

It is to evaluate the efficacy of the KSS procedure and Kshara Malahar under PCA therapy

Material and Methods

Selection of Patients: The total 76 patients were collected from Gopabandhu Ayurveda Mahavidyalaya and Hospital (GAMH) Puri, Center for Care of Ano Rectum Research by Indian System of Medicine and Allied (CCARRISMA) instituted under Indian Proctology Society, Bhubaneswar, Special Ano Rectal camps under Indian Proctology society, Odisha and Institute for Post Graduate Teaching and Research in Ayurveda (IPGTRA) Jamnagar Gujarat; different ROTP, CME training centers and JAS-Hospital Mangalore Karnataka. The period of randomly collection was recorded from 2000 to 2015.

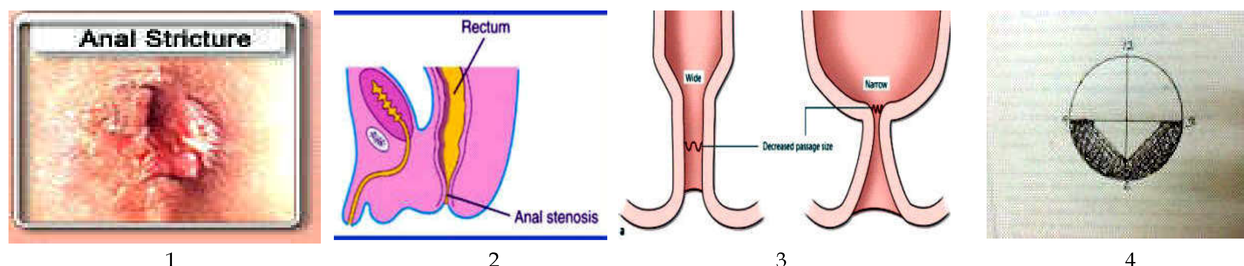
Inclusion Criteria

1. Patients suffering from increasing difficulty with tenesmus in defecation
2. Enhancement in consumption of large doses of mild laxatives
3. Passing of stools in 'pipe-stem' shape.
4. Occasional bleeding with or without mucopus in chronic cases.
5. Age from 5 years to 70 years includes male female and children

Exclusion Criteria

1. Patients suffering from type -1DM
2. Patients with the serious systemic illness like tuberculosis, carcinoma, cardiac disease, advance stage DM and leprosy, HIV
3. Drug non responding in chronic constipate bowel
4. Age below 5 years and above 70 years
5. Obse patients as per standard weight guide
6. Patient suffering from Crohn's disease

Investigation: Routine hematological examinations were conducted before and after treatment to rule out any pathological conditions and biochemical tests like diabetic profile includes fasting blood sugar (FBS), PPBS, HbIAc, lipid profile, renal function test (RFT), uric acid, liver function test (LFT), HIV and Biopsy.



1-Anal stricture, 2-Anal stenosis, 3-Decreased anal passage 4-KSS in stricture lesion

Drugs and Posology

Group-A-Under the A-group 24 patients were selected. Application of Ksharasutra suture (KSS) once in one sitting after manual anal dilatation followed with introduction Jatikshara oil 10 ml one dose at bed time once into anal canal 24 hourly for 15 days and administration of Shallaki Tablet of 500mg thrice daily 8 hourly followed by Maharasnadi Kasaya 15 ml. Daily one dose Erandbhrastaharitaki of 5 gm was given with warm water at bed time to all patients after dinner.

Group –B- This group was dealt with 20 numbers of patients including children. Application of Kshara Malahara (KM) once daily for 7 days after manual anal dilatation in rotating process around the anus followed with above adult dose to adult patients except the children. To the children, introduction of 5 ml Jatikshara oil into anal canal at bed time after trial medicine and the dose of adjuvant –Shallaki tab 500mg -8 hourly followed by10 ml of Maharasndi kasaya and once daily 2 gm of Erandabhrastaharitaki with warm water were given.

