ORIGINAL ARTICLE

A Prospective Interventional Study To Test Efficacy Of Perfact Procedure In The Treatment Of Perianal Fistulas.

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ABSTRACT

Introduction: A prospective interventional study to test efficacy of PERFACT procedure in the treatment of perianal fistulas.

Materials And Methods: All patients with fistula in ano operated by THE PERFACT PROCEDURE were enrolled in a prospective interventional study starting from December 2016 to December 2017. Last case was enrolled in September 2017 to have a 4 month follow up period.

Sample size: 20

Inclusion criteria: all cases of perianal fistulas were included in this study

Exclusion criteria: patients not consenting to get enrolled in the study

Patients below 13 years of age

Methodology: All cases to be operated by PERFACT PROCEDURE were followed up post procedure with daily dressings and the outcome wasdocumented in context with the three criteria's:

Post-operative pain

Recurrence or persistence of fistula/ patients requiring a redo surgery

Continence levels following the procedure

Results:

1. 20 cases were included in the study with a female to male ratio of 16:4. The mean age being 35 years +/-12.8 years with a maximum age of 62 and a minimum age of 22.
2. According to parks classification among the 20 cases included in the study 75% were intersphincteric, transsphincteric (15%), supralevator (10%).
3. Among the 20 cases operated, 16 cases healed (80%), 1 case did not heal (5%), 1 case healed but recurred within four months (5%), 2 cases were lost to follow up (10%). All the 16 cases healed within 4-8 weeks.
4. Among the 20 cases, cases with no associated MRI findings (simple fistulas) were 5, out of which 4 cases healed and 1 case was lost to follow up.
5. Cases with 1 associated MRI finding were 7, of which 6 cases healed, 1 was lost to follow up.
6. Cases with 2 associated MRI findings were 5, out of which 3 cases healed, 1 did not heal, 1 case did heal but showed recurrence at the end of four months.
7. Cases with 3 associated MRI findings were 3, of which all 3 cases healed.
8. In this study postoperative pain has been measured using the visual analogue scale. In all the operated cases VAS score is 0
9. In this study the continence levels were assessed by directly asking the patients in the postoperative period. Among all the 20 cases, none of the patients had any continence issues.

Conclusion: The above study has thus proven the efficacy of the PERFACT PROCEDURE in treatment of both simple as well as complex perianal fistulas.

Keywords: Perianal fistula, Perfact procedure, continence, recurrence, VAS score.

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INTRODUCTION:

Fistula is the Latin word for a reed, pipe or flute. In medicine a fistula is defined as an abnormal communication between two epithelium lined surfaces. Anal fistulas are abnormal communications between the anal canal and the perianal skin or perineum. They are associated with considerable discomfort and morbidity and patients will frequently have cyclic periods in which the external fistula opening temporarily closes causing pain and swelling until the external fistula opening opens again leading to release of purulent material or blood. The incidence of anal fistulas varies between 0.86 and 2.32 per 10.000/year(1) There is a male predominance with ratios varying from 2:1 to 5:1(1).

Fistula in ano are a troublesome and recurrent problem for the patient and may require repetitive surgeries. Anorectal sepsis is usually complicated by fistulas in 25% of the cases during the acute phase or within 6 months thereafter. Most fistulas are caused by sepsis originating in the anal canal glands at the dentate line (cryptoglandular hypothesis). The path of the fistula is determined by the local anatomy.

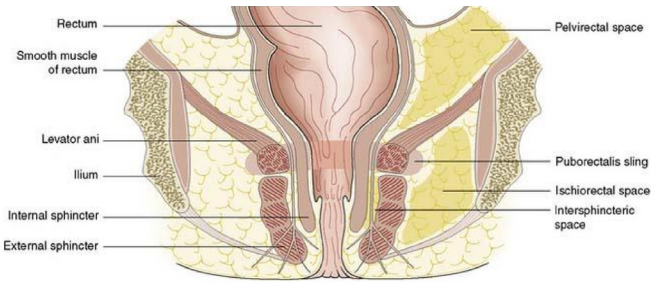


Fig1: anal canal anatomy

Anatomical classification for perianal fistulas was first described by PARK (1976) and is given as follows

Intersphincteric: most common type. Fistula track is confined to the intersphincteric plane

Transsphincteric: the track connects the intersphincteric plane to the ischiorectal fossa by perforating the external sphincter

Suprasphincteric: the track loops over the external sphincter and perforates the levator ani

