

# Proximal Anal Sinus Resection as an Advanced Operation to Fistulectomy and Seton for Reducing Recurrence Rate

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## Research article

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# Abstract

**Background** The recurrence rate of classic surgery for anal fistula has always been one of the troublesome problems. The purpose of this study was to mainly compare the recurrence rate between classic surgery (fistulectomy or seton) and proximal anal sinus resection (PASR) in case-control study.

**Methods** 106 patients who suffered from anal fistula were taken into classic surgery group (n=74) and PASR group (n=32), Then we analyzed the recurrence rate, wound healing time, surgical complications, and duration of the pain.

**Results** There was a significant difference in the recurrence rate between classic surgery group and PASR group (16.2% vs 0%). The duration of pain, mean healing time and surgical complications in the two groups had no significant difference ( $P>0.05$ ).

**Conclusion** PASR had shown lower recurrence rate and did not increase the risk of complications, and could be considered as a first line of treatment for patients at risk of recurring for anal fistula.

## Background

Anal fistula is the common disease of the anorectal surgery. According to previous report, the incidence of anal fistula in European rang from 0.01% to 0.02%.<sup>1</sup> Most anal fistula is secondary to the perianal abscess and forms an invisible fistula that connects the anorectal mucosa and the perianal skin. In general, anal fistula will not heal spontaneously, most of which need to be treated with surgery. The propose of the surgery is to eliminate local **pyaemia**, promote fistula healing and protect the function of **sphincter** contraction.<sup>2</sup>

The most common operations performed for anal fistula are the fistulotomy, **fistulectomy** and seton therapy. Surgical treatment of fistula-in-ano is associated with a significant risk of recurrence,<sup>3</sup> in previous studies, the recurrence rate of anal fistula caused the attention of many surgeons. A meta-analysis showed that the recurrence rate of anal fistula after operation was between 10% and 57%.<sup>4</sup> The three-year recurrence rate of low anal fistula treated with fistulotomy was 7%,<sup>5</sup> another study analysed a series of 279 patients who had undergone anal fistula surgery, recurrence were occurred in 7.2% patients.<sup>6</sup> In a large-scale multi-center study, a total of 537 patients with low anal fistula who underwent fistulotomy, 88(16.4%) of whom recurred after sugery operation.<sup>7</sup> Compared to other anal fistula operations, **fistulectomy** showed the lowest postoperative recurrence rate,<sup>8</sup> as anal fistulectomy are relatively safe, simple and widely used in surgery, however, anal fistulectomy is only suitable for simple low anal fistula, and the application of fistulectomy in complex anal fistula is limited. Other surgical methods such as anal plug has been put forward in recent years.<sup>9</sup> The anal plug presented vastly different recurrence rate, which range from 27% to 84%.<sup>10,11</sup>

Surprisingly, anal glands infection is considered to be one of the most common causes of anal fistula.<sup>12</sup> There are 8 to 12 glands located between, outside or inside the sphincter, opening to the dentate line and looped around. When those glands are infected, it can cause fistula subsequently. It is hypothesized that the infection of anal glands is the main cause of postoperative recurrence of anal fistula.<sup>12</sup> However, it hasn't been proved by clinical study so far, according to our clinical observation, the proximal anal sinus tended to be infected in those fistula patients, so we did this **retrospective** study to explore whether resection of anal glands around the anal fistula could reduce the recurrence rate of the procedure. The anorectal surgeon team of The Fifth Affiliated Hospital of Guangzhou Medical University participated in the trial, and proposed a new surgical approach: proximal anal sinus resection (PASR). In order to compare the recurrence rate between the classical surgery and classic surgery plus proximal anal sinus excision and to determine the effects of PASR on the anal fistula, we retrospectively analyzed 106 patients who undergone classic surgery or PASR. Our results highlight the PASR as an advanced operation to fistulectomy and seton for reducing recurrence rate.

