When to do surgery in Crohn's Perianal Disease?

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COLON & RECTAL
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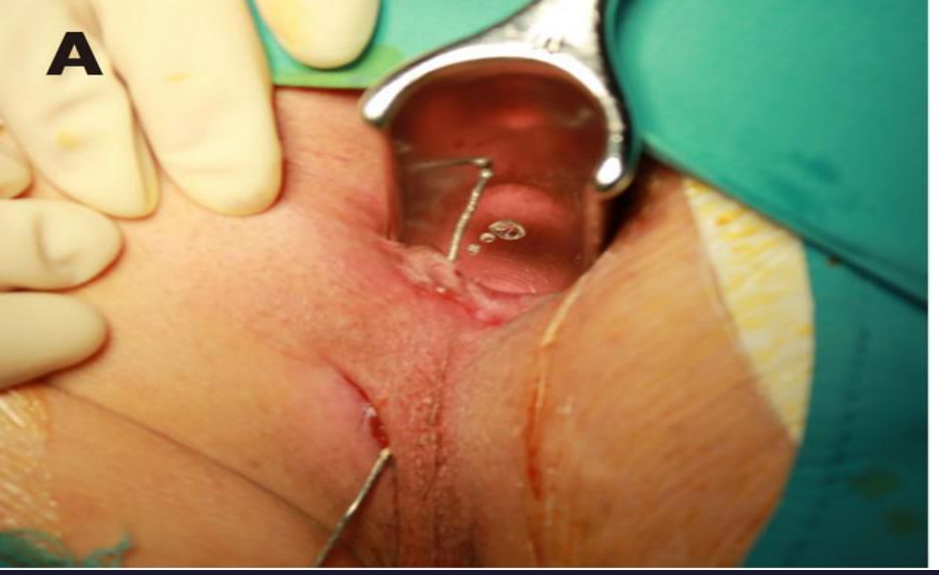
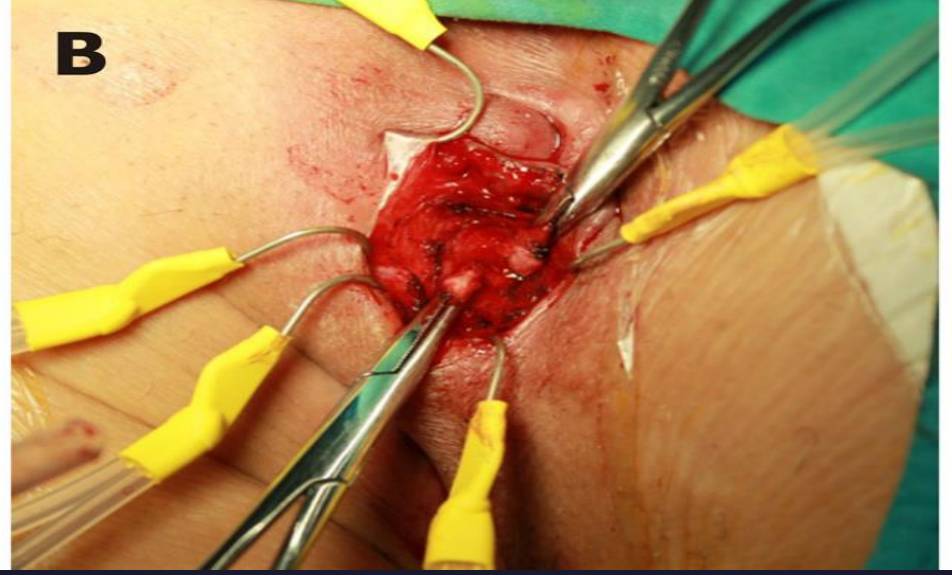
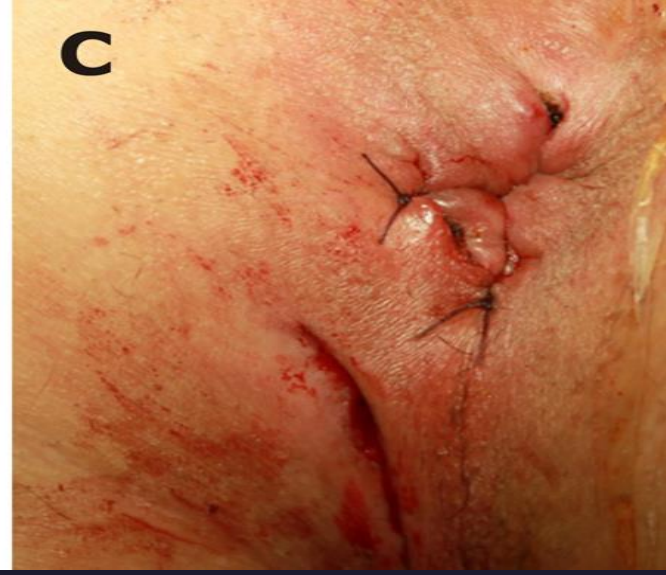
Disclosures

- Speaker and trainer for Medtronic
- Consultant for Touch Stone
- Speaker for Sanofi pharmaceutical





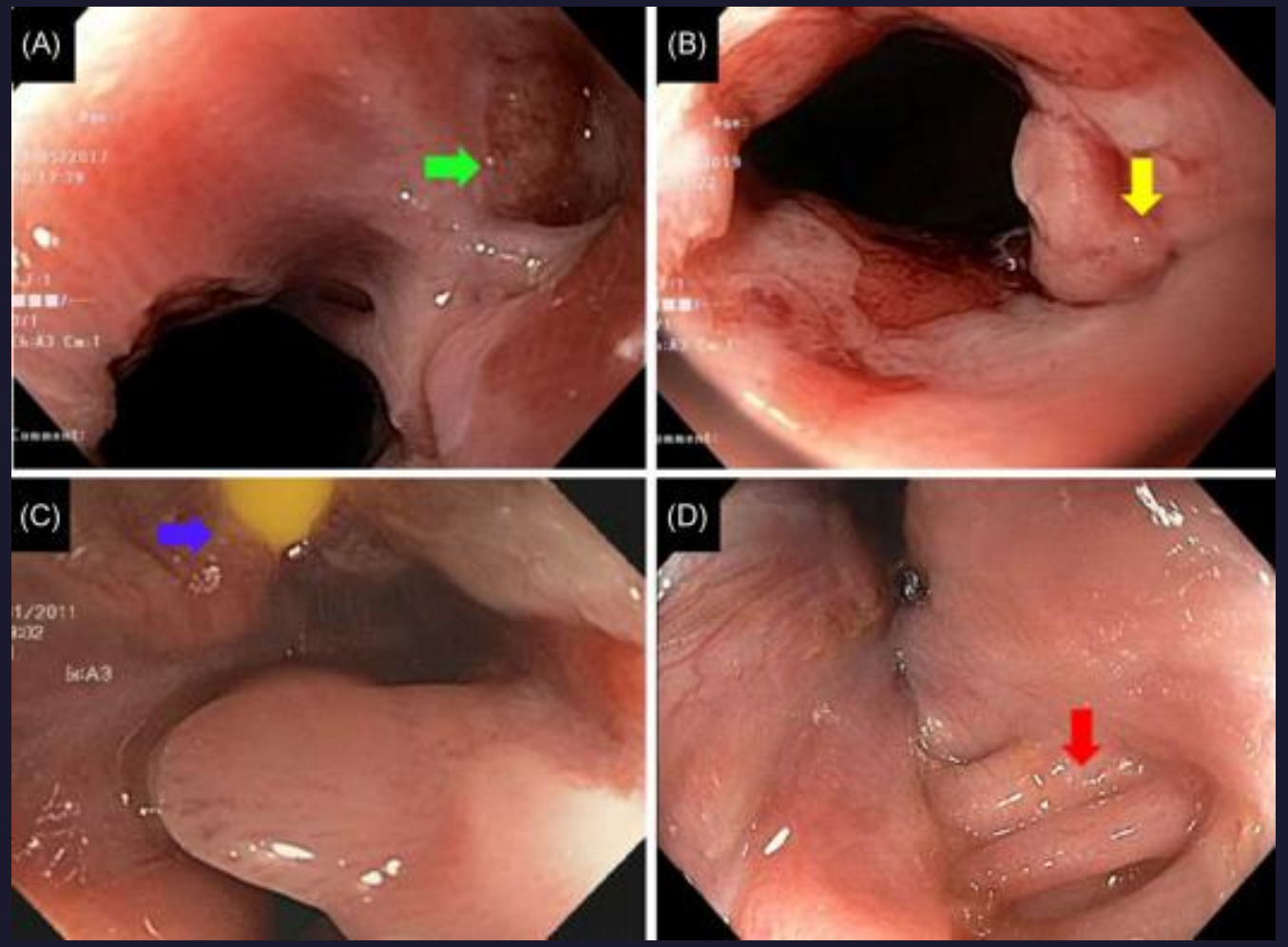


General Considerations

- Crohn's disease
  - Autoimmune inflammatory granulomatous disease
  - May involve any area of the gastrointestinal tract from the mouth to the anus
  - Approximately 13–38% of CD patients have perianal involvement and more than 80% require surgery

