What is Lysis of Epidural Adhesions?

Lysis of Epidural Adhesions (also know as the Racz® Procedure) is a technique involving site-specific catheter placement and fluid injection intended to "open up" the perineural space with various therapeutic medications. The injected medications are designed to free the nerve root from restrictions and reduce inflammation associated with swollen, painful nerve roots exiting the spinal canal in the epidural space. A unique, proprietary, steerable, soft-tip Racz® Catheter is guided to the target site where medications are delivered directly to the painful nerve roots. These Racz® Catheters are introduced through a specially designed, shear-resistant epidural needle called the RX-2™ Coudé® or RX Coudé®. They are commonly introduced in between the upper thoracic and the lower cervical vertebrae. They can also be introduced transforaminally.

Also known as:
- Lysis of Epidural Adhesions
- Percutaneous Neuroplasty
- Racz® Procedure
- Adhesiolysis

Patient Inclusion Criteria[2]

- Spinal stenosis
- Facet pain
- Osteophyte causing radiculopathy
- Failed neck surgery syndrome
- Multilevel degenerative arthritis
- Disc herniation and radiculopathy
- Spondylosis and radiculopathy (MRI, CT)
- Disc disruption/radicular or non-radicular pain
- Pain unresponsive to spinal cord stimulation and narcotics
- Radiculopathy due to epidural fibrosis (on enhanced MRI)
- Metastatic carcinoma of the spine leading to compression fracture
- Chronic neck pain and failed conservative treatment options
- Radiating upper extremity pain

Typically indicated for patients diagnosed with:
- Failed neck surgery syndrome
- Spinal stenosis
- Epidural adhesions
- Chronic neck pain from excessive scarring in the anterior lateral epidural space
- Radicular pain unresponsive to epidural steroid injections

Patient Exclusion Criteria[2]

- Spinal instability or spinal cord syrinx
- Pregnant or lactating women
- Arteriovenous malformation
- Arachnoiditis
- Local and or systemic infection
- Uncontrolled or acute medical illnesses including: coagulopathy, renal insufficiency, chronic liver dysfunction, progressive neurological deficit, urinary and sphincter dysfunction, increased intercranial pressure, spinal fluid leak, pseudo tumor cerebri intercranial tumors, unstable angina, and severe chronic obstructive pulmonary disease
- The use of anti-platelet medicants or anti-coagulants including: aspirin, Plavix, NSAID's, gingko, ginseng, vitamin E, coumadin, etc. (laboratory measurements for bleeding and clotting to be in the normal range following discontinuation for appropriate duration)
- Drug addiction and/or uncontrolled major depression of psychiatric disorders
- History of adverse reaction to local anesthetic, steroids, contrast or other injected medications

Standard Injection Volumes for Interlaminar/Cervical Lysis of Adhesions

1. Diagnostic: 1-2 mL OMNIPAQUE™240* - outline filling defect and place catheter to target site
2. To show runoff and absence of loculation, contrast 0.5-1 mL OMNIPAQUE™ 240* injected through the catheter
3. 1-2 mL OMNIPAQUE™240* through catheter for verification of enzyme effectiveness
4. Spreading Factor: Hylenex® 150-300 units (human recombinant) diluted in 5 mL of preservative-free saline
5. Steroid Injection: 4 mg dexamethasone or 40 mg triamcinolone
6. Local Anesthetic: 6 mL 0.2% ropivacaine or 10 mL of 0.25% bupivacaine
7. Depending on the physician's lysis technique, wait 20-30 min. Evaluate for motor block. If no motor block is present, with the patients painful side down, inject 5 mL of 10% hypertonic saline over 5-10 minutes. If the patient experiences pain, inject 2-3 mL of local anesthetic.

*** Critical note:** Make sure to use non-ionic water-soluble contrast media. Some physicians also use 2 mL of ISOVUE-M 200. Please refer to current literature for volumes and medications used for injections.