Group –C-In the C group 32 numbers of cases had been taken where the A group treatment with B group treatment were given to the patients in order to compare the result. The application of Ksharasutra suture once in one sitting after manual anal dilatation was done and after removal of Ksharasutra on 7th day, the Kshara Malahara was used in the lesion for one week in rotating manner around the anus followed with all above the same managements

PCA therapy (PCA)- PCA therapy denotes to Potential Cauterizing Agents which is the translation of Kshara karma. It is an indirect cauterization potentiated by different caustic agents manufactured from herbs and shrubs having scientific background and comes under Para surgical category. There are various types of agents or devices or products, out of which Kshara Sutra (KS) is the chief device while the Kshara Malahara (KM) is one of them . The products are used in the treatment of different diseases particularly anorectal disorders. Kshara karma though is refused by the text to apply in children, perhaps for irritation and pain, but the close observation from clinical study in piles, fistula, fissure and stricture has showed cured result in recurred cases. Hence the therapy has an extensive field to search the solutions for many approachable diseases beyond the textual advocacy.

Ingredients of Standard Ksharasutra (KS) - The standard ksharasutra prepared from Apamarga (Achyranthes aspera Linn) Kshara 7 times coating, 21 times smeared with Snuhi latex (Euphorbia nerufolia Linn.) and 3 times coated with curcuma (Curcuma longa Linn.) finest powder under the pharmacopeia of india.

Ingredients of Kshara Malahara(KM)

1. Apamarga Kshara- I part,
2. Purified Tutha (cupper sulphate-CuSo4)-1 part,
3. Honey bees wax-5 parts,
4. Curcuma finest powder-3 parts
5. Shatadhaut ghrita as per requirement for ointment base.

Preparation: It was prepared under the pharmaceutical guidelines of ointment and packed.

Ingredients of Shallaki Tablet (ST)

1. Shallaki (Bowellia serrata Roxb.),
2. Nirgundi (Vitex Nirgundo linn), And
3. Rasna (Pluchea Lanceolata); equal part from all drugs were taken.

Preparation: As per pharmaceutical guidelines 500 mg tablet was prepared and packed 50 tablets.

Maharasnadi Kasaya(MRK): It is classical medicine having GMP certified medicine was brought from outside

Jatikshara oil (JKO): The classical ingredients of Jatyadi oil was taken and a proportion of 1:10 i.e. 1part Apamarga Kshara in 10 parts of oil is mixed during preparation .The oil was prepared under the pharmaceutical guidelines of oil manufacturing.

Shatadhauta Ghrita (SDG): This medicated ghrita is classical one which is 100 times purified under the pharmaceutical principles and GMP certified, was procured from standard pharmacy.

Ingredients of Sphatikadi Powder (SP)

1. Sphatika-Potash Alum - one part
2. Khadira-Acacia catechu Wild - one part
3. Karanja Seed-Pongmia pinnata Linn Pierre-one part
4. Dry Neem Seed-Azadirechta indica A.Juss-half part

Preparation and Use

All these drugs are powdered separately and mixed afterwards, then kept in well covered wide faced bottle or in any suitable pot. It is used in the warm water sitz bathe with a dose of 5 gm per sitting. This medicine mainly is having many folds of actions like anti-inflammatory, analgesic, cleansing, haemostatic, which helps to relieve pain, local edema, stop oozing, maintain local hygienic condition, and promotes speed recovery.

Diets: Normal regional diets having plenty of fiber vegetables, fruits, were advised with adequate drinking water and instructed to avoid all constipate food stuffs.

Follow up: The follow up period was carried out for 08 weeks after completion of the treatment to see the longstanding effect of this innovative clinical procedures.

Methods for Treatment

Technique for KSS Operative Procedure

It is an innovative Para surgical research method being practiced in number of cases by the surgeons of Indian Proctology Society and subsequently in post graduate level and assessed the result clinically. The cases where the intervention of surgery is required are selected for PCA therapy. The satisfactory result inspired to transfer the technique from hand to hand surgery method.

Pre-Operative: All the pre- measures for KSL/ hemorrhoidectomy procedure in piles operation case, was adopted here.

Anesthesia: The spinal anesthesia was used in group A & C for operation while local anesthesia was only used in group- B & to group C after one week getting removal of Ksharasutra sutured (KSS) stricture lesion.