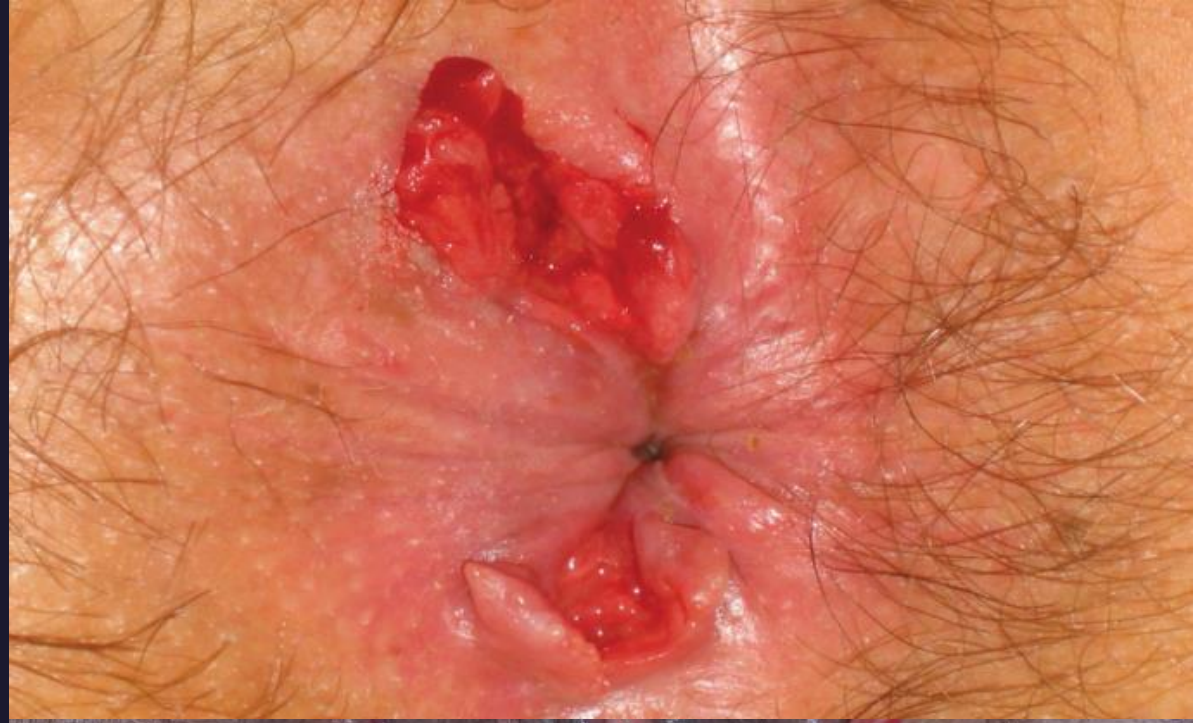
Perianal Crohn's

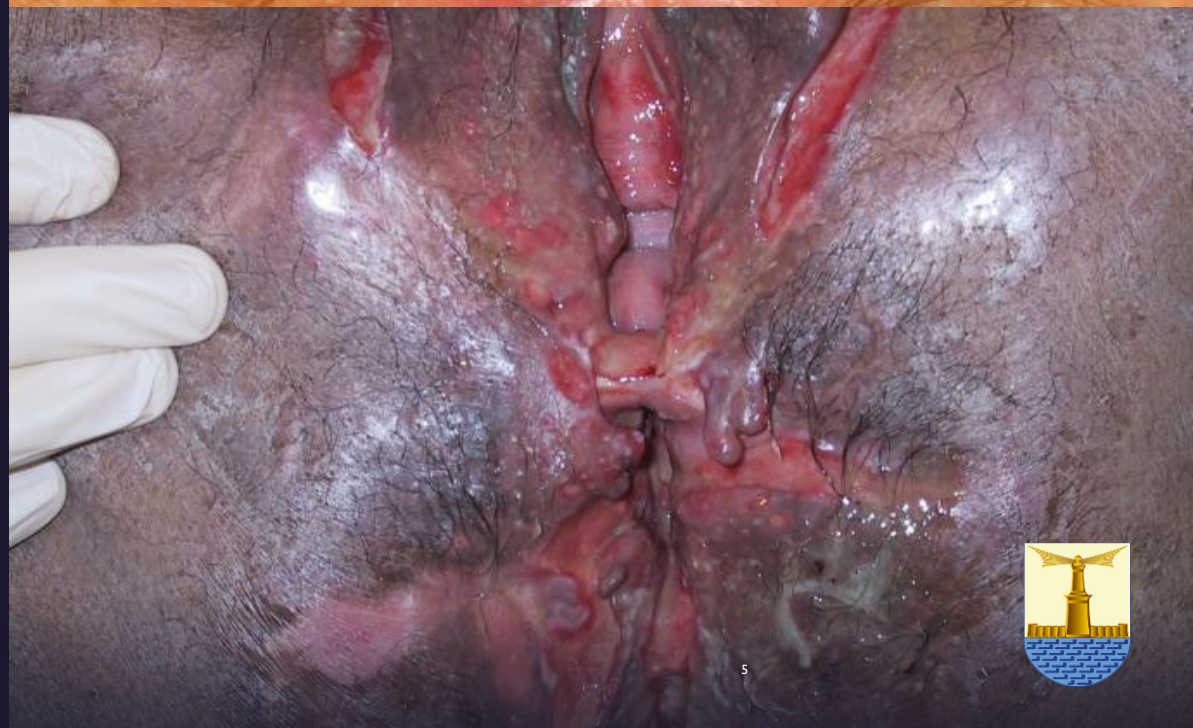
- Perianal Crohn's disease may cause
  - Pain
  - Bleeding
  - Discharge
  - Sexual and defecatory dysfunction
- Types:
  - Fistulizing (abscesses, fistulas)
  - Pathogenesis
    - Rectal inflammation causes ulcers and/or shallow fistulas, which then extend deeper with persistent exposure to feces and pressure caused by defecation
  - non-fistulizing (hemorrhoids, skin tags, anal fissures/ulcers, anorectal stricture, malignancy)



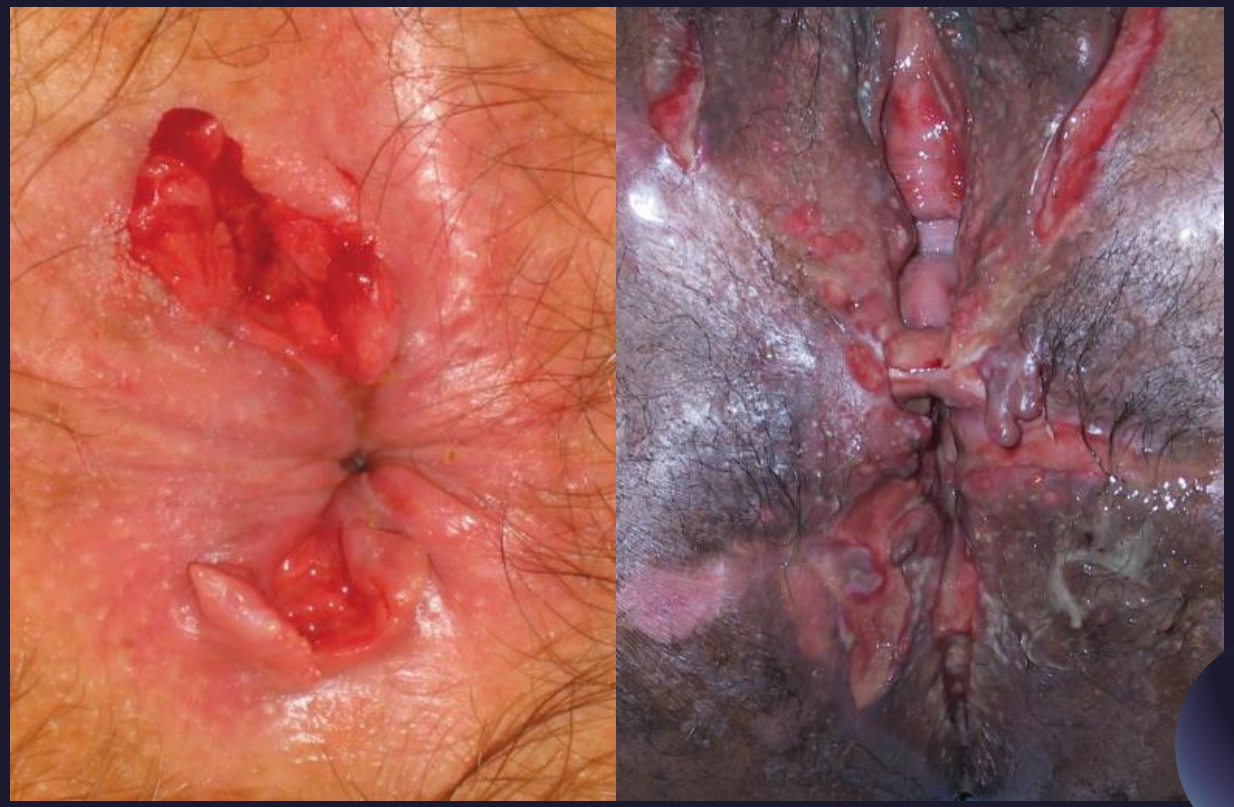
Non fistulizing perianal Crohn's Anal Fissures and Ulcers

- Repeated bowel movements traumatizing the anal canal and/ or as a sequelae of anal canal inflammation
- CD patients experience idiopathic fissures as well as atypical fissures
- Atypical fissures classically multiple and located off midline, have a granulating base with overhanging edges and may extend beyond the verge onto the perianal skin
- Large cavitating ulcers with significant tissue loss may occur



