Topical Medications for Anal Fissures and "Spasm"

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One of the most frequent questions I receive is in regard to the use of topicals in the care of anorectal patients. There is a fair amount of controversy regarding this as most of the topicals involved constitute an "off-label" use of the medications, but I have found this information very helpful in obtaining the best possible patient results.

The following information is a summary of the practices which I, along with many of my colleagues, have used in our clinics with tens of thousands of patients, and where indicated, is backed up by various pieces in the literature. From our experience, it seems clear that the most "under diagnosed" entity encountered is that of an anal fissure. The pathophysiology of a fissure is beyond the scope of this piece, but it is basically a poorly healing wound that occurs in the posterior (80-90%) or anterior (10-20%) midline, and may involve the anoderm anywhere from the dentate line "downward". The "classic" fissure is easy to identify, with excruciating tenderness and a visible fissure, but this scenario is seen in only a small percentage of patients. The remaining fissures are in various stages of healing, and so may often be superficially re-epithelialized (and thus not visualized). These patients also may not be terribly tender, or even deny tenderness until the area is palpated. In our opinion, each of these patients should be treated just as vigorously as the more classic patient — as we've found in doing so, there was a huge improvement in many of our more resistant patients.

Treatment for an anal fissure

- Behavioral and dietary
    - Depending on the study, from 20 – 50% of patients will improve with the following measures:
        - 15 – 20 gm supplemental dietary fiber per day
        - Increased fluid consumption to aid in softening stool
        - Warm sitz baths (which lowers the internal sphincter pressure and so is very comforting
        - Minimizing the time on the commode
- Topical medications - Nitroglycerin, diltiazem, nifedipine, cardizem
    - Helpful in 50 – 80% of patients
    - See discussion below for more information
- Botulinum Toxin (so-called "chemical sphincterotomy")
    - Up to 85% success
- Surgery – lateral internal sphincterotomy
    - 90%+ success rate with a 2-4% incidence of incontinence

Topical Medications:

There are 2 "camps" as it relates to these medications. There are those (myself included) who are fans of topical nitroglycerin ointment, and others that favor one of the calcium channel blockers. The proposed mechanism of action for any of these compounds is the relaxation of the spastic internal sphincter as well as local vasodiliataion, helping the fissure to heal. The "knock" on NTG is the fact that headaches (often severe) have been reported with its use, and the "knock" on the calcium channel blockers is that their efficacy has been questioned by many. A simple adjustment to the delivered "dose" of nitroglycerin seems to limit the headaches which occur while still being effective, and this is

why I'm such a huge proponent. These medications have been used individually as well as compounded with other materials (lidocaine, various emollients, each other, etc), as many have their favorite "recipes" for these medications.

1. Nitroglycerin Ointment:

The literature that I've seen in regard to the use of NTG involves the use of compounds ranging from 0.2 – 0.5%, and the amount of the compound utilized per dosage varies just as widely. The result in some of these studies is as much as a 70% incidence of "significant – severe" headaches, which in some patients results in their discontinuing the medication. We have found that the use of a "pea-sized" amount of 0.125% NTG has been quite effective in these patients without much of an incidence of headache. The instructions are to place this pea-sized drop of ointment intra-anally, three times daily for 3 months, decreasing the dose to twice daily when the internal sphincter tone has returned to normal. The patient is cautioned to lie down the first few times that the medication is taken, and to avoid the use of erectile dysfunction medications. I personally do not prescribe this in the face of orthostasis or other instability of the blood pressure, but have found very few issues with this dose.

2. Calcium Channel Blockers:

Diltiazem and nifedipine seem to be the most frequently used calcium channel blockers and the literature is fairly mixed as it relates to their efficacy. Headaches are very infrequent, but at least 2 meta-analyses reported by ASCRS have questioned their advantage over placebo. We use these if the patient takes erectile dysfunction medication, or in the very uncommon case of a patient with headaches when using the low dose NTG. We've always been very leery of performing a sphincterotomy because of the risk of incontinence (albeit a small risk) unless we've exhausted the use of more conservative measures.

<u>Treatment for patients with "spasm"</u>

If the use of the above medications in the face of a fissure is "off-label", then the following discussion is "off-off-label"! When we have patients with "tight" anal canals, "long" canals, a widened intersphincteric groove or some patients with incomplete evacuation, we've frequently prescribed NTG ointment to be used during the hemorrhoid banding process. These folks stay on the NTG until a week or so after the last banding. Our impressions from this use of NTG include:

- Fewer patients have pain after hemorrhoid banding
- Patients are easier to band on their subsequent visits
- It seems as if the "incidence" of proctalgia and/or dysynergia is less

The "theory" as to why the above findings were noted may be that some of these patients with the clinical findings of "spasm" actually have small fissures that are too subtle for us to pick up on, and so some of the patients previously given the diagnosis of "proctalgia" etc., may have just had little fissures.

I realize that there is nothing in the literature that I've found to back up these last recommendations regarding "spasm", but Dr. Iain Cleator's clinical results, what we've seen in our own clinics, as well as the reports from many of our Partners in the field all help to support this liberal use of these ointments.