Operative Procedures: The lord's manual anal dilatation was made for well visible of stricture lesion. Good-Sall's rule in anus division was followed. The posterior division is divided in two portions. Each stricture portion is treated under sub mucous Ksharasutra ligation procedure. Then continuous suture was given by curved round body needle loaded with standardized Ksharasutra in anal sub mucous stricture lesion from right posterior laterally at 9'o'clock to 6'o'clock, one third portion and continued the same method from 6'o'clock to 3'o'clock, two third portion, i.e. left posterior laterally. The ligated Ksharasutra was removed spontaneously and fell down during the stool passing within 03- 05 days. The standard suture method was adopted i.e. not so proximally or distally suture was given. More bite of anal tissue by suturing takes more days for spontaneous removal. It was observed that more stricture tissue lesion was found in posterior part, and also it was thought that the posterior part of the anus gives more relaxation. The wound was treated with healing ointment and immigration of oil. No slough or fibrosis was allowed to lodge Proper clean dressing was continued till healing with follow up of warm water sitz bathe.

Post–Operative Cares

Group A: Daily dressing with warm water sitz bath 8 hourly, followed by Jatikshara oil-10 ml irrigation into anus after removal of ksharasutra and used laxative Erandabhrastharitkai 5gm with warm water at bed time.

Group B: Daily dressing with warm water sitz bath and laxative followed as per above planned dose with oil irrigation

Group C: The same pre and post operative measures of Group –A was maintained, but on 7th day Kshara Malahar was used in the lesion for one week followed with irrigation of Jatikshara oil 10 ml one dose at bed time into anal canal once 24 hourly for 2 weeks.

Technique for application of Kshara Malahara (KM): The bowel was clearly evacuated. After ensuring complete evacuation of bowel, about 10 ml 2% Xylocaine jelly was introduced into anal canal with its nozzle, 5-10 minutes waited for the effect of anesthesia. The Kshara ointment was applied once daily morning after manual anal dilatation , with a globed finger in rotating method for a period of 7 days followed with irrigation of Jatikshara oil as per above procedure.

Criteria for Assessment of Results: The overall effect was assessed as per the following criteria on the basis of relief in chief complaints as only subjective criteria.

Complete remission - 100%

Marked improvement -<100% > 75% relief

Moderately improvement -75%> 50% relief

Mild improvement -50%>25% relief

Unchanged -25%-0% relief

Observation

The study analysis revealed the incidence of sex, age, chronicity of disease, treatment factors etc. Out of 76 patients the maximum patients 72% were male while 27.65% were female patients and 63% belonged to age between 31 to 56 and 25 % age between 56 to 70 where as 12% belonged to age between 5to 30.The maximum 71% of cases were having 1to 5 years of chronicity while 28% of cases were suffering from more than 5 years of chronicity. As regards of reoccurred cases after operation 46% was found, out of which 52 .6% was male and 7.8% were female. The chief complaint case of painful tenesmus stool passing was maximum 54%; pipe-stem passing stool case was 32% where as 12-6% cases were having bleeding per rectum with stool. n relation to nature of diet more patients 73% were found non vegetarian following to constipation and irregular bowel habit with delay of stool passing. Regarding the addictions there were number patients i.e. 62% were found smoking with irregularly regular alcohol drinking and spending maximum time in latrine to pass the stool. In regard of bowel consideration maximum number 83% of patients had reported the constipate bowel. The majority 42% of patients in group C, while 31.5% of cases in group A and 15% of cases were treated under group B. In treatment it was observed that maximum cases 73.6% had undergone of KSS procedure where as 26% of cases had the treatment with KM followed by the same managements. The spontaneous removal of KS in the KSS procedure was observed maximum 65.7% of cases on 4th day of treatment. It was noted that maximum number 89 % of patients had complete ambulation while 6.5% of patients had partial ambulation and 3.5 % had non ambulation in the 1st week of treatment. The pain was relieved 99% of cases in group C on 14th day where as 88% pain in group A and 74% in group B. The healing of anal wound was found 86.7% in group C while 76% was in group A and 71% in group B. The study was keenly observed from all aspects with regard to the treatment, diet, social behavior, mental status etc.

