

CLINICAL PRACTICE GUIDELINE

Cryptoglandular Anal Fistulas

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SUMMARY

Background: Cryptoglandular anal fistula arises in 2 per 10 000 persons per year and is most common in young men. Improper treatment can result in fecal incontinence and thus in impaired quality of life.

Method: This S3 guideline is based on a systematic review of the pertinent literature.

Results: The level of evidence for treatment is low, because relevant randomized trials are scarce. Anal fistulae are classified according to the relation of the fistula channel to the sphincter. The indication for treatment is established by the clinical history and physical examination. During surgery, the fistula should be probed and/or dyed. Endo-anal ultrasonography and magnetic resonance imaging are of roughly the same diagnostic value and may be useful as additional studies for complex fistulae. Surgical treatment is with one of the following operations: laying open, seton drainage, plastic surgical reconstruction with suturing of the sphincter, and occlusion with biomaterials. Only superficial fistulae should be laid open. The risk of postoperative incontinence is directly related to the thickness of sphincter muscle that is divided. All high anal fistulae should be treated with a sphincter-saving procedure. The various plastic surgical reconstructive procedures all yield roughly the same results. Occlusion with biomaterials yields a lower cure rate.

Conclusion: This is the first German S3 guideline for the treatment of cryptoglandular anal fistula. It includes recommendations for the diagnostic evaluation and treatment of this clinical entity.

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With an incidence of around 2 per 10 000 head of population per year, anal fistula is a frequent condition with a peak incidence between 30 and 50 years of age (1). Men are affected more often than women (2).

Method

The content of the present guideline is based on an extensive review of the literature (*Figure 1*). Definitions of evidence level, recommendation grade, and consensus strength were established (e1, e2) (*Table 1, 2*). The text was agreed by the guideline group (*Box 1*) at two consensus conferences.

Classification

Cryptoglandular anal fistulas arise from an inflammation of the proctodeal glands, which in humans are only rudimentary, and are situated in the intersphincteric space (e3). A communication forms between an opening at the level of the dentate line and one in the perianal region.

In clinical routine, classification according to the relationship to the sphincter has proved useful (3) (*Figure 2*). Types 4 and 5 are not cryptoglandular fistulas.

In clinical routine, intersphincteric and distal trans-sphincteric fistulas are called low fistulas and proximal trans-sphincteric and suprasphincteric fistulas are called high fistulas. The most frequently encountered are uncomplicated distal fistula tracts (e4) (evidence level: 4; recommendation grade: 0; consensus strength: strong consensus).

Symptoms and diagnosis

The typical symptom of anal fistula is discharge from a perianal opening.

Digital examination and probing are sufficient for diagnosis (4).

The tract of the fistula and its relationship to the sphincter muscle can be investigated by probing and/or dyeing intraoperatively with the patient under anesthesia (5, e5).

If the history suggests it, chronic inflammatory bowel disease should be ruled out perioperatively. Sphincter function should be assessed before any operative intervention, on the basis of the history and, if appropriate, an incontinence score (evidence level: 4; recommendation grade: B; consensus strength: strong consensus).