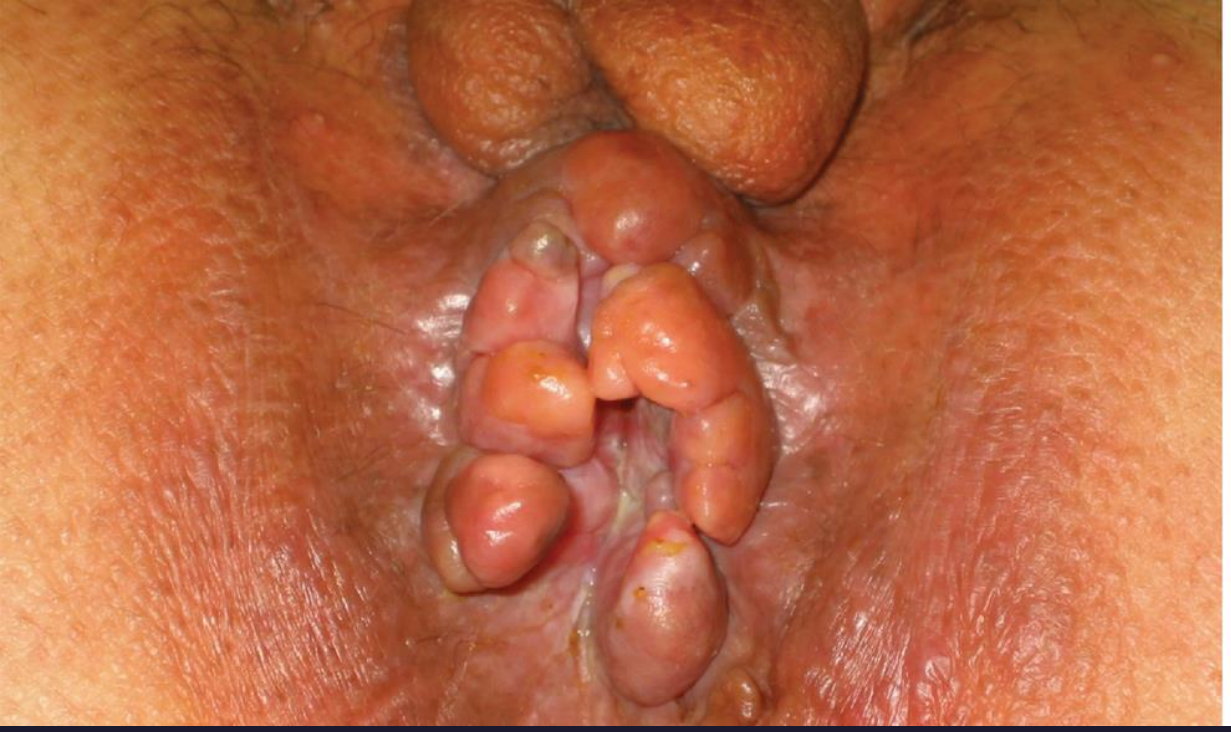


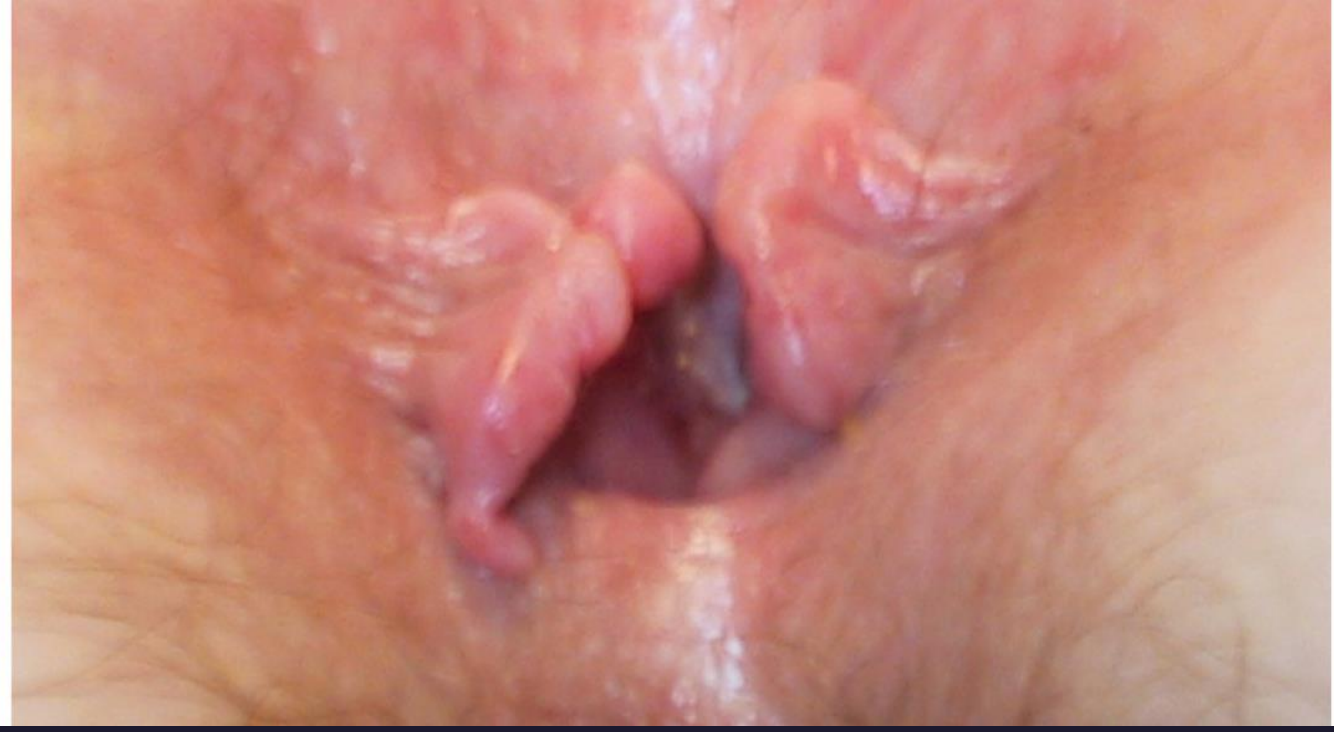
CD
Anal Fissures and Ulcers Management



- Treat the underlying luminal disease
- Anti-diarrheal or bulking agents
- Minimizing toilet time, gentle perianal skin care
- Nitroglycerine, calcium channel blockers, and botulinum toxin injections
- In single, midline fissure associated with a hypertonic sphincter and a disease-free rectum, LIS is appropriate

Fleshner , DCR 1995

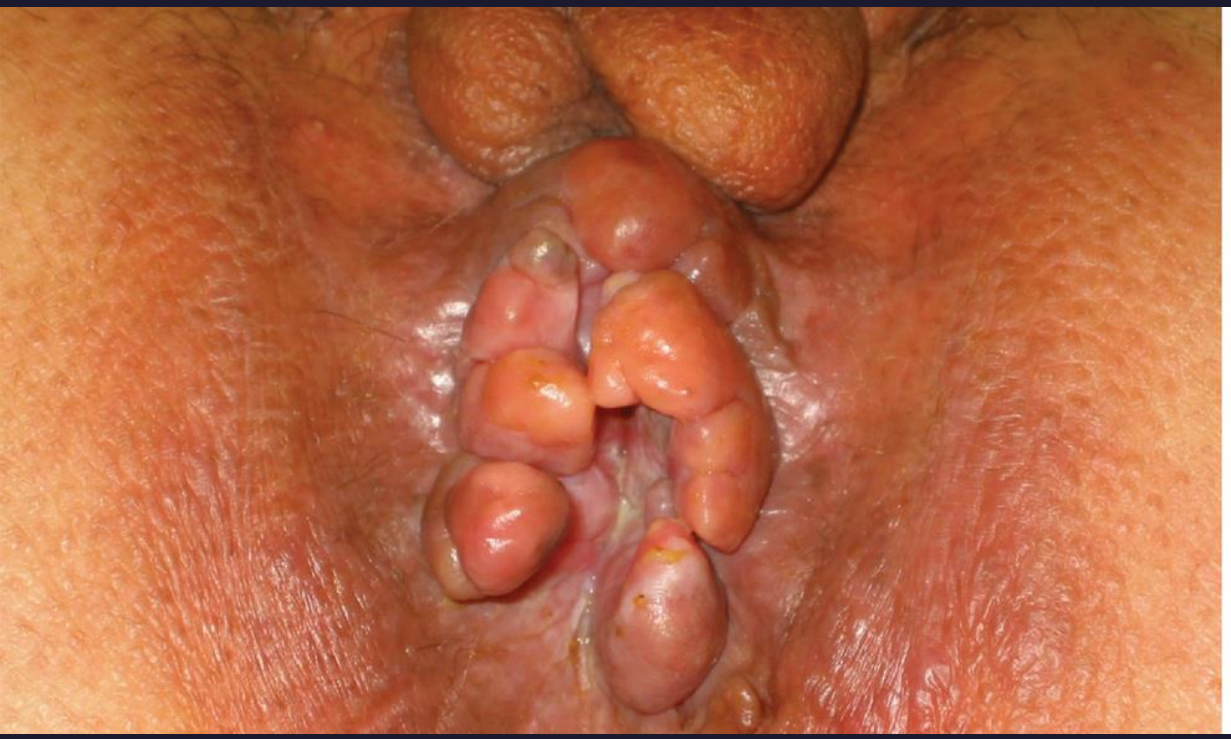


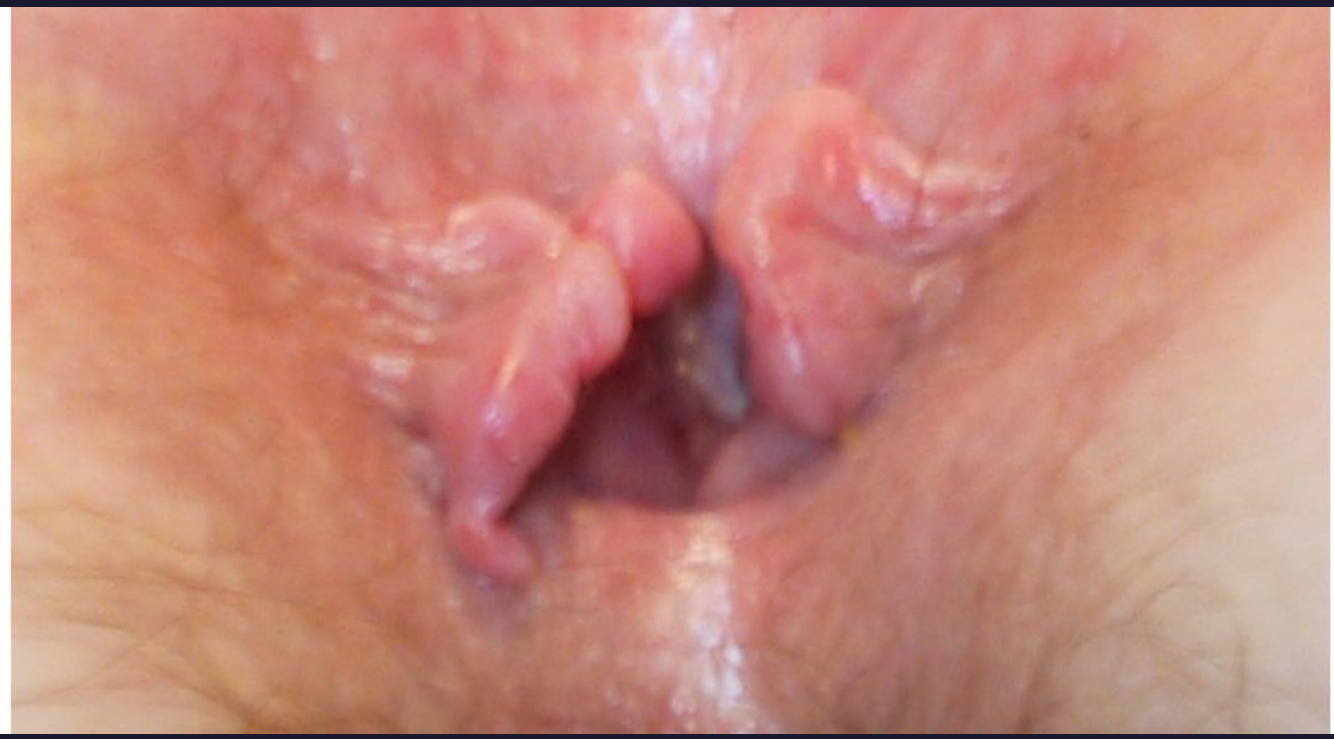


Skin tags

The ASCRS Textbook of Colon and Rectal Surgery

- Type 1 skin tags are edematous and hard and may be cyanotic and tender
- Type 2 skin tags are raised lesions with a range of shapes from broad to narrow and soft or firm; these painless tags are often referred to as "elephant ear tags" and generally occur in multiplicity





The ASCRS Textbook of Colon and Rectal Surgery

Skin tags

- Patients with symptomatic skin tags and active proctitis ……treatment directed at controlling inflammation
- Sitz baths, moistened wipes for hygiene, and careful cleansing ……reduce the symptoms of irritated skin tags
- Patients with large or multiple skin tags,……..excision particularly when tags are narrow-based and resulting defects will be small

Non fistulizing perianal Crohn's Hemorrhoids

Uncommon (3–20% of CD patients)

Craco et al, Color Dis. 2014

Association between hemorrhoids and skin tags with severe distal disease

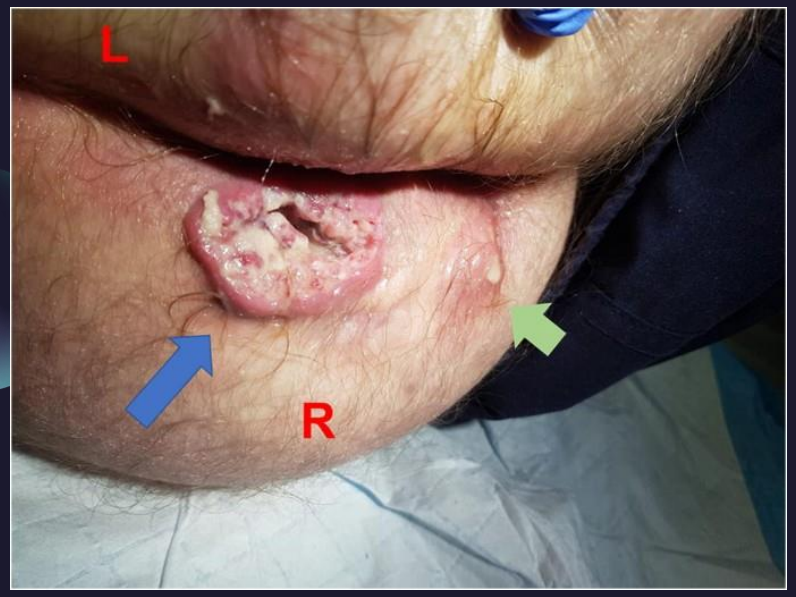
Wolkomir et al, DCR 1993

Outcome of surgery is bad with delayed wound healing

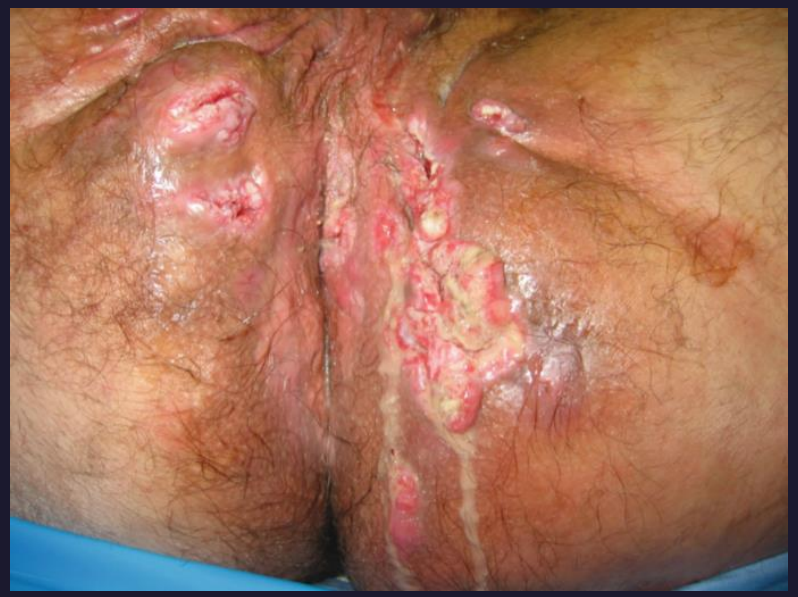
Reasonable in those with luminal remission without the need for corticosteroids and a CDAI <150