Extrasphincteric: track passes from rectum to perianal skin completely external to the sphincter complex(2)

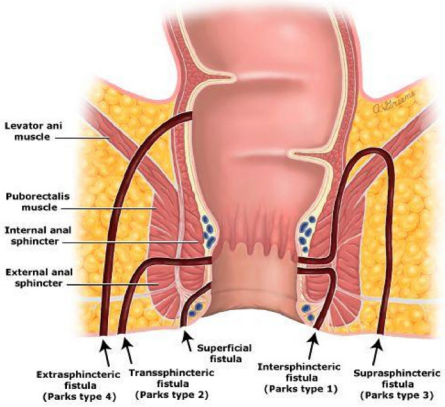


Fig2: Types of fistulas

Various procedures have been developed over the years for the treatment of fistula in ano, but the primary objective of all these procedures remains the same that is to eradicate the track and drain all associated sites of infection while simultaneously preserving anal continence.

- Fistulotomy n fistulectomy still remain the mainstay for treatment of anal fistulas
- Mucosal flap procedures
- Seton technique
- LIFT technique: ligation of intersphincteric track
- VAAFT: video assisted anal fistula track ligation
- Latest techniques include closing the track using FIBRIN GLUE or PORCINE SMALL INTESTINAL SUBMUCOSAL (SIS) PLUG.
- PERFACT PROCEDURE (PROXIMAL SUPERFICIAL CAUTERIZATION OF INTERNAL OPENING REGULAR EMPTYING OF THE FISTULA TRACK AND CURETTAGE OF THE TRACK).(2)

This study is a prospective interventional study to test the efficacy of the PERFEACT PROCEDURE in the treatment of perianal fistula.

PERFACT PROCEDURE:

This is another novel, sphincter saving procedure devised by Chandigarh based colorectal surgeon Dr Pankaj Garg for the treatment of anal fistulas.

PERFACT Procedure (Proximal superficial cauterization, Emptying Regularly of Fistula tracts And Curettage of Tracts) (3)

The procedure entails two steps: superficial cauterization of mucosa at and around the internal opening and keeping all the tracts clean. The principle is to permanently close the internal opening by granulation tissue. This is achieved by superficial electrocauterization at and around the internal opening and subsequently allowing the wound to heal by secondary intention. Along with this, all the tracts are curetted and it is ensured that they remain empty and clean in the postoperative period until they heal completely. The latter step also facilitates the closure of the internal opening by preventing collected fluid in the tracts from entering the internal opening and thus not letting it close. The PERFACT Procedure was presented at the annual conference of the American Society of Colon and Rectal Surgeons (ASCRS) held in Miami, Florida, USA on May 21, 2014.(3)

There is no satisfactory treatment of complex fistula- in-ano to date. A fistula-in-ano is termed "complex" when the track crosses > 30%-50% of the external sphincter (high-transsphincteric, suprasphincteric and extrasphincteric), is anterior in a female, is recurrent, has multiple tracks, or the patient has preexisting incontinence, local irradiation or Crohn's disease. The two main issues in managing such fistulas are to minimize the recurrence rate and prevent any deterioration in continence levels.(4)

AIMS AND OBJECTIVES

To test the efficacy of THE PERFACT PROCEDURE in the treatment of perianal fistulas based on the following three criteria:

Post-operative pain

Recurrence or persistence of fistula/ patients requiring a redo surgery

Continence levels following the procedure

METHODS

All patients with fistula in ano operated by THE PERFACT PROCEDURE were enrolled in a prospective observational study starting from December 2016 to December 2017. Last case was enrolled in September 2017 to have a 4 month follow up period.

Sample size: 20

Inclusion criteria: all cases of perianal fistulas were included in this study

Exclusion criteria: patients not consenting to get enrolled in the study

Patients below 13 years of age.

PROCEDURE: The PERFACT procedure had three steps (1) proximal superficial cauterization: the area around the internal opening was freshened and de- epithelized by electrocautery and the wound was encouraged to heal by secondary intention (granulation tissue). This usually closed the internal opening in about 10-12 d; (2) curettage of tracts: all the tracts were

thoroughly curetted and debrided of their lining with a curette; and (3) emptying regularly fistula tracts: the curetted tracts were kept clean and empty of any serous fluid so as to ensure that the tracts healed (closed) by granulation tissue. Keeping all the tracts clean until they healed completely was a challenging task and the most demanding step of the procedure. It took 4-8 week (occasionally even longer) for all the tracts to heal fully. Until that time, regular cleaning of the tracks was done.