## Methods

### Patients

From May 2016 to May 2018, 106 patients with anal fistula were selected and divided into two groups. 74 patients were conducted to the classic surgery, 32 patients were conducted to the PASR group. Age and gender differences between the two groups were not statistically significant ( $P > 0.05$ ) as shown in table1. The study was approved by the institutional review board of our hospitals.

### Inclusion and exclusion criteria

**Inclusion criteria:** The anal fistula was confirmed by clinical examination. There was no contraindication of surgery for those patients. It was the first time for patients that they suffered from anal fistula. They all suit the requirements of the ethics committee.

**Exclusion criteria:** The patients that complicated by colorectal cancer, mental illness or diabetes, and other diseases such as the heart, liver, kidney and other related diseases. Females that pregnant or in their lactation period. The patients in the course of the acute inflammatory reaction. The patients with inflammatory bowel disease.

### Operation type

**Fistulectomy:** Firstly we tried to find and confirm the external anal fistula opening and inject 1% **methylene blue** into the fistula via the opening, then the surgeon insert the index finger into the patient's rectum as a guide. The fistula was explored from the external opening by blunt probe, the blunt probe go

through the whole fistula to confirm the inner opening. Next we cut and open the fistula, the electrotome was performed along the periphery of the fistula for removing the fistula completely.

Seton: The fistula was explored from the external opening by blunt probe, the blunt probe go through the whole fistula, then came out from the inner opening. Meanwhile the **rubber band** passed the whole fistula following the movement of blunt probe. Then we cut and open the skin and **subcutaneous tissue** located between external and inner opening of fistula, next we performed the seton therapy.

The proximal anal sinus resection: On the basis of the above two surgery operations, alicé's tissue forceps were used to pick up the inner opening (the primary antral sinus and two other antral sinus which located at both sides), then using electric knife to remove all the three antral sinus, approximate position as shown in the figure 1.

Postoperative care: After routine postoperative lying for 4–6 hours, the diet was changed to a normal diet. If the patients were difficult to urinate, we handle it with a urine tube. The first generation of cephalosporin was used for 1 day. Topical application of analgesic ant swelling drugs for 2 weeks, and sitting bath for 4–6weeks. The patients were advised to avoid heavy physical work for two weeks.

Follow-up: After discharging from the hospital, the patients were followed up and monitored for the situation of healing, complications, recurrence in the clinic. Clinical healing was defined as complete closure of the internal opening and the external wound and no symptoms of inflammation. We usually do not check the healing with ultrasound or MRI. Recurrence was defined as reappearance of a fistula. Follow-up appointments were scheduled in the second week after surgery unless it required sooner when considering the patients' symptoms. The patients came to the clinic once or twice perv week until the wound meets the criteria for healing. Telephone interview were performed at six weeks, three months, six months and one year after the surgery. After one year, we acquiesced the favourable conditions of patients unless they informed us some aberrant situations.

Statistical analysis: Statistical analysis was performed using SPSS 19.0. T tests were used to compare continuous variables, and fisher exact tests were used for proportion comparison. Survival analysis were used to compare the time of recurrence in two groups. All p values were two-sides and considered statistically significant when  $p \leq 0.05$ .

## Results

We compared the differences between the classic surgery group and the PASR group, there was a significant difference in the recurrence rate (16.2% vs 0%) during the follow-up period ( $P < 0.05$ ). In the classic surgery group, 2 patients recurred after 3 months, 1 patient recurred after 5 months, 6 patients recurred after 6 months, 1 patient recurred after 8 months, 2 patients recurred after 12 months(Figure 2). In the classic surgery group, 2 patients' wound swelled during hospital and another 3 patients still had a little amount of exuded liquid from the surgical incision accompanied by pain when discharged. In the PASR group, there were 4 patients who had a little amount of exuded liquid from the surgical incision

accompanied by pain when discharged. The mean healing time of the two groups had not significant difference, which were 41.6 days (classic group)( $P>0.05$ ) and 40.8 days (PASR group). Our results found no significant difference in the duration of pain between the two groups, which were  $5.1\pm 1.5$  days (classic group) and  $5.0\pm 1.0$  days (PASR group) ( $P>0.05$ )(Table 2).