D' Ugo et al , BMC Gastroenterol. 2013

Conservative management is generally preferred



Journal of Gastrointestinal Surgery (2021)



ASCRS Textbook

Anal Cancer and Anal Stricture

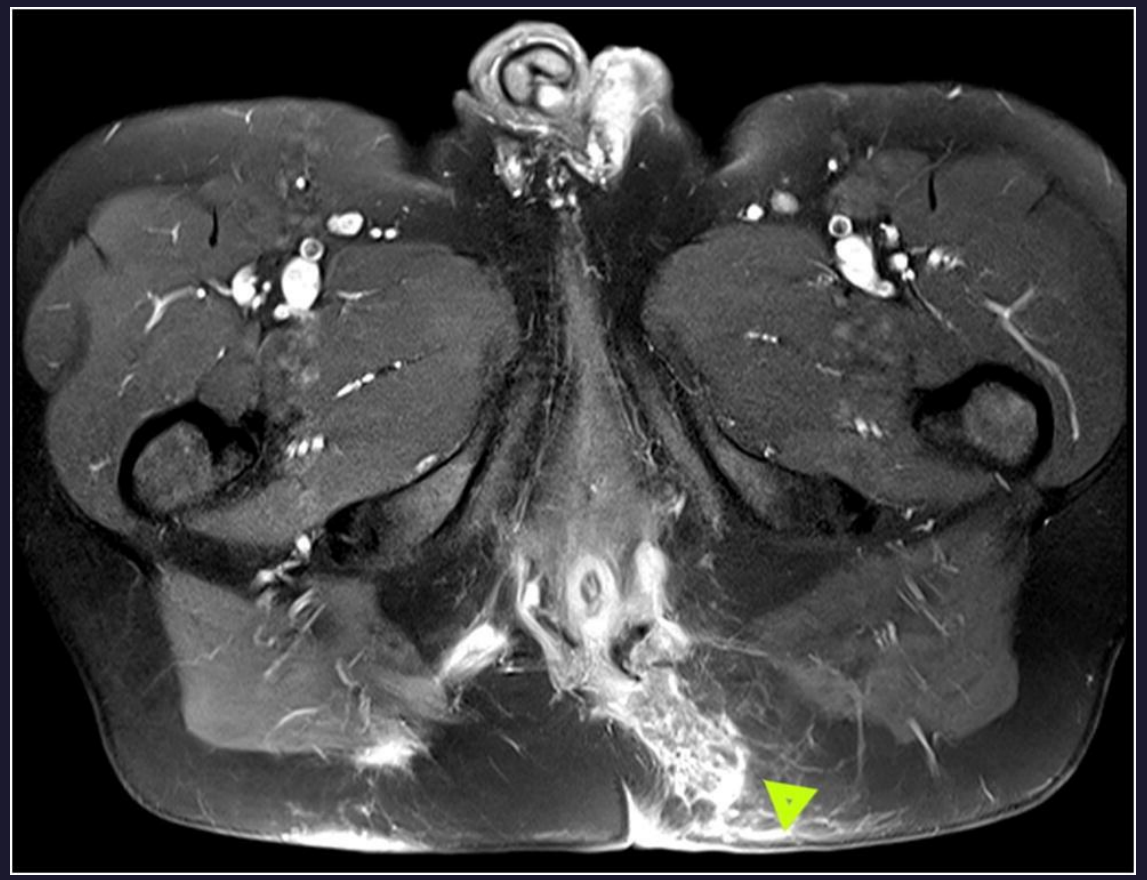
- Risk of both adenocarcinoma & SSC is increased

  Bauer JJ et al, AJS 1986, Shwaartz et al, DCR 2016

- Anal or rectal strictures arise due to prolonged transmural inflammation in 17% of patients with perianal CD
- Asymptomatic strictures do not require any treatment
- When strictures obstruct defecation, dilation manually or with balloon or Hegar
- Rectal advancement ……for anal stricture
- Half of patients with an anorectal stricture eventually undergo proctectomy

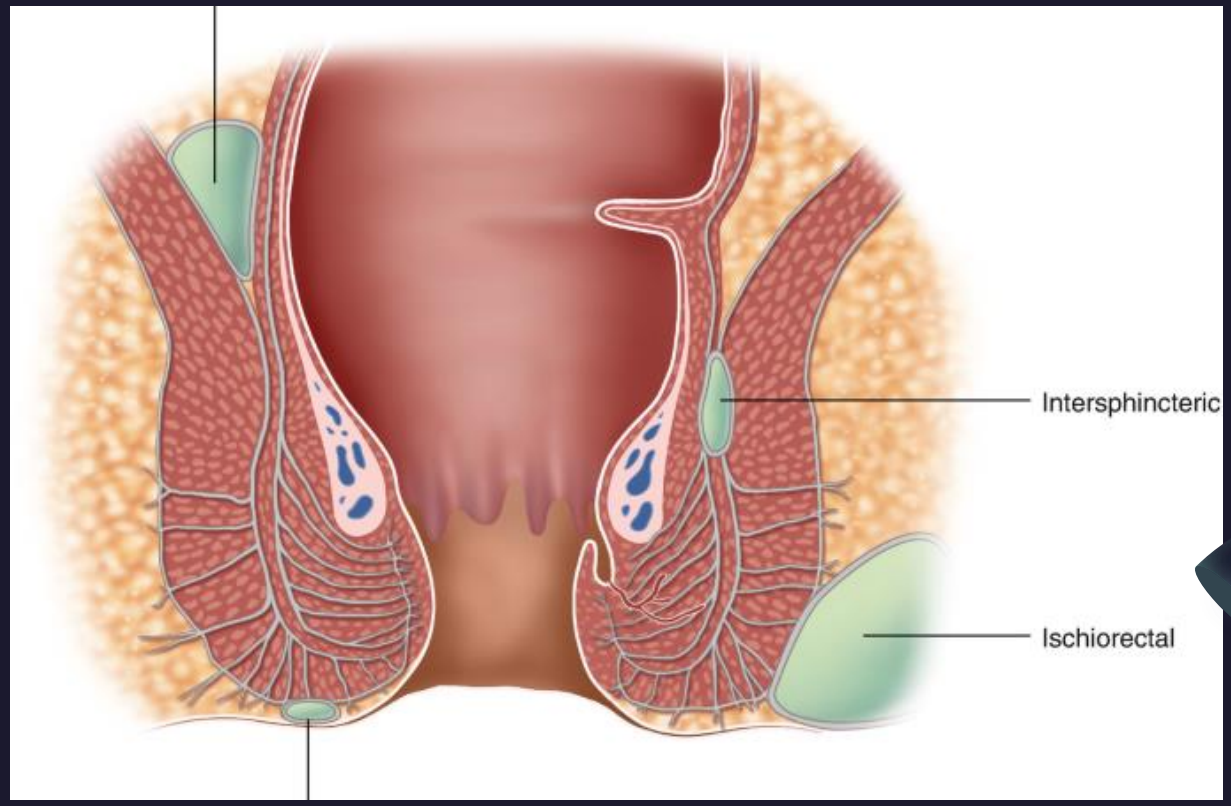
  Bauer JJ et al, AJS 1986

Fistulizing Crohn's

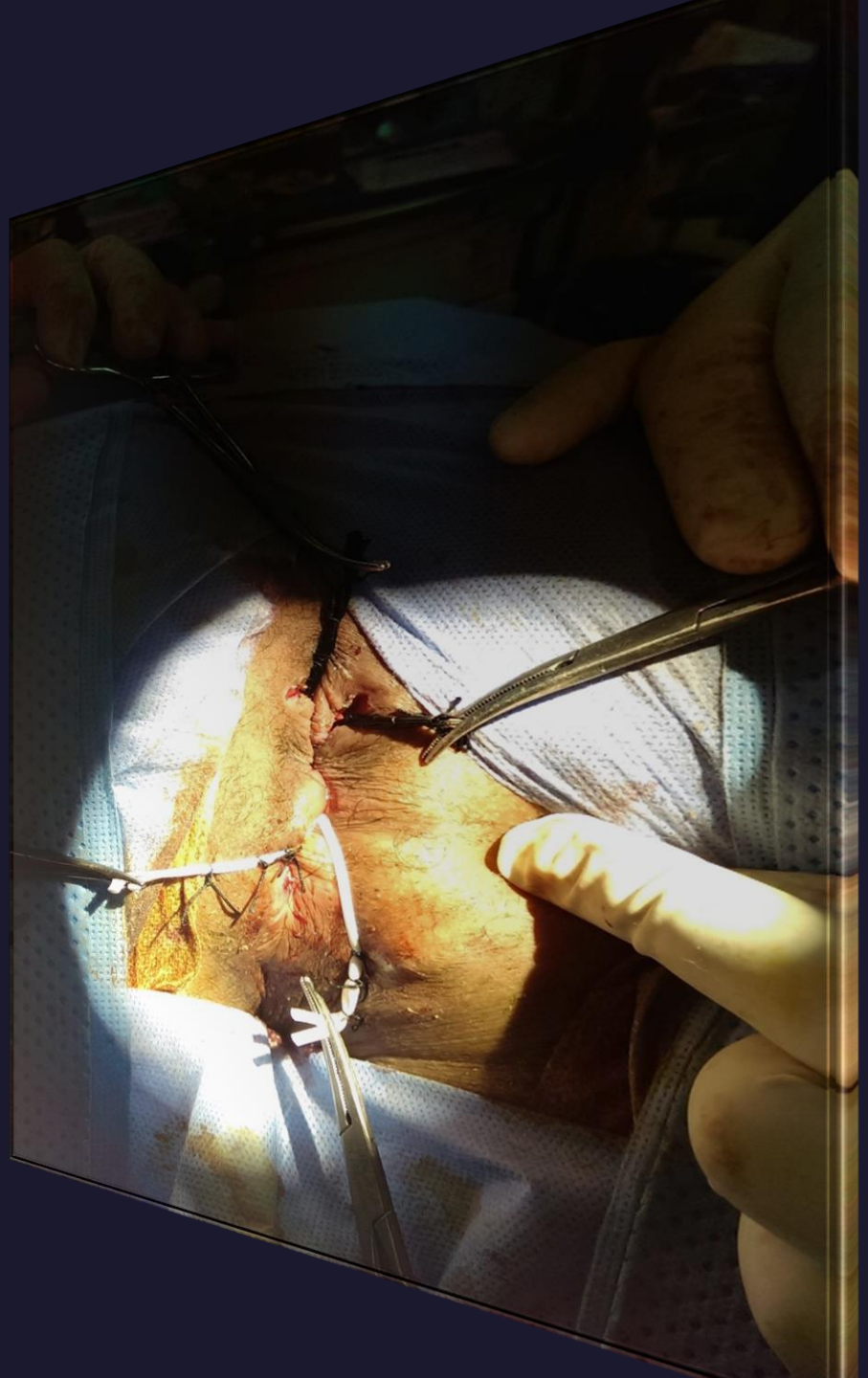


- Patients with fistulizing perianal CD may present acutely with abscesses or chronically with draining fistulas
- Additional signs of systemic sepsis may occur
- Fistulas without abscess with discharge from an external opening in the perianal skin, groin, or vagina or associated with pneumaturia or fecaluria (Urinary fistula)