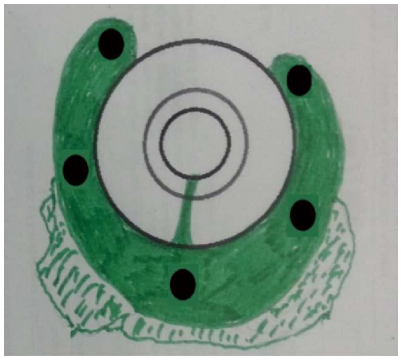


Fig3: preoperative MRI showing complex fistula

To ensure proper cleaning of the tracts, the following steps (one or multiple depending upon the requirement and fistula characteristics) could be done in a patient: (1) multiple holes were made along the straight or the horseshoe track in such a way that the farthest corner of the track could be cleaned with ease; (2) the external opening was widened and the scarred puckered skin (if present) was excised. The aim was to make the opening bigger than 1 cm × 1 cm. This facilitated cleaning of the tracts for a longer duration; and (3) loose seton or tube were put in the tracts to prevent the premature closure of the external opening. These were removed 10-12 d after the operation.(4)

Intraoperative- A saddle block (spinal anaesthesia) or a short general anaesthesia was given. The patient was positioned in a lithotomy or a prone jack-knife position. The internal opening was localized. This was facilitated by injecting saline, povidone iodine or hydrogen peroxide through the external opening.

Proximal superficial cauterization was carried out with electrocautery around the internal opening, cauterizing only the mucosa and superficial part of the internal sphincter. The crypt glands, the internal opening and the tissue around it were cauterized. This usually resulted in an oval area, approximately 1 cm (wide) and 2 cm (long), with the internal opening at the centre of the wound. After cauterization, the wound was left as such and no attempt was made to close the internal opening with any suture, stapler, glue or plug.(4)

After this, the tracts were curetted in accordance with the MRI diagram and the tract lining was scraped out as much as possible with a blunt curette. While doing so, a finger was kept in the rectum so as to ensure that the curette did not accidentally perforate the rectum. He/she could resume all his/her normal activities on the same day.

Fig4: Intraoperative pic

Postoperative cleaning aimed at healing two areas:

the cauterized wound in the anal canal (around the internal opening) and the curetted tracts. The former was pivotal as the closure of the internal opening depended upon it and generally took about 10-12 d to heal. The latter was also needed for the complete closure of the fistula and took a variable time (4-8 weeks) depending on the fistula characteristics (number, length and complexity of the tracts) and the patient co-morbidities (diabetes, anaemia, hypoproteinaemia etc.)

The cleaning process entailed cleaning the cauterized wound in the anal canal and regular cleaning and emptying of the curetted tracts. The former was done by gentle rubbing of the wound by doing a per rectal finger insertion. The latter was done by a cotton swab mounted on an artery forceps. No povidone iodine, hydrogen peroxide or any liquid was injected in to the tract during the cleaning process as this would have prevented the internal opening from closing. The cleaning was done by a trained nurse, a medical attendant or a relative. In our setting, teaching a relative was an economical and preferred option. The cleaning process was done four times a day. For the first 10 d, the patient was called to the outpatient clinic for supervised cleaning once or twice a day depending upon the complexity of the fistula. After this, the patient could do the cleaning process at home.(4)

Fig5: 15 days post-operative

Fig 6 : 6 months post op pic

Methodology: All cases to be operated by PERFACT PROCEDURE were followed up post procedure with daily dressings and the outcome was documented in context with the three criteria as already mentioned above

Postoperative pain

Recurrence or persistence of fistula/ patients requiring a redo surgery

Continence levels following the procedure

Each case was documented in detail, the presenting symptom, whether presented with a fistula for elective surgery or presented with an abscess in emergency setting and later requiring a fistula surgery, MRI fistulogram of every patient to specify the exact track of the fistula, post procedure any complication mainly pain n faecal incontinence.

Statistical Analysis: All the data collected was analysed using MICROSOFT EXCEL SHEETS inbuilt with statistical tests.

Data distribution using simple tests like mean and percentage was used.

End Point : The end point of the study was a comprehensive review of all cases of perianal fistula operated by PERFACT PROCEDURE. It will enable us to understand the efficacy of PERFACT PROCEDURE in correcting perianal fistulas.

RESULTS

1. Age And Sex Distribution:

20 cases were included in the study with a female to male ratio of 16:4. The mean age being 35 years +/-12.8 years with a maximum age of 62 and a minimum age of 22.