## Discussion

Another trail analyzed a series of 279 patients who had undergone anal fistula surgery, and they considered that the factors of the recurrence included the type of fistula (extrasphincteric/suprasphincteric), nonidentification of internal opening, complex fistulae, and associated chronic abscess, but within those factors, only complex fistulae and nonidentification of internal opening were statistically significant in the multivariate analysis.<sup>13</sup> In a retrospective case-control study of 251 patients with high transsphincteric fistula who were treated with seton placement, those factors which lead to recurrence include previous fistula surgery, anterior anal fistula, and presence of secondary tracks or branches as supralelevator extension, and horseshoe fistula.<sup>14</sup> New surgical procedures emerged in recent years, such as ligation of intersphincteric fistula tract(LIFT), It is being said to have satisfactory results in short and long follow up, with low risk of complications. However complex and recurrent fistulas seem to be risk factors of LIFT failure.<sup>15</sup> Stem-cell therapy was attempted to resolve very complex anal fistula, and 10 patients with highly recurrent and complex fistulae were treated with stem-cell therapy, one year later, six patients (60%) remained healed, and it seems there is still room for improving recurrence.<sup>16</sup>

According to our experience in treating recurrent fistula, the causes of recurrent anal fistula can be divided into the following situations: (1) The preoperative diagnosis is insufficient, the doctor only check the anorectal location without noticing complications such as tuberculosis, crohn's disease, diabetes and other systemic diseases. It's worth noting that anal fistulas are a common manifestation of Crohn's disease,<sup>17</sup> those diseases is not good for the healing of fistula. (2)The fistula is improperly evaluated, which results in the inaccurate incision and drainage. (3) The inner opening is the key of the treatment of fistula. When the inner opening is not fully cut apart, the situation will lead to poor post-operative healing. (4) Both ends of the fistula incision are easy to close, the surrounding skin grow to be together, however, the fistula cavity is not fully filled by granulation tissue, this is known as the pseudo healing. Besides above clinical practice experiments, in theory some potential source of infection maybe still exist in those recurrent patients, therefore it is important to inspect inner opening carefully, on the basis of these consensus, we attach great importance to another cause of recurrence, the sinus anal infection near the internal opening, and it maybe plays a significant role in the recurrence.

Our results showed the recurrence rate of the classic surgery plus PASR was lower when compared with the classic surgery, in fact, this was the first report to use the new operation PASR for improving the efficacy of anal fistula surgical treatment on the basis of classical surgery. Interestingly, no one recurred within those patients who undergone PASR during one year follow up period, while there were twelve

patient recurred in classic surgery control group within one year. The outcomes indicated that the apparent relationship between the proximal anal sinuses and the recurrence of anal fistula, and the potential role of PASR in preventing recurrence.

The PASR needed to cut off the external two adjacent anal sinuses, but our results revealed that the major evaluation index which included the duration time of pain, the wound healing time didn't show significant difference, which suggested this advanced operation didn't worsen the recovery of surgery treatment. During the follow-up period, all patients didn't present complications such as the stricture of anal, which indicated external excision didn't increase the risk of serious complications.