End- und Dickdarmpraxis Essen: Dr. med. Ommer

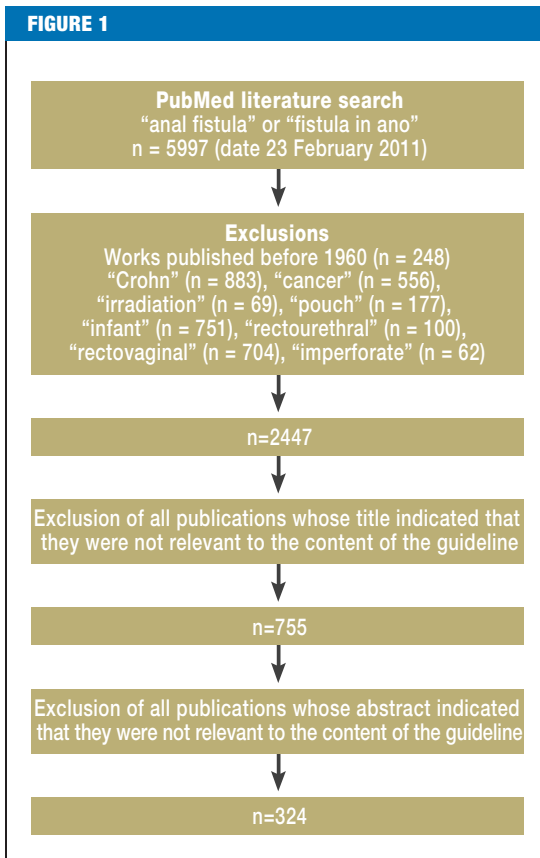
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Flow chart of literature review

In cases of complex recurring anal fistulas the use of imaging techniques should be considered (6, e6).

Because of the radiation burden, visualization of fistulas using contrast media (e7) and computed tomography (CT) is regarded as obsolete.

A simple and cheap technique available is endosonography, the usefulness of which can be improved by contrast enhancement, e.g., using hydrogen peroxide. The correlation between intra-anal ultrasonography and intraoperative clinical examination is better than 90% (6, e8–e10). The advantage of endosonography is that it is easy and cheap to use, but it does depend to a high degree on the examiner’s experience.

Magnetic resonance imaging (MRI) can be employed either as an external investigation with or without contrast medium, or using an intrarectal coil (7, e11). MRI is cost-intensive, not always available, and its diagnostic value depends on technical conditions; however, it is to be preferred to endosonography for lesions distant from the anus. Other advantages of MRI are that it allows pain-free acquisition of images that can be evaluated independently of the examiner (evidence level: 1a; recommendation grade: A; consensus strength: strong consensus).

Therapeutic procedures

A diagnosis of anal fistula is usually an indication for surgery in order to prevent a recurring septic process. The choice of operative technique is governed by the fistula tract and its relation to the anal sphincter. The literature on treating anal fistulas has been covered in several reviews (8–10) and a Cochrane analysis (11).

Unfortunately a total of only 10 randomized studies have been carried out, each of which compared only partial aspects of treatment for fistula. The other studies are observational studies from various hospitals with inhomogeneous patient groups. Because of this, the conclusions of the reviews are mostly of a general nature.

Published guidelines of other professional organizations (12, 13) are partly out of date, since for example the plug technique is not included.

To produce the present guideline, the available literature was analyzed afresh and the results set out in evidence tables. These may be accessed via the Internet at www.awmf.org/uploads/tx_szleitlinien/088-0031_S3_Kryptoglanduläre_Analfisteln_2011_10.pdf (German-language publication).

Fistulotomy

The most common operative technique in use is fistulotomy, that is, division of the tissue between the fistula tract and the anal canal. Twenty-eight studies, most of them retrospective, that dealt with this treatment were identified. Healing rates are between 74% and 100%. Rates of impaired continence vary between 0 and 45% (14–16, e12–e18). For low fistulas, a healing rate of almost 100% can be achieved. Postoperative incontinence rates are described in the literature as relatively low, but this is still a sequela to be taken seriously. In all cases the incontinence rate rises with the amount of sphincter that is divided. Extensive division should always be avoided (evidence level: 2b; recommendation grade: B; consensus strength: strong consensus).

Seton drainage

Placement of a seton drain is another frequently employed technique in anal fistula surgery. The material used is either a strong braided non-resorbable suture or a plastic (vessel-loop etc.) suture thread. Three different techniques are in use:

Drainage seton (loose seton)

The aim of this technique is long-term drainage of the abscess cavity. This helps to prevent premature closure of the external fistula opening. The thread is removed later to allow spontaneous healing of the fistula. Healing rates in the retrospective observational studies identified vary between 33% and 100%. Impaired continence is reported in 0 to 62% of cases (12, 17, e19–e22). These data are due to the fact that interventions undertaken in addition to placement of the seton are not always clearly defined. To date, no randomized studies exist on this subject.