Literature and Scientific Articles

One Day Cervical Lysis of Adhesions Step by Step: Poster Presentation, 4th Croatian Congress on the Treatment of Pain, Osijek, Croatia, May 2018

1. Gerdesmeyer L, Wagenpfeil S, Birkenmaier C, Veihelmann A, Hauschild M, Wagner K, Al Muderis M, Gollwitzer, H, Diehl P, Toepfer A. Percutaneous Epidural Lysis of Adhesions in Chronic Lumbar Radicular Pain: A Randomized, Double-Blind, Placebo-Controlled Trial. *Pain Physician* 2013; 16: 185-196
2. Racz G, Heavner J, Smith J, Noe C, Al-Kaisy A, Matsumoto T, Lee S, Nagy L. Epidural Lysis of Adhesions and Percutaneous Neuroplasty Racz Procedure. *Intech - Pain and Treatment;* Chapter 10: 289-333
3. Racz G, Day M, Heavner J, Smith J. The Racz Procedure: Lysis of Epidural Adhesions (Percutaneous Neuroplasy). *Comprehensive Treatment of Chronic Pain by Medical, Interventional, and Integrative Approaches (Deer Ed.)* 2013; Chapter 50: 521-534
4. Park E, Park S, Lee S, Kim N, Koh D. Clinical Outcomes of Epidural Neuroplasty for Cervical Disc Herniation. *Journal Korean Medical Science* 2013; 28: 461-465
5. Dunn A, Heavner J, Racz G, Day M. Hyaluronidase: a review of approved formulations, indications and off-label use in chronic pain management. *Expert Opinion on Biological Therapy* 2010; 10(1): 127-131
6. Veihelmann A, Devens C, Trouillier H, Birkenmaier C, Gerdesmeyer L, Refior H. Epidural neuroplasty versus physiotherapy to relieve pain in patients with sciatica: a prospective randomized blinded clinical trial. *Journal of Orthopaedic Science* 2006; 11: 365-369
7. Heavner J, Racz G, Raj P. Percutaneous Epidural Neuroplasty: Prospective Evaluation of 0.9% NaCl Versus 10% NaCl With or Without Hyaluronidase. *Regional Anesthesia and Pain Medicine* 1999; 24(3): 202-207
8. Racz G, Heavner J. Complications Associated with Lysis of Epidural Adhesions and Epiduroscopy. *Complications in Regional Anesthesia and Pain Medicine, 2nd Edition*; Chapter 33: 373-384
9. Moon DE, Park HJ, Kim YH. Assessment of Clinical Outcomes of Cervical Epidural Neuroplasty Using a Racz-Catheter and Predictive Factors of Efficacy in Patients with Cervical Spinal Pain. *Pain Physician* 2015; 18:E163-E170

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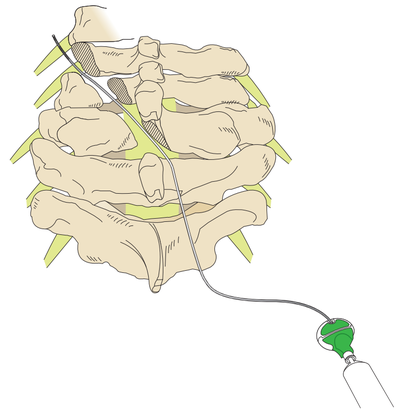
NOTE: *Although this step-by-step guide is based on the technique and clinical experience of a physician, the information contained in this guide is for general guidance on matters of interest only and shall not be substituted for or assimilated to legal or medical advice. You should always consult current literature for appropriate techniques, volumes, and medications used for injections and procedures.*
Before using any medical device, read all the instructions for use supplied with the product. This guide and its contents are not a substitute for the operator's manual of any medical product, which include important warnings and precautions. This white paper does not instruct on the proper medical use of this equipment. It is the responsibility of the physician and/or support staff using the described equipment to decide the suitability of the procedure for each patient, and to refer to current literature for appropriate techniques, volumes, and medications used for injections and procedures.