Seton therapy is one of the classic surgeries for anal fistula, which has been popular for many years worldwide. It is safe for incontinence, as the seton stimulates the [contact segment](#) continuously, which keep the anal sphincter always conjoint,<sup>18</sup> but the wound heal slowly, the recurrence rate is also not optimistic. The fistulectomy showed lower recurrence rate because of the surrounding tissue of the fistula was removed, but the risk of incontinence increased.<sup>8</sup> The ideal advanced surgery should improve [therapeutic](#) efficacy without impacting other evaluation indexes. Anal fistula is one of the most complex diseases, therefore surgeon has explored the advanced surgery procedures continuously. In consideration of the advantages and disadvantages of classic surgery, as well as the main factors influencing surgical efficacy, we designed the PASR on the basis of classic surgery. However, this study was limited by its small samples, in order to further confirm the effect of PASR, it requires a large sample size in future study. Our results confirmed the PASR can be adapted to recurrent or persistent anal fistula, and our research gain a key evidence for anal glands as the potential source of recurrence and provided a new way to solve the problem of recurrence.

## Conclusion

The classic surgery plus PASR reduced the recurrence rate obviously, meanwhile the advanced surgery procedures neither increase the risk of surgery complications, nor prolong the duration time of pain, the wound healing time. The proximal anal sinus maybe considered as an effective therapeutic target to reduce the recurrence rate and as a first line of treatment for recurrent anal fistula patients.

## Abbreviations

*PASR*: proximal anal sinus resection

## Declarations

*Ethics approval and consent to participate*

The study was approved by the ethics committee of the Fifth Affiliated Hospital of Guangzhou Medical University. And written, informed consent was obtained from all participants.

### *Consent for publication*

Not Applicable

### *Availability of data and material*

Not applicable. We consulted to all of the patients, they refused to upload the raw data.

### *Competing interests*

The authors have declared that no conflict of interest exists.

### *Funding*

Not applicable.

### *Authors' contributions*

Study conception and design: ZHL; Acquisition of data: CLei, CLi, ML, ChenL, ZHL; Analysis and interpretation of data: CLei, CLi; Drafting of manuscript: CLei, CLi; Final approval: CLei, CLi, ML, TL, Chen L, NS, XL, ZHL; critical revision: TL, XL, Chen L, NS, ZHL.