Abscess



- Prompt surgical drainage of perianal abscesses is required to control sepsis and limit damage to the sphincters and surrounding anorectal tissues



Anorectal Fistula

- Combined
  - Clinical
  - Imaging (EUS and MRI)
  - Operative
- EUS 64-91%
- MRI 87%
- EUA 91%
- A combination of MRI or EUA with EUS provided an accuracy of 100%

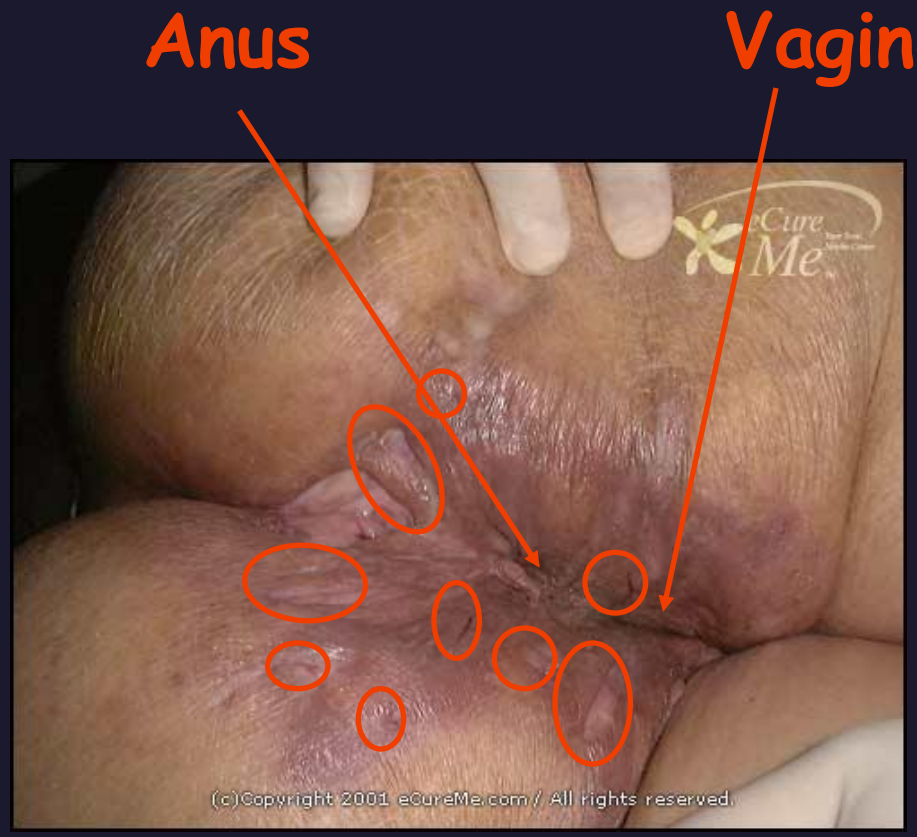
Schwartz DA et al (2001). Gastroenterology

Spradlin NM, et al (2008). Am J Gastroenterol

Perianal Crohn's Disease: Surgical Tx

Principles:

- **Control sepsis (antibiotics)**
- **Define and eradicate tracts**
- **Preserve sphincter function**



FINAL GOAL IS TO AVOID / DELAY OOSTOMY Vs. Proctectomy

Perianal Crohn's Disease Management

- Antibiotics
- Surgery
- Biological drugs
- Surgery + biological drugs
- Surgery + biological drugs + biological prothesis
- Etc…

WHAT IS THE ALGORITHM

Treatment Algorithm

History & physical
Endoscopy
Imaging
(MRI or EUS)

- Simple fistula **without** rectal inflammation
- Simple fistula with rectal inflammation
- Complex fistula

PERIANAL CROHN'S DISEASE: SURGICAL TX

SIMPLE PERIANAL FISTULAE

Symptomps	Treatment	Healing rate / reason	Level of evidence	grade
Asymptomatic fistula	**No intervention**	**Healing -- Unknown** **Not to subject the patient to the operative morbidity**	**IV**	**B**
Simple low symptomatic	**Fistulotomy**	• **High healing rate 62 -100%** • **Long healing time up to 6 months** • **Minor incontinence 0-12%**	**IV**	**B**

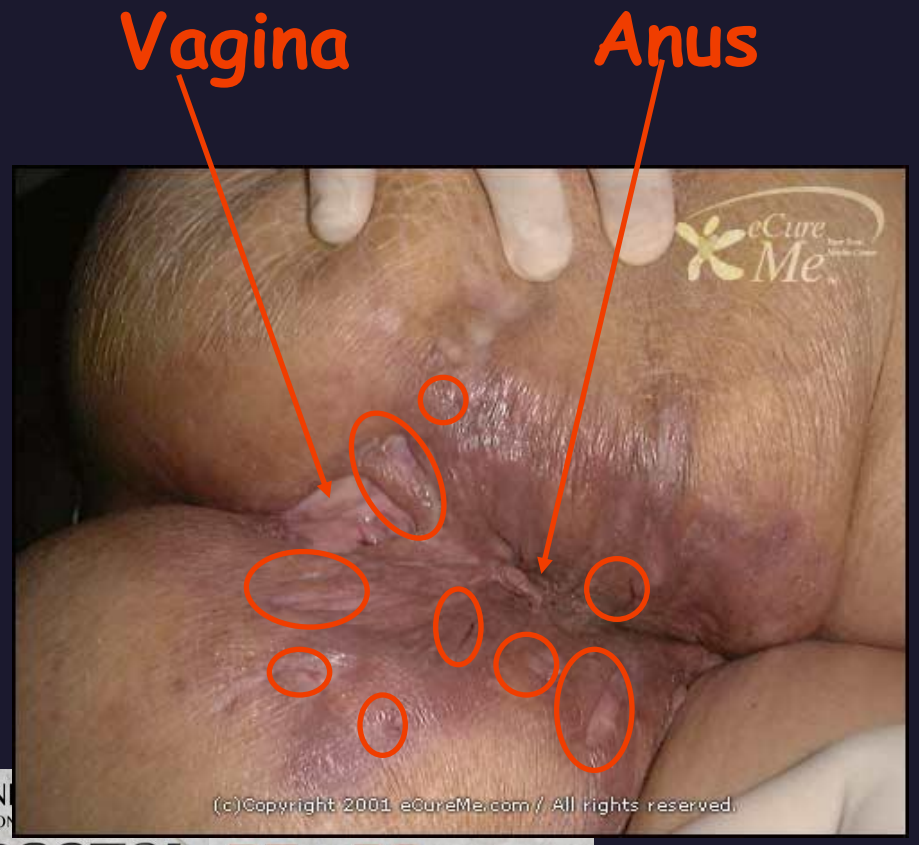
Symptomatic Trans-sphincteric

INTIAL THERAPY

- Drainage of abscess
  - In office
  - In operating room

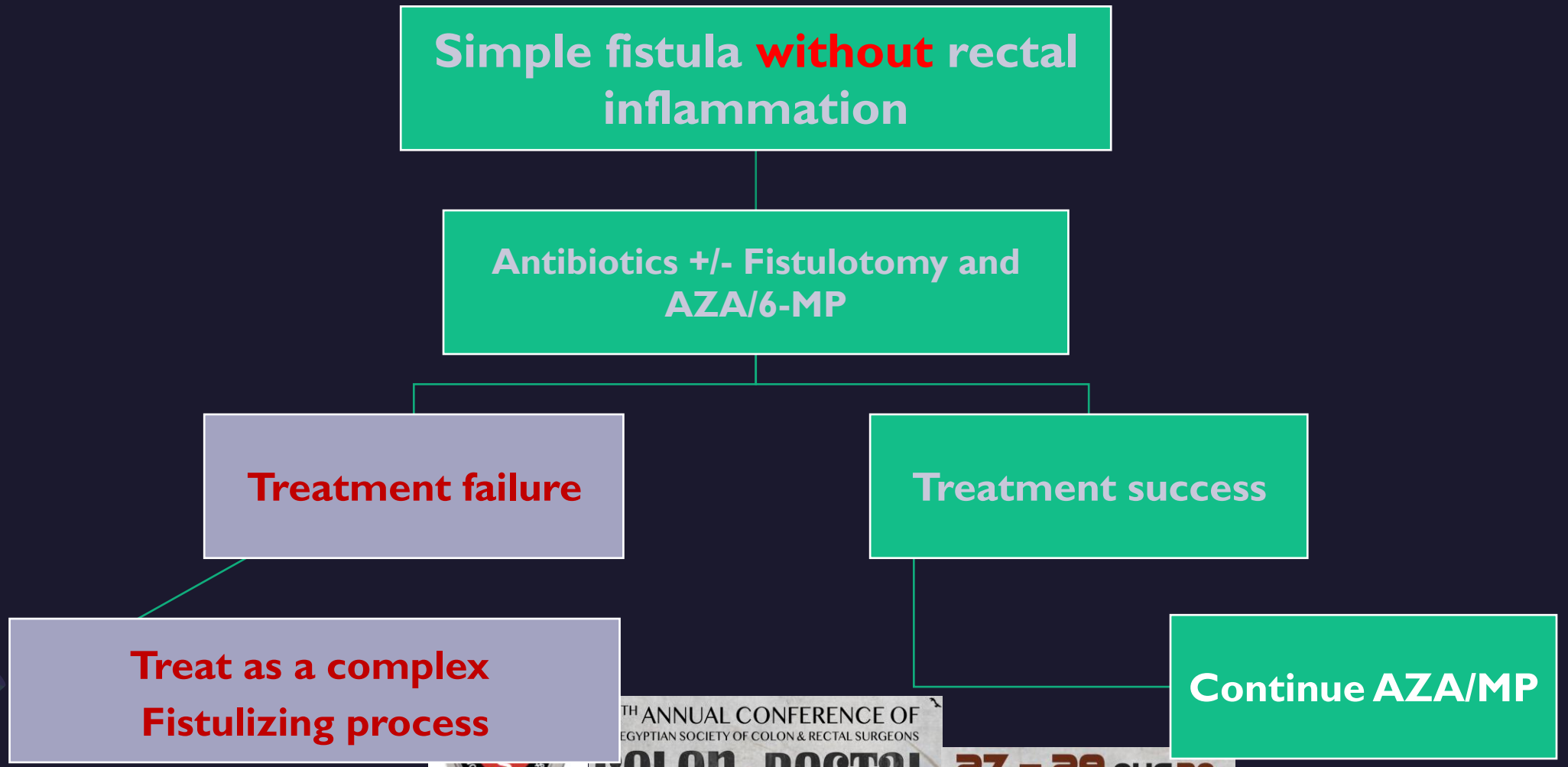
•Use of *Draining* seton

•Fistulotomy of superficial posterior fistula



Treatment Algorithm

(Simple fistula without rectal inflammation)