Definitive healing of cryptoglandular anal fistulas, even in the long term by leaving a loose seton in place,

can be the goal only in extremely rare cases. Usually, further intervention is required.

Fibrosing seton

Placement of a fibrosing seton usually occurs either primarily or secondarily in the setting of an acute or persistent inflammation.

The aim is to fibrose the fistula tract before further surgical interventions. Most often described in the literature is secondary lay open of remaining fistula. The observational studies identified in the literature search report healing rates of nearly 100% (e12, e23–e25). However, this is associated with a high rate of impaired continence. Overall, the data in the literature vary between 0 and 70%.

In Germany, the fibrosing seton is used mainly in high fistulas before definitive reconstruction surgery. Whether the use of the seton promotes success of a reconstructive procedure is not clear.

Cutting seton

The aim of the cutting seton is successive division of the parts of the sphincter enclosed by the fistula tract once the inflamed area has been cored out. The seton may be made of various materials. Either it is stretchable (usually rubber) and will gradually cut through the tissue, or repeated tightening will be required. So-called chemical or medicated setons are a particular case; the principle is loose placement of a thread (ksharasootra), as used in ayurvedic therapy. This thread must be changed every week. The aim of treatment is spontaneous loss of the thread after chemical division of the fistular tissue (17).

Thirty-five observational studies were identified, most of them retrospective, which showed a mixed patient group including almost all types of fistula. Healing rates were reported between 80% and 100% (e13, e15, e21, e26–e31). Reported rates of impaired continence were between 0 and 92%.

Recent reviews (18, e32) point to an unacceptably high incontinence rate after use of the cutting seton. In view of the current literature, the recommendation for this method as seen in other guidelines (12, 13) should not be continued.

In the authors' opinion, the most important function of seton drainage is in preparation for subsequent definitive treatment of high anal fistulas demonstrated during abscess drainage (evidence level: 2a; recommendation grade: B; consensus strength: strong consensus).

Closure by surgical reconstruction

The aim of the various procedures is excision of the fistula and the cryptoglandular focus of infection with closure of the inner fistula cavity. Five different techniques are used:

Direct suture without advancement flap

In some studies the internal fistula cavity was not covered up after direct suturing of the sphincter muscle;

TABLE 1

Definition of evidence levels and recommendation grades*¹

Recommendation grade	Evidence level	Types of treatment studies
A („should“)	1a 1b 1c	Systematic review of randomized controlled studies (RCTs) Individual, well-designed RCT All-or-none principle
B („ought to“)	2a 2b	Systematic review of well-designed cohort studies Individual cohort study (including low quality RCT; e.g., <80% follow-up)
0 („may“)	3a 3b	Systematic review of well-designed case-control studies Individual, well-designed case-control study
0 („may“)	4	Case series, or poor-quality cohort and case-control studies
0 („may“)	5	Expert opinion without explicit critical appraisal, or based on physiology, bench research or “first principles”

*¹ Adapted from the Centre for Evidence-Based Medicine, Oxford

reported healing rates were between 56% and 100% (e33, e34).

Mucosal/submucosal advancement flap

Alternatively, the sphincter sutures can be protected by being covered with an advancement flap. This flap can be formed from mucosa, submucosa and superficial parts of the internal muscle (mucosal/submucosal flap). The 30 studies identified showed healing rates between 12% and 100% (15, e34–e45).

Rectal advancement flap

Alternatively, a rectal full thickness advancement flap may be used to cover the sutures. The results of the 17 studies identified are largely similar to those using the mucosal/submucosal flap, with healing rates between 33% and 100% and incontinence rates between 0 and 71% (19, e34, e39, e46–e49). Four randomized studies have been published (19, e48–e50).