Results

The overall result was quite effective. The assessment of result in the group-C was 98.7% success and in the group- B it was 68.8% while in group –A the result was assessed 84%. The group C treated with the KSS procedure and KM showed the maximum benefit to the patients due to both procedures had continuous action to remove the stricture lesions from the anal area. Totally 89% cases were cured while 6.5% cases of group B marked improvement after 1st week of treatment and 2.6% cases of group A had moderately improved while 1% of case got complication of abscess tending to sinus which was treated immediately under PCA therapy and got cured later on.

Discussion

Maximum number of patients 72% was found male and also 63% belonged to age group between 31 to 56. It can be inferred that young middle –aged patients are more sufferer because they bear more family burden; they usually consume irregular diets with fast foods like junk and spice foods, outsides foods as per availabilities to spare more time for fulfilling their responsibilities. Number of male patient is more; the reason might be the more awareness about the disease and consciousness towards health. Among male in comparison to female, the female patients are also shy and hesitate to consult a surgeon and neglect their health due to many factors. The incidence of habit of prolong sitting was reported in 74%. This could be a cause for disease, due to constant pressure on the pelvic region which results to exert the referral pressure on the blood vessels, so as to manifest the predisposing factor for the disease. The 83% of patients were observed to be having irregular bowel habit which might be due to indigestion and improper digestion of foods leading to constipation develops the mind set for delayed defecation by exerting pressure in anal region and in long run might be losing the normal tonicity of anorectal tissue gives rise to abnormal tissue. The spontaneous removal of KS leads to a fresh anal wound supporting to normal granulation and maximum patients showed wound healing after 03 weeks. Daily dressing with close observation helped to avoid the hyper or hypo granulation. Therefore this clinical study favors the principles of wound healing that the clean and healthy wound takes minimum 03 weeks or 21 days for complete healing. Moreover the anal wound is a restless ulcer and the area remains alert in action form.

The warm water sitz bath with the addition of Sphatikadi powder and instillation of jatikshara oil per ano rectal definitely helped to achieve the conditions of cleaning and healing of the wound. During the treatment period, the general heath conditions with systemic disorder if any found was maintained for well nourishment of the body.

The wound healing was found better in group –C than group –A and less in group-B, because sphincter muscle spasm became more relaxed in group –C due to both treatment of KSS and KM. The application of KM acted to remove the entire anal stricture lesion around the anus, and allowed for developing the normal physiology which helped in early healing. It was observed that in group –A, and - B the changing developmental conditions in wound cleaning with healing took little more time in comparison to group –C due to presence of some sphincter spasm even after KSS; as complete relaxation could not be achieved without KM application after the removal of KS. It became clear that both KSS and KM treatment made the stricture lesion complete removal of fibrotic tissue relaxation of sphincter muscle, free from spasm and soothing environment which provided necessary rest for cleaning and healing of the wound. In cases of group –A and C, slight oozing in the form of serous discharge was marked from the raw and clean wound of tissue bed after removal of KS. The smeared Latex and coated Kshara on the standardized KS is alkaline in nature having – pH -10.39, which is capable to inhibit the bacterial growth. Thus the created wound after cut through and spontaneous removal of KS was found clean and non infected wound. Maximum patients of in group A and C had relief from oozing within the postoperative day and few patients had taken 02 weeks to cease oozing. The serous discharge was created due to the inflammation present around the anal wound in early stage, but irrigation of Jatikshara oil into anal canal daily helped to control the oozing.

Maximum in 65.78% patients of KSS at anal stricture lesion sloughed out spontaneously on 4th postoperative day while 07.89% patients were observed sloughing out of KS on 5th postoperative day. The sloughing out of sutured KS was taken almost similar time in both A & C group of cases. The KS is an absolutely mechanical phenomenon and there was no significant role of anal dilatation done before the procedure in all groups. Bleeding was stopped after KSS in all patients within a week as removal of anal stricture had taken place contributing a clean and healthy wound. The oozing in the form of serous discharge was considered as an important parameter to assess the effective result of KSS. It can be inferred that the KSS was effective to stop the bleeding as the anal stricture lesion was removed and no further trauma occurred to the healthy wound. And also it was observed that there was bleeding per rectum nil, in maximum cases of group–B after application of KM except in few cases which was stopped in second week.