Treatment Algorithm

History & physical
Endoscopy
Imiging
(MRI or EUS)

- **Simple fistula without rectal inflammation**
- **Simple fistula with rectal inflammation**
- **Complex fistula**

Infliximab For The Treatment Of Fistulas In Patients With Cd

D. Present et al (New England J Med, 1999)

94 pts (abdominal and perianal fistulas)

Achieve healing the primary end-point of the trial

5 mg/Kg ⇒68 %; 10 mg / Kg ⇒56 %; Placebo ⇒26 %

NO SURGERY

Primary end-point efficacy: reduction of 50% or more in the number of draining fistulas

The primary end-point was based on the Investigators' physical evaluation ….A fistula was considered closed when it no longer drained DESPITE GENTLE FINGER COMPRESSION

Infliximab For The Treatment Of Fistulas In Patients With Cd

TABLE 4. ADVERSE EVENTS THAT OCCURRED IN AT LEAST 10 PERCENT OF PATIENTS IN ANY TREATMENT GROUP.

EVENT	PLACEBO (N=31)	INFLIXIMAB		
		5 mg/kg (N=31)	10 mg/kg (N=32)	5 OR 10 mg/kg (N=63)
	number (percent)			
Headache	7 (23)	5 (16)	6 (19)	11 (17)
Abscess	1 (3)	2 (6)	5 (16)	7 (11)
Upper respiratory tract infection	2 (6)	1 (3)	5 (16)	6 (10)
Fatigue	2 (6)	2 (6)	4 (12)	6 (10)

But .....

10% develop an absecess while on IFX.

Setons:
fistula drainage
reduce the risk of abscess
permit more complete fistula healing
Reduces risk of recurrence

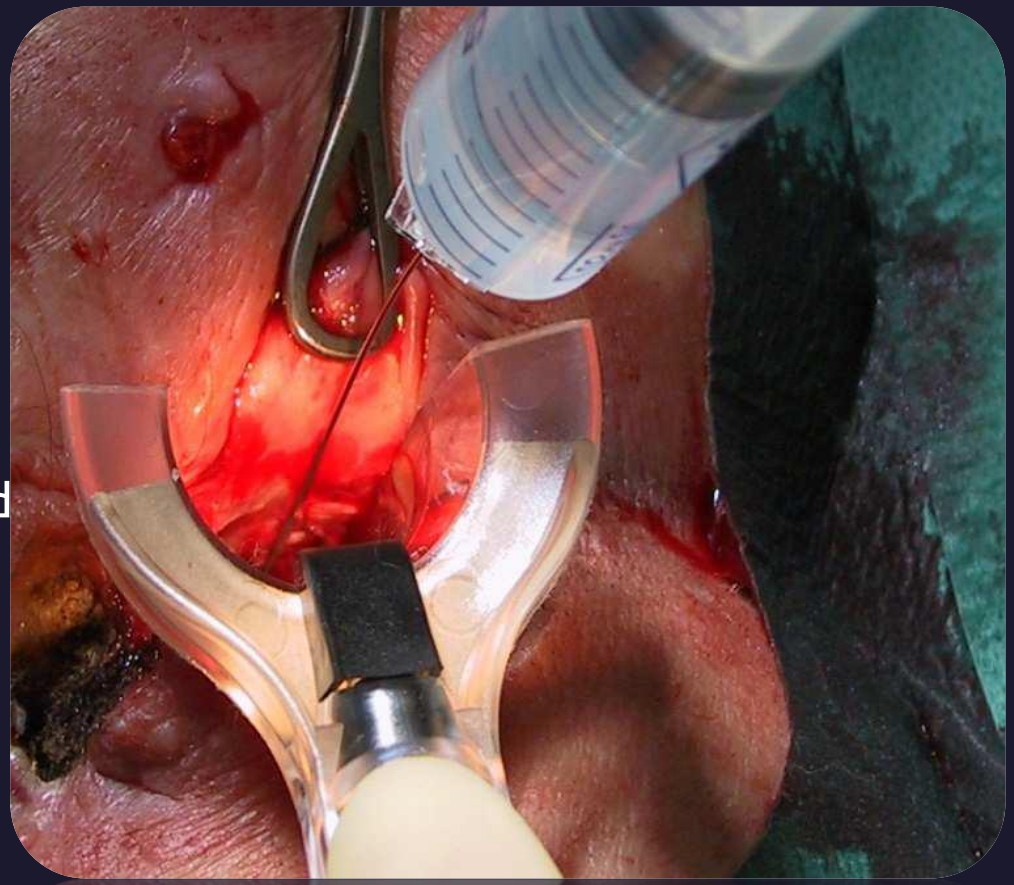
COMPLETE CLOSURE IN 46%

What happened when surgery was added?

AUTHORS	STUDY ESIGN	METHOD	RESULTS	P
Topstad et al. Dis Colon Rectum 2003	Uncontrolled study on 29 pts (perianal and R-V fistulas) Surgery and IFX	Surgery+IFX	PERIANAL FISTULA Healing 67% - Partial healing 19% R-V FISTULAS Healing 13% Partial healing 62%	
Talbot et al. Colorectal Dis 2005	Uncontrolled study on 21 pts with Surgery and IFX	Surgery+IFX	Healing 47% Partial healing 53%	
Sciaudone et al. Can J Surg 2009	Controlled study on 35 pts with • IFX • Surgery or • IFX+Surgery	IFX Surgery+IFX	IFX - Healing 63% Surgery - Healing 70% Surgery+IFX - Healing 78%	N.S

Local injection of Infliximab for the treatment of perianal Crohn's disease

- Mantoux test before first infusion
- EUA (Spinal or General anesthesia)
- 15-21mg / patient
- 6 initial infusions at 0, 4 and 8 , 12, 16, 20 weeks and eventually subsequent infusions every 4 weeks
- 82 patients
- Overall success : 65%



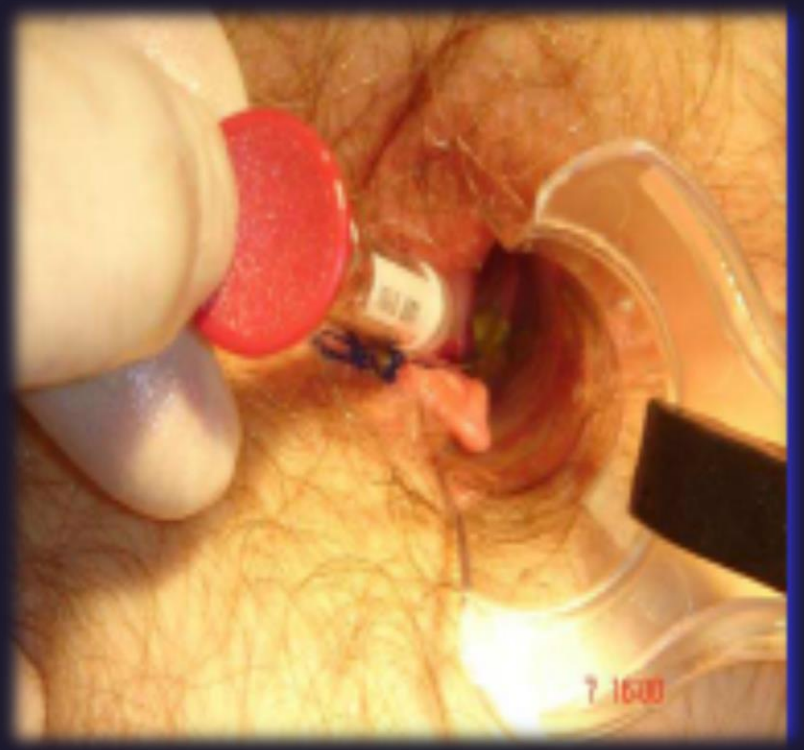
Dis Colon Rectum. 2005 Apr

Local Injection of adalimumab for perianal Crohn's Disease: Better than infliximab?

Poggioli G, Inflamm Bowel Dis, 2010

34 pts treated

- 12 rescue therapy after local injection of IFX
- 22 naïve therapy
- Injection of 40 mg every 15 days
- Outpatient treatment
- Consistence more convenient for local injection
- Same technique as Infliximab local injection



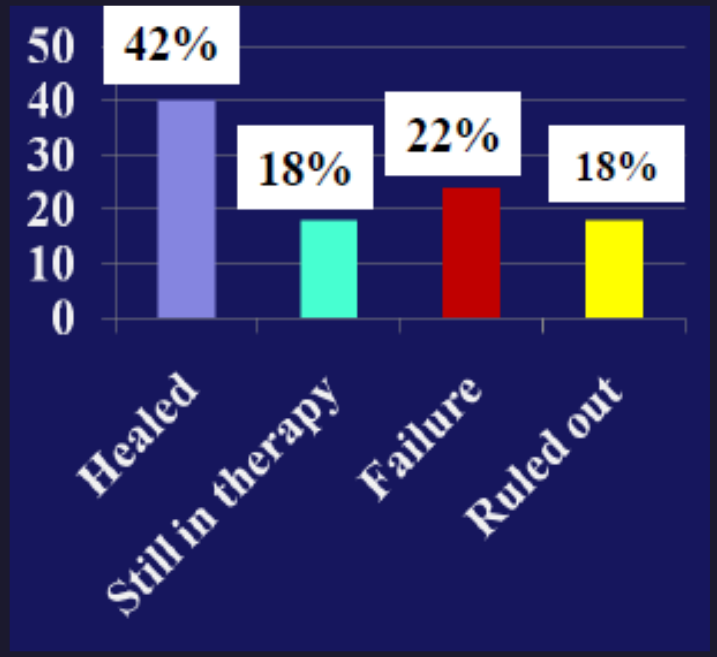
Local Injection of adalimumab for perianal Crohn's Disease:

Better than infliximab?