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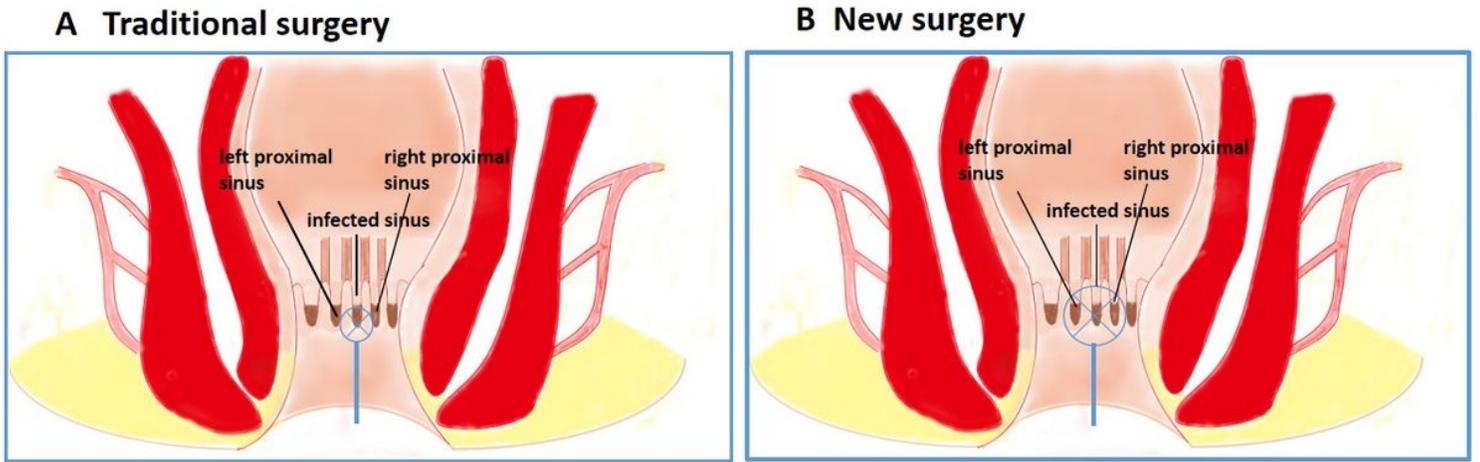
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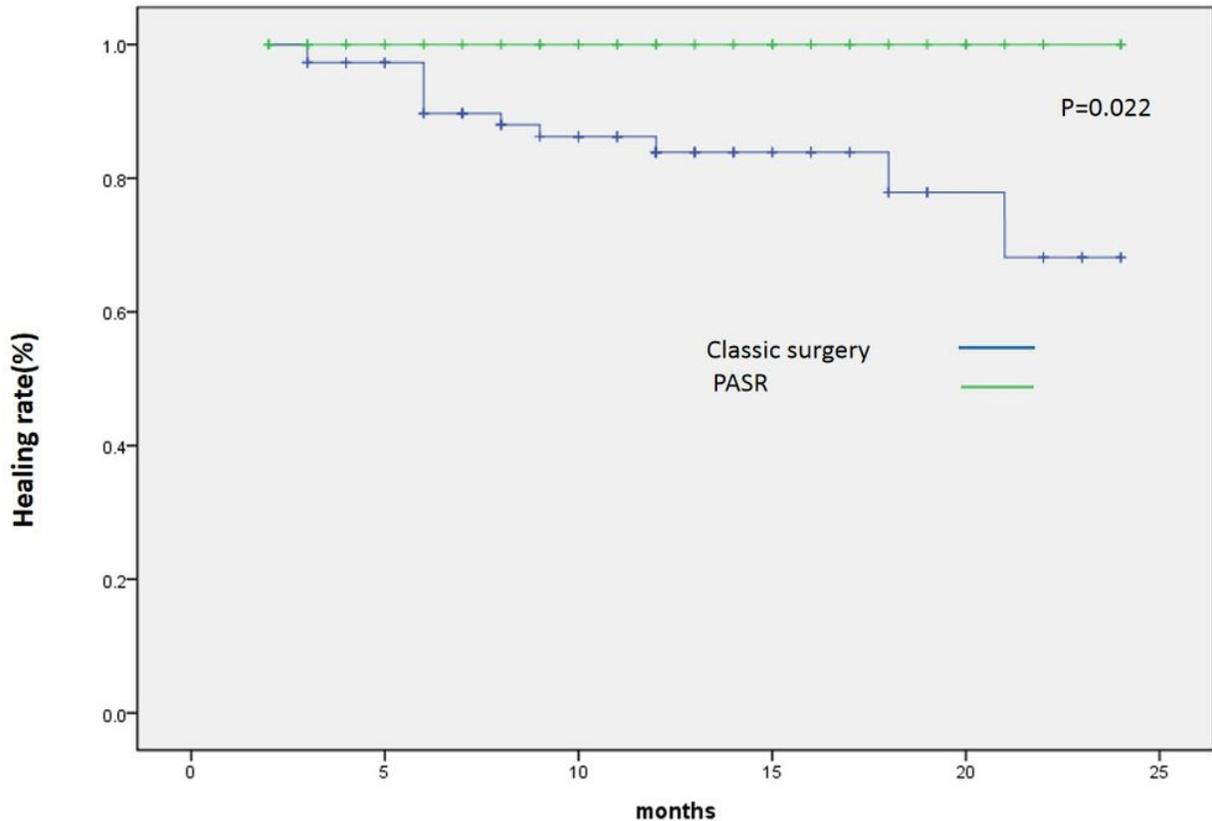
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## Figures



**Figure 1**

A: New surgery: the classic surgery plus PASR resected all the three antral sinus. B: Traditional surgery: The classic surgery only resected the most relevant antral



## Figure 2

Kaplan-Meier curves showing the healing rate between the two groups. P=0.022.