Data Distribution According To Sex

	Frequency	Percent
Valid 1 Male	16	80.0
2 Female	4	20.0
Total	20	100.0

Table1: Data distribution according to sex

Data Distribution According To Age

Frequency	Percent	Valid Percent	Cumulative Percent
22	2	10.0	10.0	10.0
25	1	5.0	5.0	15.0
26	1	5.0	5.0	20.0
29	1	5.0	5.0	25.0
30	1	5.0	5.0	30.0
Valid 32	1	5.0	5.0	35.0
34	3	15.0	15.0	50.0
36	1	5.0	5.0	55.0
45	3	15.0	15.0	70.0
48	1	5.0	5.0	75.0
49	1	5.0	5.0	80.0
55	1	5.0	5.0	85.0
59	2	10.0	10.0	95.0
62	1	5.0	5.0	100.0
Total	20	100.0	100.0	

Table2. data distribution according to age

2. Type of Fistula:

In this study all the fistulas have been classified in two ways:

· PARKS classification

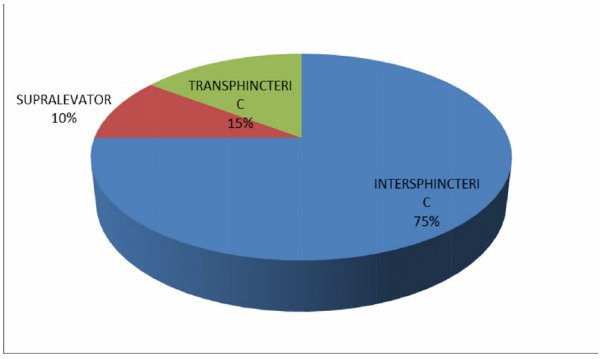
· According to MRI findings: presence or absence of abscess, multiple tracks, horseshoe shaped fistula

According to parks classification among the 20 cases included in the study 75% were intersphincteric, transsphincteric (15%), supralevator (10%).

Type of Fistulas (Parks Classification)

	Frequency	Percent
INTERSPHINCTERIC	15	75.0
SUPRALEVATOR	2	10.0
TRANSPHINCTERIC	3	15.0
Total	20	100.0

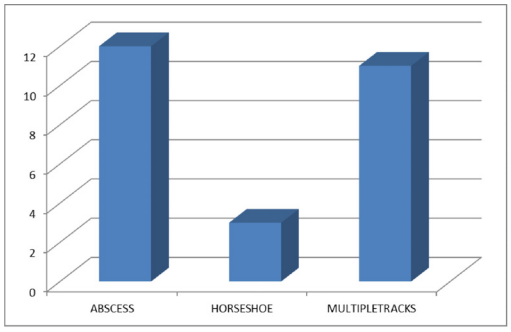
Table3: data distribution according to type of fistula



Graph1: distribution of types of fistula

According to the MRI findings, among the 20 cases 11 had multiple tracks (55%), 12 had associated abscesses (60%), 3 had horseshoe abscess (15%).

Among the 20 cases 5 cases were simple fistulas had no associated finding (25%), 7 cases had one of three findings (35%), 5 cases had two of three findings (25%), 3 cases had all three associated findings (15%).



Graph2: Data distribution of findings on MRI

3. .Data Distribution According To Outcome:

Among the 20 cases operated, 16 cases healed (80%), 1 case did not heal (5%), 1 case healed but recurred within four months (5%), 2 cases were lost to follow up (10%). All the 16 cases healed within 4-8 weeks.

Among the 20 cases, cases with no associated MRI findings (simple fistulas) were 5, out of which 4 cases healed and 1 case was lost to follow up.

Cases with 1 associated MRI finding were 7, of which 6 cases healed, 1 was lost to follow up.

Cases with 2 associated MRI findings were 5, out of which 3 cases healed, 1 did not heal, 1 case did heal but showed recurrence at the end of four months.

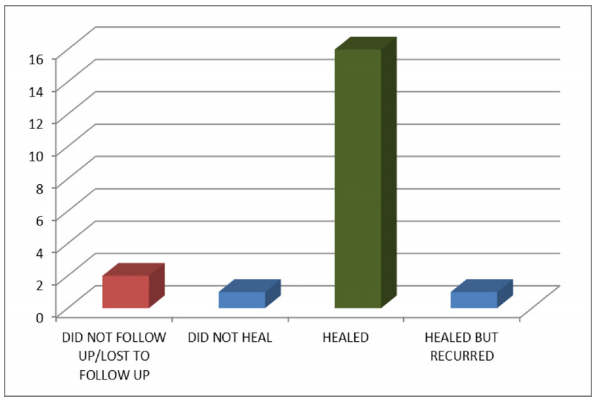
Cases with 3 associated MRI findings were 3, of which all 3 cases healed.