Every procedure including surgical and Para surgical has its own limitation with advantages and disadvantages. In 1% of case had complication with abscess leaded to sinus which was treated with Ksharasutra threading /tying (KST) procedure like the fistula treatment. As there were minor complication and patients were cured completely; but they required little bit more time for getting complete relief and shown moderate and mile improvement.

Probable Mode of Action of Ksharasutra Suture (KSS)

The patients of group –A & B were treated with KSS procedure. The Ksharasutra contains Apamarga Kshara, Snuhi latex and curcuma powder The mechanical action of this medicated thread and chemical actions of the drugs smeared and coated collectively do the work of mainly cutting, curetting, and cleaning of the scar/fibrotic tissues from the stricture lesion by sloughing out and creating fresh wound thus promotes healing with granulation of the anal wound. It also helps to act as antiseptic agent to induce healing. In fact, the healing process starts from the level of deeper tissues and moves towards the periphery.

Probable Mode of Action of Kshara Malahara (KM)

The Kshara Malahara contains Kshara having the pH-8.5. It is least irritant and palatable pain reducing agent. All the patients in group-B from very beginning, & group - C, after 07 days over removal of KS were treated with KM procedure as per plan of the study. The ingredients of KM dissolved, scrapped layer by layer with continuous effect of curetting the fibrous tissue bed from the stricture area and honey bees wax stimulated the part for healthy granulation and the Shatadhauta ghrita supported the part for the widening the anal way by its fat action. It helped for better dissolving and scrapping the fibrotic tissues of stricture, surrounded to the anal region by its permeable capacity and no infection was made by the action of Kshara, making the anal wound clean in slow and steady process for healing after the KS removal. The KM maintained continuous aseptic condition, leads to develop the tonicity of anal muscle power. It developed the healthy granulated tissues replacing the undesired scar tissues from the base level surrounding of anus and allowed the tissues

for normal function and provided antispasmodic, neurologic nourishment to the anal sphincter muscle in case of hypertonic anal sphincter by regulating the tissues action due to the best effect of Shatadhauta ghrita. The sustainable fat action in ghee helped to grow the elasticity of the tissues which brought the normal tonicity of sphincter muscle.

Probable Mode of Action of Adjuvant Drugs

Shallaki tablet and Maharasnadi Kasaya contain analgesic anti inflammatory, digestive and mild laxative drugs which helped to relieve not only pain, but also improved digestion followed by bowel evacuation. The laxative Erand bhrastharitaki has been indicated for removal of constipation with reduction of anal spasm. Haritaki (Terminalia chebula Ritz) and Eranda (Ricinus communis Linn) have the laxative property and rendered an action of easy and smooth evacuation of stool by regulating neurological spasms. The Sphatikadi Powder was used for warm water sitz bath has antiseptic, haemostatic, anti inflammatory and analgesic effect which helped to relieve pain, local edema stop oozing and maintained perianal hygiene. It promoted for cleaning and healing of the anal wound.

Advantages of PCA Therapy over Other Surgical Procedures for Anal Stricture

This PCA therapy is simple and non-invasive and low cost effective; it can be affordable for all common people. The treatment option can be taken without fear and apprehension of postoperative complications like incontinence, recurrence and retention of urination. It takes less duration for complete wound healing. There is no need of skin grafting as wound heals within time. This therapy is ambulatory; hence no social burden to others. There is least complication like abscess, subcutaneous sinus /fistula which can be successfully treated without further adverse effect.

Conclusion

The group –C patients treated with Ksharasutra suture (KSS) and Kshara Malahara (KM) application had less postoperative pain and were cured early as compared to other groups. Healing of post operative wound was within 03 weeks in both groups A&C where as 04 weeks took in group –B. The overall effect of this therapy was observed that all the patients were cured except few of them with improvement within time. No adverse effect of any drug or untoward effect of the PCA therapy were noticed during or after the treatment even up to the follow up of period. Therefore it can be recommended that this PCA therapy consisting of KSS with KM procedure can be practiced as one of the modalities for the treatment of anal stricture.

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