A comparison between rectal full thickness advancement flap and fistula excision with primary reconstruction of the sphincter showed similar results in terms of healing and continence. Two other studies which randomized patients to receive either rectal advancement flap or an anal fistula plug showed significantly higher healing rates for the advancement flap but at the same time a higher risk of impaired continence.

Anodermal advancement flap

Another option to cover the inner fistula cavity is an anodermal or anoderm flap. This uses an advancement flap made of anodermal tissue. The anodermal flap can be especially advantageous in patients with a narrow anal canal (e.g., scar tissue from previous operations)

BOX 1

Guideline group

- **For the German Society for General and Visceral Surgery (DGAV, Deutsche Gesellschaft für Allgemein- und Viszeralchirurgie)**

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 Dr. Bernhard Strittmatter, Freiburg

In addition to the DCAV, the following surgical professional bodies participated in the development of this guideline: the Surgical Working Group for Coloproctology (CACP, Arbeitsgemeinschaft für Coloproktologie), the German Coloproctology Society (DGK, Deutsche Gesellschaft für Coloproktologie), and the Association of Coloproctologists in Germany (BCD, Berufsverband der Coloproktologen Deutschlands).

- **For the German Dermatological Society**
 Dr. Bernhard H. Lenhard, Heidelberg
- **For the Working Group on Urogynecology and Surgical Reconstruction of the Pelvic Floor (AGUB, Arbeitsgemeinschaft für Urogynäkologie und plastische Beckenbodenrekonstruktion) of the German Society of Gynecology and Obstetrics (Deutsche Gesellschaft für Gynäkologie und Geburtshilfe)**
 Prof. Werner Bader, Hannover
- **For the German Society of Urology**
 Prof. Jürgen E. Gschwend, Munich
- **For the German Society of Digestive and Metabolic Diseases**
 Prof. Heiner Krammer, Mannheim
 Prof. Eduard F. Stange, Stuttgart

Complete guideline text in German
www.awmf.org/uploads/tx_szleitlinien/088-003l_S3_Kryptoglanduläre_Analfisteln_2011_10.pdf

TABLE 2

Definition of consensus strengths

Consensus	Definition
Strong consensus	More than 95% of participants agree
Consensus	75% to 95% of participants agree
Majority agreement	50% to 75% of participants agree
No consensus	Less than 50% of participants agree

that might prevent complete exploration and proximal flap formation. Healing rates in the 10 observational studies identified vary between 46% and 95%, while impaired continence rates range from 0 to 30% (e34, e51–e54).

Fistula excision with direct sphincter reconstruction

In fistula excision with primary reconstruction of the sphincter muscle, after complete excision of the fistula and its associated inflammatory tissue, primary readaptation of the divided sphincter apparatus is carried out. The eight studies identified mostly treated high fistulas. Healing rates between 54% and 97% were reported; rates of impaired continence were noted to be 4% to 32% (e55–e58). Especially in patients with high fistulas, wound dehiscence after division and reconstruction is associated with a high risk of incontinence. Overall the data for this technique are still relatively few and the role of reconstruction of even small sphincter defects is at present unclear.

To sum up, surgical reconstruction is an established technique with healing rates between 60% and 80%, and there is no meaningful difference between the various procedures. Reported rates of impaired continence vary, and the risk of impaired continence must be explained to the patient before informed consent to surgery can be given (evidence level: 1b; recommendation grade: A; consensus strength: strong consensus).

Biomaterials

Fibrin glue

After curettage of the fistula tract, the tract is filled with fibrin glue. Results in the literature show healing rates that vary widely between 0 and 100%. Only eight studies give information about continence and report having observed no impairment. The majority of these studies are personal case series involving inhomogeneous patients with a wide variety of fistula types (e31, e59–e65).

The three review articles identified in the literature search (e66–e68) confirm the great heterogeneity of the studies, especially since the good results reported in the

earlier studies could not be reproduced in the more recent ones. In the view of the guideline working group, therefore, the use of fibrin glue should be reserved for special cases (evidence level: 1b; recommendation grade: B; consensus strength: strong consensus).