LT-204 Rev. 0

ONE DAY CERVICAL LYSIS OF ADHESIONS

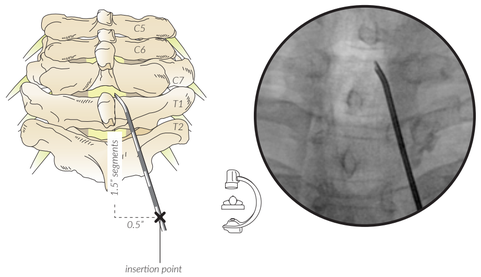
A Step-By-Step Guide On Racz® Catheter-Based Procedure

A White Paper Series by Gabor B. Racz M.D., DABPM, FIPP, DABIPP



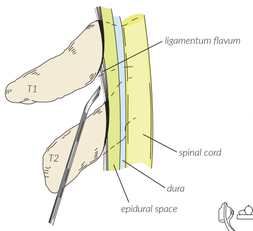
1 RX-2™ Coudé® Needle Entry

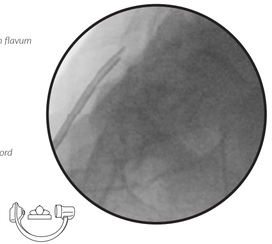
The recommended needle for this technique is the 18g RX-2™ Coudé® Needle which has a second interlocking stylet that protrudes past the needle tip. This atraumatic tip functions to push the dura away while the needle is being rotated. Place the patient in the prone position with a C-arm rotated slightly cephalad to compensate for the kyphosis. Start with the skin wheal needle technique to numb the entry point of the introducer needle. The skin entry point is paramedial (0.5" off the midline) and one and a half interlaminar spaces below the target interlaminar space of C7-T1 or T1-T2, which can be confirmed fluoroscopically.



2 RX-2™ Coudé® Needle Advancement

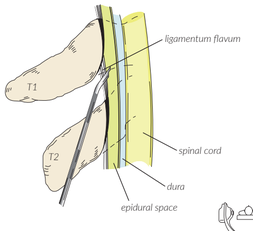
While still using the A/P view with the tip facing anterior medially, advance and direct the needle towards the midpoint of the chosen interlaminar space. Once the needle engages the deeper tissue planes, rotate the C-arm to the lateral view to confirm needle depth. (It is important that the tip of the needle is parallel to the ligamentum flavum). Continue to advance towards the epidural space and obtain an A/P view to recheck the direction of the needle before furthur advance. If the tip of the needle crosses the midline, withdraw the needle to allow redirection.

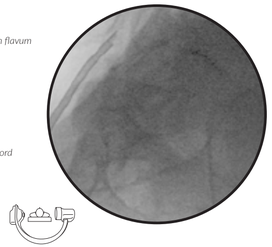




3 Epidural Entry (LOR)

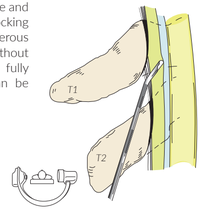
Using the loss-of-resistance technique, advance the needle to identify the epidural space. The tip of the RX-2™ Coudé® Needle must be pointed caudally.



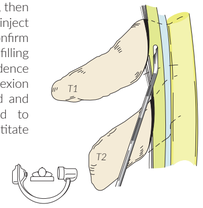


4 Introduction of Blunt Stylet, Cephalad Orientation of Needle, Followed by Epidurogram - Inject 1-2 mL of OMNIPAQUE™ 240

A. Remove the LOR syringe and insert the second interlocking stylet. It is extremely dangerous to rotate the needle tip without the atraumatic stylet fully inserted, as the dura can be easily cut.

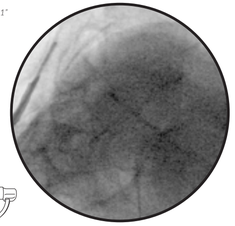


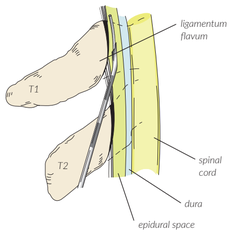
B. Rotate the tip cephalad, then remove the stylet. Next, inject 1-2 mL of contrast to confirm entry and to check for filling defects. If there is no evidence of contrast runoff, then flexion with rotation of the head and neck should be performed to open up the foramen to intitate runoff.



