

I Policy Guidelines

1. The following are the indications for the procedure:
 - a. Done for the treatment of symptomatic hemorrhoids of any grade.
 - b. Done in order to treat bleeding, swelling, itching, prolapse or "seepage" in these hemorrhoid patients.
 - c. Done to ligate an actively bleeding vessel in the lower rectum or upper anal region.
2. Patients are made to change into a comfortable and clean hospital gown provided by the hospital, or covered with a sheet or drape after undressing from the waist down.
3. Patient's complete clinical/medical history and physical examination are reviewed carefully, making certain to check their history of anticoagulant use, latex allergy, or use of erectile dysfunction medication.
4. Unless otherwise instructed by the ordering physician, patients are not required to undergo a bowel prep of any kind, or need to be "N.P.O" in advance of the treatment, as sedation or anesthesia of any kind is rarely used.
5. Done in a clinic setting or in a procedural room at the discretion of the physician and facility.

II. Procedures

1. The clerk inputs the patient's information in the computer database.
2. The patient is asked to change into a gown or to undress from the waist down with a sheet or drape to cover them.
3. Examiner puts on exam gloves, inspects the perianal region for signs of inflammation, external hemorrhoids, tags, fissures, fistulae thromboses, abscesses, and various skin lesions, with findings noted.
4. Examiner performs a digital rectal examination, evaluating for signs of anal fissures, fistulae, anal spasm, hemorrhoids, neoplasms and other mass lesions, with findings noted.
5. If significant anal spasm is noted, then a small quantity of 0.125% nitroglycerin ointment may be placed into the anal canal to relieve that spasm, and if significant tenderness is noted, then a quantity of a topical anesthetic may be placed into the anal canal as well.
6. Anoscopy is done if indicated with findings noted.
7. If indicated, the CRH O'Regan System is opened, the Ligator is assembled with a rubber band loaded onto the end of the device. This may be done in advance of the procedure commencing at the Examiner's option.
8. If indicated, the Ligator is lubricated, and then advanced into the anal canal, to an appropriate depth.

9. The "plunger" of the Ligator is pulled back, aspirating some of the hemorrhoid tissue into the barrel of the syringe.

10. The "plunger" is locked in place, and the Ligator is left in place, allowing a bit more tissue to be trapped into the Ligator.

11. The Ligator is rotated 90 degrees in either direction, and the patient is questioned, as they should feel no pain or "pinching" -- only a sense of "pulling", "pressure", or tenesmus.

12. If pain or "pinching" is experienced, then the Ligator is "unlocked" and then placed more deeply into the rectum by repeating #11.

13. If no pain or "pinching" is experienced, the Ligator band is deployed by the Examiner.

14. The Ligator is removed and set aside.

15. A digital rectal examination is performed, so that the examiner can assess the adequacy of the banding — if an inadequate amount of tissue has been banded, then the Ligator is reloaded, and steps 8 – 15 are repeated. If too much tissue was ligated, or the band was deployed a bit too low in the anal canal, the band and banded tissue is manipulated to "loosen" the band or remove it.

16. The patient should be questioned to see if they are experiencing pain or a "pinching" sensation. If so, then #15 is repeated, otherwise the patient is encouraged to get dressed and is readied for discharge.

17. Prior to discharge, the patient is again questioned by staff to see if they are experiencing pain or a "pinching" sensation, or if they look as if they are uncomfortable. If not, and they are only experience a sensation of pressure or a bit of tenesmus, they are discharged. If not, they are encouraged to go back to the exam room, so that the Examiner can re-perform #15.

18. A copy of the CRH O'Regan System's "Post Banding Instructions" is given to the patient for their reference, and a follow-up visit is made for that patient at the interval requested by the Examiner.

19. A record of the procedure is created, including the findings of the examination as well as a reporting of the number of bands placed, the location of their placement, and a record of the reaction of the patient to the Ligation as well as the need for "adjustment" of the band.