Anal fistula plug

The anal fistula plug is a biomedical product made of porcine small-intestinal submucosa. Unlike the “conventional” procedures, with this technique the inflammatory tissue is not excised, but merely occluded with the cone-shaped plug, which acts as a matrix for the body’s own tissue to grow into.

Some authors combine plugging with closing of the internal fistula cavity using an advancement flap. The published observational studies show healing rates between 14% and 93%. Most of them did not investigate continence impairment. Only three studies report unchanged continence (19, 20, e69–e75).

The two randomized studies that compared plugging with surgical closure found markedly lower healing rates with plugging. One study (19) was stopped early because of an unacceptably high rate of recurrence. It appears to be important that the fistula tract is long enough (20).

One review (21) found success rates to vary between 24% and 92%. The rate of recurrent abscess after fistula plugging was 4% to 29%, and the frequency of plug loss was 4% to 41%. A notable feature is the low morbidity of the procedure. Any effect of plugging on continence is expected to be negligible.

To sum up, plugging has added a new option for the treatment of high anal fistula (evidence level: 1b; recommendation grade: B; consensus strength: strong consensus).

Other techniques

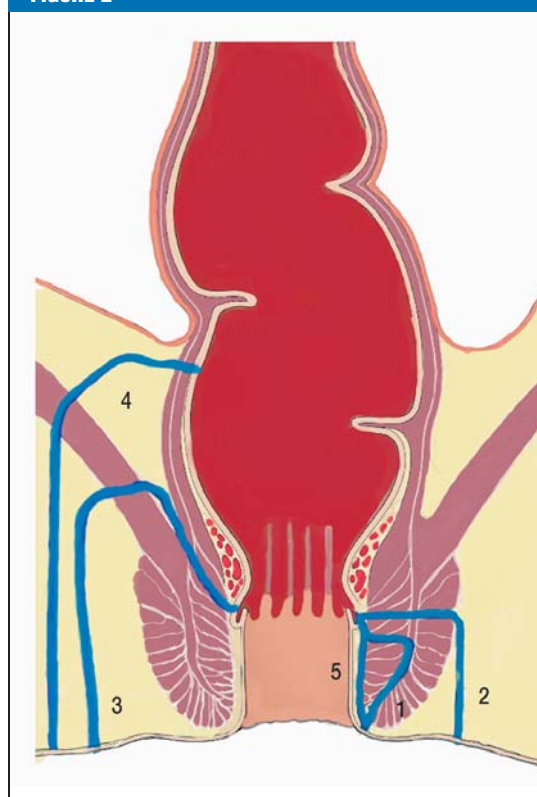
A variety of other techniques have been described in the literature only in the form of case reports from individual working groups: radiofrequency ablation, stapling, autologous stem cells, collagen injection, Bio-LIFT, LIFT (ligation of the intersphincteric fistula tract) (evidence level: 5; recommendation grade: 0; consensus strength: consensus).

Perioperative management

Postoperative care after anal surgery is unproblematic. The external wound heals by secondary intention and should be regularly cleaned by showering.

In anal fistulotomy or seton drainage, no special bowel preparation or postoperative treatment is required. Whether preoperative bowel cleansing and/or delaying the passing of stool after the operation influences healing rates after reconstructive surgery, or whether antibiotic therapy does, is currently unclear despite recent studies (22, e76). Smoking appears to have a negative influence on results (23, e54). Stoma placement is indicated only in exceptional cases (evidence level: 5; recommendation grade: 0; consensus strength: consensus).

FIGURE 2



Classification of anal fistulas

1. Intersphincteric
2. Trans-sphincteric
3. Suprasphincteric
4. Extrasphincteric
5. Subanodermal

Complications

Perioperative complications

Complications after anal fistula interventions are basically no different from those after other anal interventions (the main ones are urinary retention and postoperative bleeding). With surgical fistula reconstruction, rates of local infection are between 5% and 20% (e77, e78). In most cases, wound dehiscence is associated with persistence of the fistula.