5 Catheter Placement with Visualization of Runoff, 150 Units of Hylenex® Diluted in 5 mL of Preservative-Free Saline, Bolus of Steroid and Local Anesthetic

Make a one inch, 15°- 20° bend in the catheter tip for optimum steerability and insert it through the needle. The opening of the needle should be directed towards the target site. Slowly advance the catheter and once the target level has been reached, rotate the tip of the catheter towards the foramen inject another 0.5-1 mL of contrast to visualize the targeted nerve root and to ensure runoff.

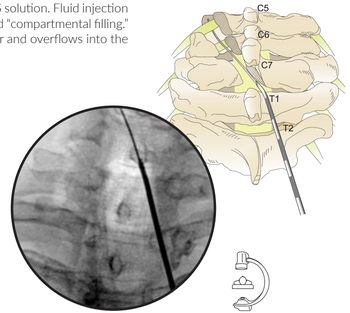




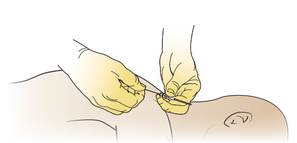
Slowly inject 150 units of Hylenex® dissolved in 5 mL of preservative-free normal saline. Follow this with an additional 1-2 mL of contrast and observe for "opening up" of the "scarred in" nerve root. Next, give a 2 mL test dose of a 6 mL solution of local anesthetic and steroid (5 mL of 0.2% ropivacaine and 1 mL of 4mg of dexamethsaone). After five minutes, if there is no evidence of intrathecal or intravascular spread, inject the remaining 4 mL of the LA/S solution. Fluid injection under gentle presssure opens up the perineural space. This process is called "compartmental filling." Compartmental filling is where the fluid finds the weakest spot in the scar and overflows into the adjoining compartment. Hyaluronidase is used to facilitate the spread.[1,5,7]

Be aware of allergic and anaphylactic reactions, as any injected material can trigger such reactions. These reactions are very rare, but the physician must be able and ready to treat any and all reactions by having the necessary medications and monitoring equipment available.

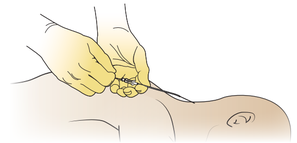
The RX Coudé® Needle should always point in the direction of the target. Catheter tip is placed towards the C6 ventral-lateral epidural space. Bacterial filters are recommended in all instances when more then one time injection is used or the catheter is left in place for a prolonged period of time. Anytime there is a disconnect of the catheter and the connector, the system should be removed from the patient. This is an essential precaution to prevent infection.



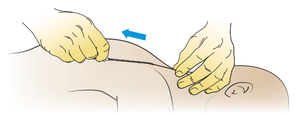
6 Removal of the Needle and Observation Period for the Absence of Motor Block - Followed by Infusion of Hypertonic Saline



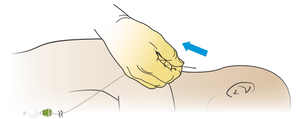
A. Stabilize the catheter to prevent catheter tip displacement



B. Withdraw the introducer needle while holding the catheter in place



C. Stabilize the catheter then remove the introducer needle



D. After completion of the procedure, gently remove the catheter

After the injections have been completed, remove the needle. Next attach the bacterial filter to the Stingray® connector, assuring its sterility. The patient should be taken to the recovery room in order to evaluate motor function. If the patient tests positive for a motor block, STOP the procedure. This is an indication of a possible subdural spread.

Wait 20-30 minutes and if no motor block is present, place the patient with their painful side down and infuse 5 mL of hypertonic saline (10% NaCl) over 5-10 minutes. Most hypertonic saline injections should not be painful. (This volume should be the same or less than the local anesthetic volume previously injected. If pain is experienced during the injection, STOP and inject 2-3 mL of local anesthetic before proceeding with the injection). Hypertonic saline is used for osmotic reduction of edema and disconnection of C fibers (sinuvertebral system) function.[3]

After injections have been completed, withdraw the catheter from the patient (introducer needle should have been previously removed). Start neural flossing exercises as soon as possible (shown on next page).

During the one-month follow up visit, it is common to see patients with pain-related facet joint arthropathy. These patients may need a diagnostic block followed by a cryoanalgesia or radiofrequency denervation of the facet joint.

7 Begin Neural Flossing Exercises

After the procedure, have the patient perform the neural flossing exercises as soon as possible.