Fistulas As Mentioned Above Have Been Classified According To Their Mri Findings

Data Distribution According To Outcome Of Different Types Of Fistulas

		Outcome		Total	
	Did Not Follow Up /Lost To Follow Up	Did Not Heal	Healed	Healed But Recurred	
MRI_finding	.00	1	0	4	0	5
	1.00	1	0	6	0	7
	2.00	0	1	3	1	5
	3.00	0	0	3	0	3
Total	2	1	16	1	20	

Table4 : Data distribution of outcome of different types of fistulas



Graph3: Data distribution of post op outcome

4. Data Distribution According To Post Operative Pain And Continance Level:

In this study the efficacy of the PERFACT procedure has been tested on three criteria

- Postoperative pain
- Continence level after surgery
- Recurrence/persistence at the end of four months

In this study postoperative pain has been measured using the visual analogue scale. In all the operated cases VAS score is 0. In this study the continence levels were assessed by directly asking the patients in the postoperative period. Among all the 20 cases, none of the patients had any continence issues.

Data Distribution Of Post Operative Pain

Post Operative Pain Measured According To Vas Scoring

	Frequency	Percent	Valid Percent	Cumulative Percent
Valid VAS 0	20	100.0	100.0	100.0

Table 5: data distribution of postoperative pain

Data Distribution Of Faecal Incontinance If Any Following The Procedure

	Frequency	Percent	Valid Percent	Cumulative Percent
Valid 2 No	20	100.0	100.0	100.0

Table 6 : Data distribution of post op faecal incontinence

Data Distribution Of Recurrance/Persistance At The End Of Four Months

	Frequency	Percent	Valid Percent	Cumulative Percent
1 Yes	2	10.0	11.1	11.1
Valid 2 No	16	80.0	88.9	100.0
Total	18	90.0	100.0	
System	2	10.0		
System				
Total	20	100.0		

Table 7 : Data distribution of recurrence/persistence at the end of four months

DISCUSSION

Before this study only two studies have been reported by Dr Pankaj Garg , the inventor of this procedure, in which he has proven its efficacy in the treatment of complex fistulas.

1. First study: PERFACT procedure: a new concept to treat highly complex anal fistulas. It was published in 2015 in WORLD JOURNAL OF GASTROENTEROLOGY, and included total sum of 51 patients.(4)

2. Second study: PERFACT procedure to treat supralevator fistula in ano. It was published in 2016 in WORLD JOURNAL OF GASTROENTEROLOGY, and included total sum of 17 patients.(5)

This study has included all types of fistulas simple and complex, hence proving its efficacy in treatment of perianal fistulas. All the results of this study will be compared to the results of the above two mentioned studies.

1. Age And Sex Distribution: 20 cases were included in the study with a female to male ratio of 16:4. The mean age being 35 years +/-12.8 years with a maximum age of 62 and a minimum age of 22.

In the first study Fifty-one patients with complex fistula-in-ano were prospectively enrolled. The median follow-up was 9 mo (5-14 mo). The mean age was 42.7 ± 11.3 years. Male:female ratio was 43:8.(4)

In the second study 17 patients were enrolled for a median of 13 mo (3-21 mo). Mean age: 41.1 ± 13.4 years, M:F - 15:2. (5)

2. Type Of Fistula: In this study all the fistulas have been classified in two ways:

- PARKS classification
- According to MRI findings: presence or absence of abscess, multiple tracks, horseshoe shaped fistula

According to parks classification among the 20 cases included in the study 75% were intersphincteric, transsphincteric (15%), supralevator (10%).

Even in the literature about perianal fistulas the most common type encountered is the intersphincteric type, which is consistent with the above finding. (6)

All the patients in both the comparative studies were complex anal fistulas , so all belonged to type 3(supra levator)type. (4)(5)

According to the MRI findings, among the 20 cases 11 had multiple tracks (55%), 12 had associated abscesses (60%), 3 had horseshoe abscess (15%).

Among the 20 cases 5 cases were simple fistulas had no associated finding (25%), 7 cases had one of three findings (35%), 5 cases had two of three findings (25%), 3 cases had all three associated findings (15%).