Impaired continence after anal fistula operations

Impairment of continence is a frequent complication after anal fistula operations. The causes are usually multifactorial, with sphincter lesions to the fore. The risk of postoperative continence impairment rises with the amount of sphincter that has been divided. The degree of impairment varies greatly and depends to a large extent on pre-existing injury. Its effect on the patient also relates to subjective experience.

In the literature, impaired continence rates are reported as 10% in low fistulas and 50% in high fistulas (24, e78).

Against this background, it is important to give the patient comprehensive information. The sphincter apparatus must be spared as much as possible (evidence level: 1c; recommendation grade: A; consensus strength: strong consensus).

Malignant transformation

It is rare, but possible, for a malignant tumor to develop in a chronic anal fistula. The literature provides various case reports of advanced tumor stages (25). For this reason, histological analysis of the resected specimen is recommended (evidence level: 5; recommendation grade: 0; consensus strength: strong consensus).

Conflict of interest statement

Dr. Ommer has received honoraria from the DGAV for developing four guidelines on the subject of anal fistulas. He has also had travel and accommodation expenses reimbursed by Gore and by Johnson & Johnson. He has received fees from Kade and from MSD for lectures given at continuing medical education events.

Professor Herold has received financial support for conferences from the Falk Foundation, Johnson & Johnson, Prostrakan, MSD, and Aesculap. Other projects received third-party support from Cook, Gore, SLA-Pharma, the Falk Foundation, and Kreussler.

Dr. Berg has had attendance fees at conferences and travel and accommodation expenses reimbursed by Johnson & Johnson. He has received fees from the Falk Foundation and Johnson & Johnson for the preparation of continuing medical education events.

Professor Fürst has received support for travel to conferences from Johnson & Johnson and from Braun-Aesculap, and fees for carrying out commissioned clinical studies from Bayern Innovativ GmbH.

Professor Sailer has received fees for continuing medical education events from Covidien, Johnson & Johnson, the Falk Foundation, and Hitachi Medical.

Professor Schiedeck has had attendance fees and travel and accommodation expenses reimbursed, and fees for preparation of scientific continuing education events, from Aesculap Akademie GmbH, Falk Foundation e.V., Johnson & Johnson, and Medical GmbH. He has received fees for carrying out commissioned clinical studies from Solesta and Medela.

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Translated from the original German by Kersti Wagstaff MA.

KEY MESSAGES

- Cryptoglandular anal fistulas are frequent (2/10 000 head of population) and show a peak incidence in young male adults. Anal fistulas are classified by their relationship of the fistula tract with the anal sphincter.
- History, clinical examination, and intraoperative probing and/or dyeing of the fistula tract suffice for diagnosis. Endosonography and magnetic resonance imaging are possible additional investigations for complex fistulas or those that are difficult to classify clinically, and for abscesses (evidence level: 1a; recommendation grade: A).
- Treatment for anal fistula is basically surgical. Fistulotomy should only be performed on superficial fistulas. The risk of postoperative continence impairment increases with the amount of transected sphincter (evidence level: 2b; recommendation grade: B).
- In all high anal fistulas, a sphincter-sparing procedure should be carried out. The results of the various techniques for surgical reconstruction are largely identical. In general, occlusion using biomaterials leads to lower healing rates but also lower incontinence rates (evidence level: 1b; recommendation grade: A).
- Every treatment for anal fistula is associated with the risk of reduced continence, and this risk rises with the extent of transected sphincter. Contributing causes, in addition to intentional transection of parts of the sphincter muscle, include pre-existing injury, previous operations, and other factors (age, sex, and others) (evidence level: 1c; recommendation grade: A).

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www.aerzteblatt-international.de/ref4211

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