Poggioli G, Inflamm Bowel Dis, 2010

34 pts treated

- 42 % 15 pts healed
- 18 % 5 pts still in therapy pts
- 22 % 8 pts failure (80% waiting for rescue surgical procedure)
- 18 % 6 pts ruled out

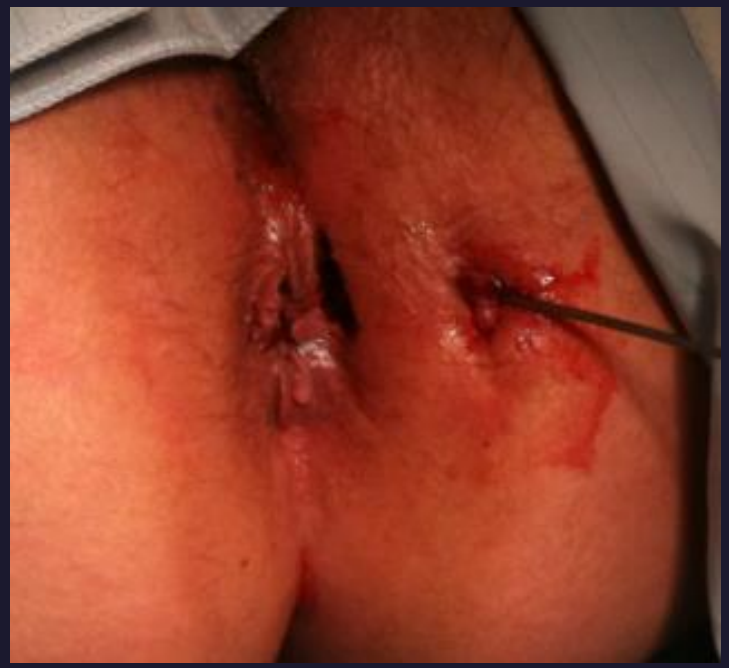


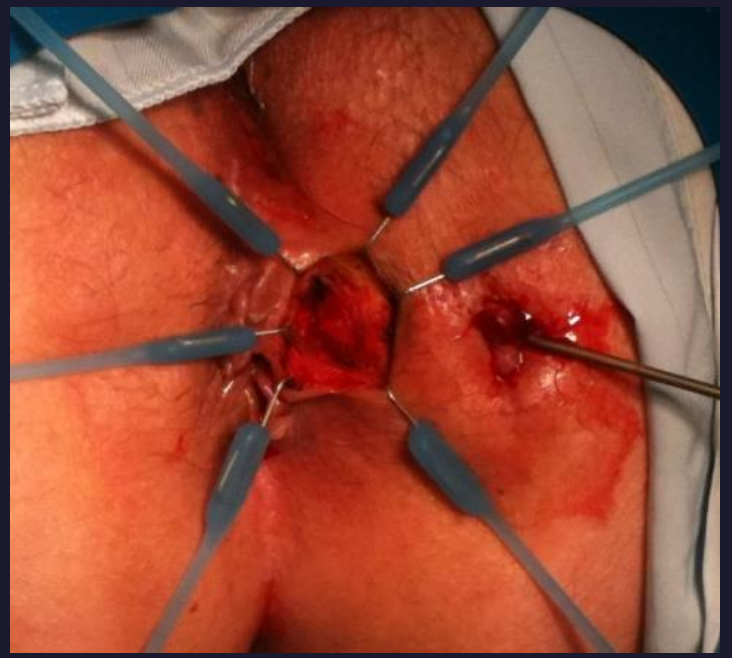
PERIANAL CROHN'S DISEASE: SURGICAL TX

Surgical options

1. Combined/local medical treatment
2. Fistulotomy
3. Flap
4. VAAFT
5. LIFT
6. Glue
7. Cell-based therapy

Perianal Crohn's Disease: Surgical Tx





Ligation Of The Intersphincteric Fistula Track (Lift)

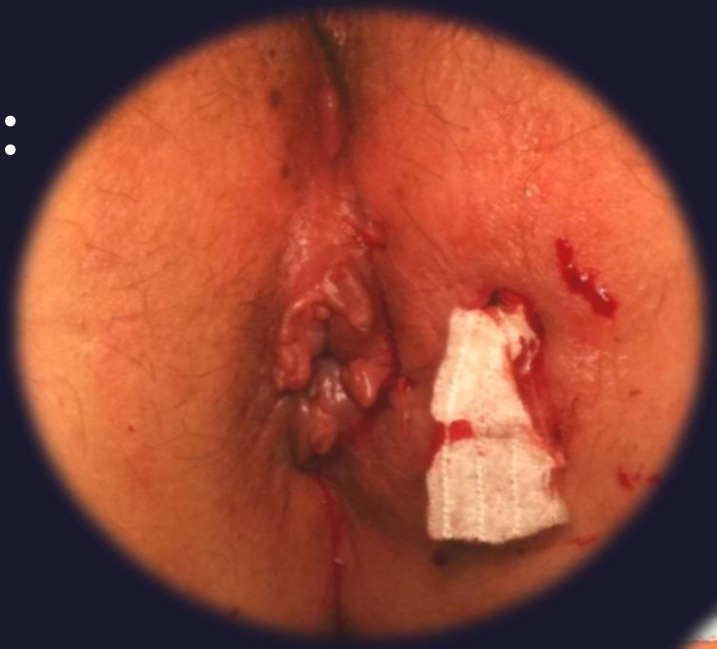
- 15 consecutive patients with complex fistulae
- healing rate of the LIFT site in 8 of 12 patients (67%)

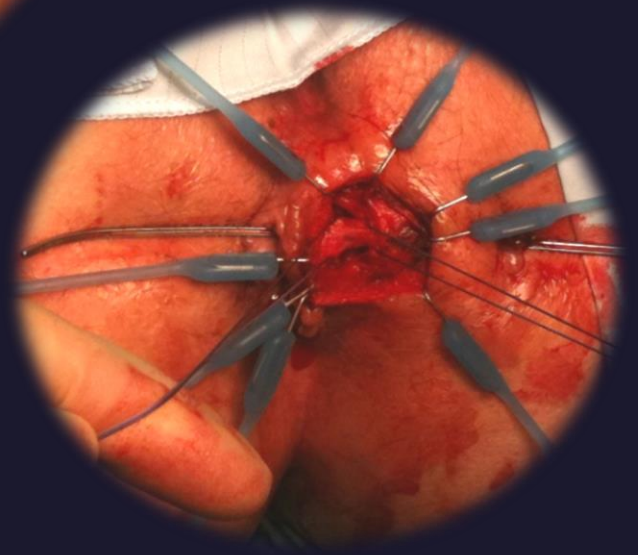
D. S. Gingold, Z. et al *Annals of Surgery*, 2013

Perianal Crohn's Disease: Surgical Tx

(LIFT) procedure

- Suggested predictors that
  - lateral versus midline location (P = 0.02)
  - longer mean fistula length (P = 0.02)
  - No patients experienced incontinence





D. S. Gingold et al, *Annals of Surgery*, 2013.

Perianal Crohn's Disease: Surgical Tx

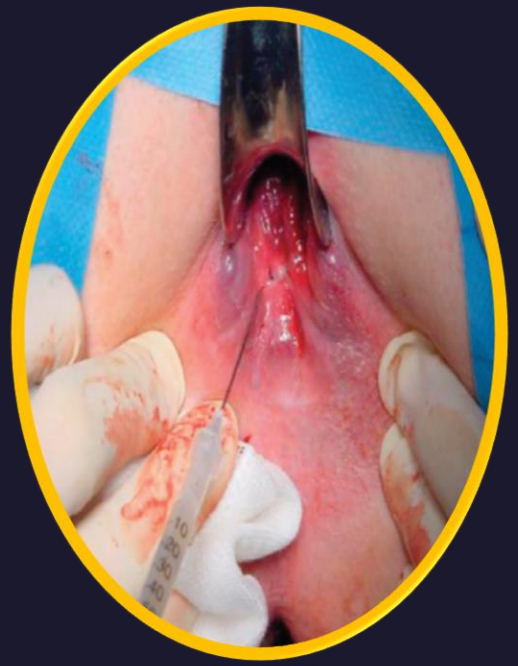
Fibrin Glue Closure

- Long fistula tract
- Transsphincteric
- Not amenable to fistulotomy
- No downside except for cost
- Can repeat if fails initially

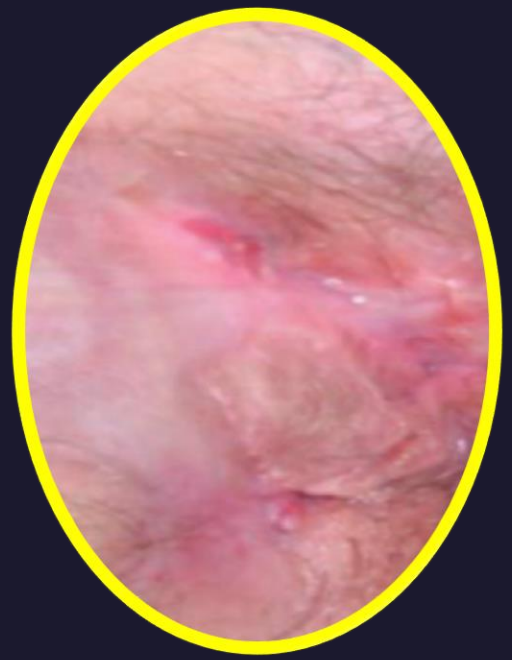
Dis Colon Rectum. 2009 Jan;52(1):79-86.

Expanded adipose-derived stem cells for the treatment of complex perianal fistula: a phase II clinical trial.

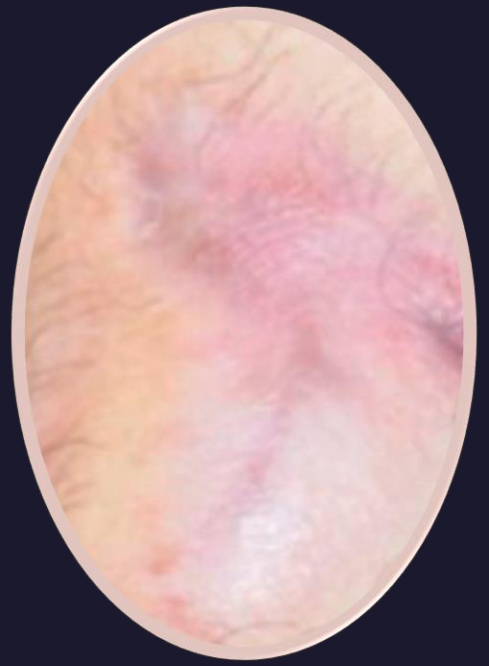
Fibrin Glue and adipose-derived stem cells