In the comparative First study: The fistula characteristics were recurrent in 76.5% (39/51), horseshoe in 50.1% (26/51), multiple tracts in 52.9% (27/51), associated abscess in 41.2% (21/51) and anterior fistula in 33.3% (17/51). The internal opening could not be definitely traced intraoperatively in 15.7% (8/51) and there was associated supralevator extension in 9.8% (5/51) .(4)

In the second comparative study: Fourteen (82.4%) had a recurrent fistula, 8 (47.1%) had an associated abscess, 14 (82.4%) had multiple tracts and 5 (29.4%) had horseshoe fistulae.(5)

3. Data Distribution According To Outcome: Among the 20 cases operated, 16 cases healed (80%), 1 case did not heal (5%), 1 case healed but recurred within four months (5%), 2 cases were lost to follow up (10%). All the 16 cases healed within 4-8 weeks.

Among the 20 cases, cases with no associated MRI findings (simple fistulas) were 5, out of which 4 cases healed and 1 case was lost to follow up.

Cases with 1 associated MRI finding were 7, of which 6 cases healed, 1 was lost to follow up.

Cases with 2 associated MRI findings were 5, out of which 3 cases healed, 1 did not heal, 1 case did heal but showed recurrence at the end of four months.

Cases with 3 associated MRI findings were 3, of which all 3 cases healed.

In the first comparative study: The fistula and all the associated tracts healed completely in 79.5% (35/44) of patients and there was recurrence of symptoms in 20.5% (9/44) of patients. Out of these, three underwent reoperation (two PERFACT procedure, one fistulotomy) and all three were successful. The subgroup analysis showed that although the presence of multiple tracts and an abscess reduced the cure rate, it was not statistically significant (Fisher exact test $P > 0.05$). The only complication was a non-healing tract in 9.1% (4/44) of patients.(4)

In the second comparative study: Out of 15 patients, 11 (73.3%) were cured and four patients (26.7%) had a failure of treatment. All the patients with recurrence had transsphincteric supralevator extension. Two patients with recurrence were re operated on with the same procedure and one was cured. Thus, the overall healing rate was 80% (12/15).(5)

4. Data Distribution According To Post Operative Pain And Continance Level: In this study the efficacy of the PERFACT procedure has been tested on three criteria

- Postoperative pain
- Continence level after surgery
- Recurrence/persistence at the end of four months

In this study postoperative pain has been measured using the visual analogue scale. In all the operated cases VAS score is 0

Even in the two comparative studies there is no significant postoperative pain(4)(5)

In this study the continence levels were assessed by directly asking the patients in the postoperative period. Among all the 20 cases, none of the patients had any continence issues. In the first and second comparative studies, similar findings were seen.

CONCLUSION

The above study has thus proven the efficacy of the PERFACT PROCEDURE in treatment of both simple as well as complex perianal fistulas.

To conclude, the PERFACT procedure is a simple novel method to treat simple and complex and highly complex anal fistula. Complex fistulas include fistula-in-ano with multiple tracts, horse shoe fistulas, recurrent fistulas, anterior fistula in females, supralevator fistula, fistula where internal opening cannot be localized and as a first line definitive procedure in patients with fistula-in-ano presenting with ischiorectal or perianal abscess. However, long term multicentre trials are needed with larger numbers of patients to substantiate these findings.(4)

REFERENCE

1. Chapter:Anal fistulas. Denis J, du Puy-Montbrun T, Ganansia R. Vol. 35, La Revue du praticien. 1985. 3442-8 p.
2. Chapter.Anus. Amit M, David L. Vol 2, Sabiston textbook of surgery 1394-1417 p.
3. New procedure to treat Complex Anal Fistula | India Medical Times [Internet]. [cited 2017 Nov 23]. Available from: http://www.indiamedicaltimes.com/2015/05/06/new-procedure-to-treat-complex-anal-fistula/
4. Garg P, Garg M. PERFACT procedure: A new concept to treat highly complex anal fistula. World J Gastroenterol. 2015;21(13):4020–9.
5. Garg P. PERFACT procedure to treat supralevator fistula-in-ano: A novel single stage sphincter sparing procedure. World J Gastrointest Surg [Internet]. 2016;8(4):326. Available from: http://www.wjgnet.com/1948-9366/full/v8/i4/326.htm.
6. Chapter:Rectum and Anal canal.Bhat S. SRB's Manual of Surgery. Fourth edition. 888-927 p.

DECLARATION

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