Administration of expanded ASCs for treatment of a complex perianal fistula



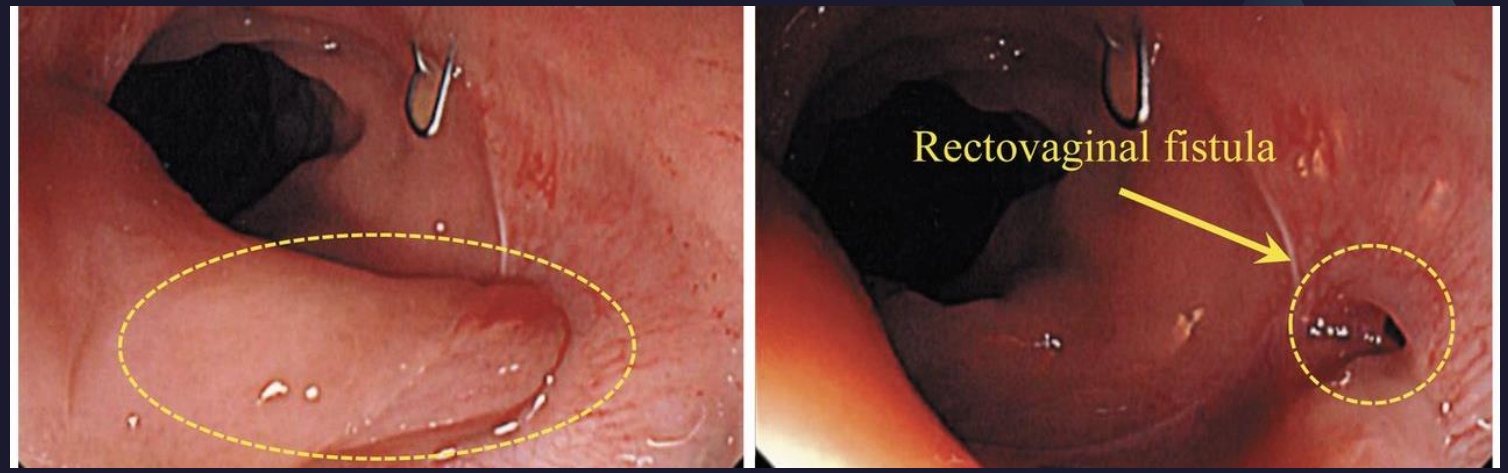
A. Nonhealed fistula



B. Healed fistula, with complete epithelialization of the external opening

- Increase in healing rate from
  1. 18% with fibrin glue alone
  2. 71% in patients receiving the glue added with ASCs
  3. A low proportion of the stem cell-treated patients with closure after the procedure remained free of recurrence after more than 3 years of follow-up

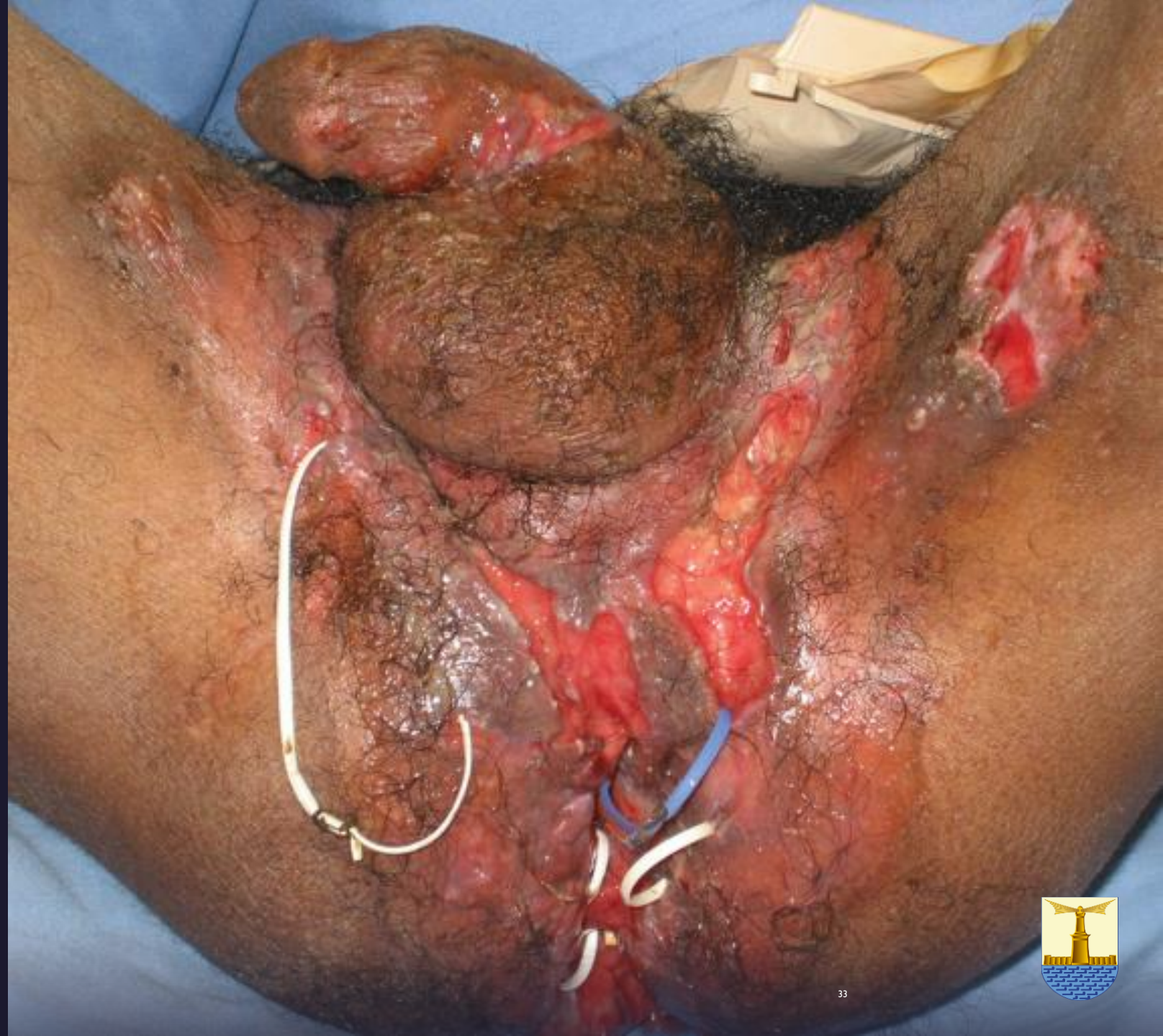
Rectovaginal Fistula

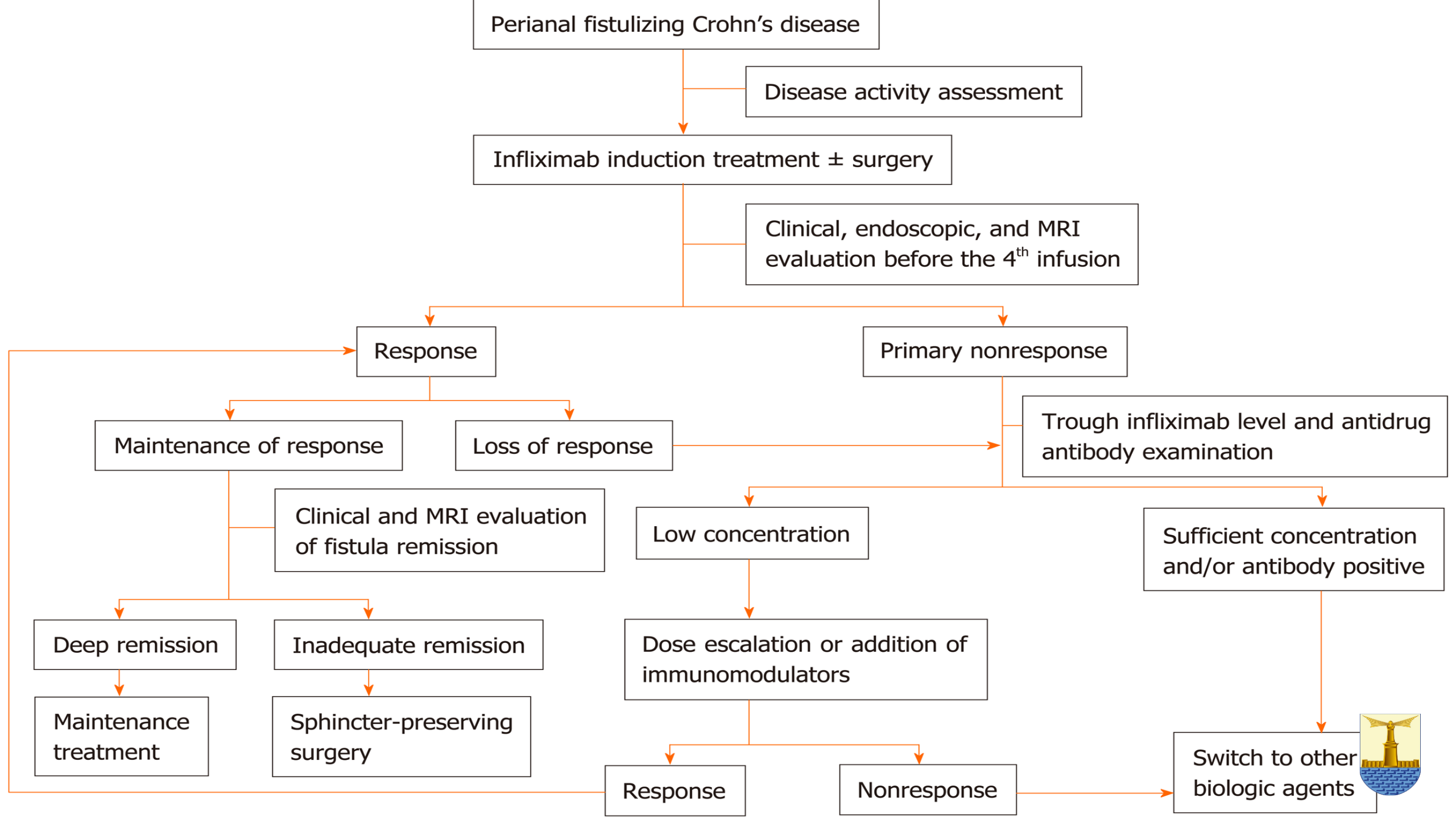


- Incidence of anovaginal or rectovaginal fistula (RVF) in women with CD : 10%
- Prior to considering repair of an RVF , control of perianal sepsis and optimization of medical management
- Advancement flaps from the anal or vaginal side, interposition either with gracilis or Martius (bulbocavernosus) flaps, or abdominal approaches such as pull-through procedures
- Fibrin glue or stem cell injection, fistula plugs, mesh interposition, and other novel techniques.
- The data on outcomes following RVF repair tends to be small case series
- Predictors of successful healing are largely unknown

Diversion

- Severe perianal CD may require temporary or permanent fecal diversion




Perianal fistulizing Crohn's disease
Disease activity assessment
Infliximab induction treatment ± surgery
Clinical, endoscopic, and MRI evaluation before the 4th infusion
Response
Primary nonresponse
Maintenance of response
Loss of response
Trough infliximab level and antidrug antibody examination
Clinical and MRI evaluation of fistula remission
Low concentration
Sufficient concentration and/or antibody positive
Deep remission
Inadequate remission
Dose escalation or addition of immunomodulators
Maintenance treatment
Sphincter-preserving surgery
Response
Nonresponse
Switch to other biologic agents

Take Home Messages

- Control sepsis: Infection must be addressed before starting immunosuppressive medications
- Treat underlying luminal disease and control diarrhea, but avoid steroids for perianal Crohn's disease
- Perineal care: Perineal hygiene should include gentle cleansing with sitz baths and skin protection with barrier creams
- Avoid surgery in patients who are asymptomatic or in the setting of active proctitis
- In patients who are optimized, fistulas may be treated with draining setons, advancement flaps, or LIFT
- Skin tags or hemorrhoids should generally not be treated
- Diversion may appropriate as component of the management of perianal Crohn's disease for some patients.

Take home messages

- Combined medical and surgical treatments are needed to treat perianal CD
- The management of complex perianal CD provides an appropriate surgical therapy, usually with draining seton placement, in combination with antibiotics and immunosuppressives
- Anti-TNF-α agents (as the first line treatment) + surgical therapy in complex perianal CD seems to be the optimal strategy for the induction and maintenance of fistula closure
- New topical treatment modalities, including the use of glues, and stem cells injection, are still with low success rates

Thank you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