

Anal Adrenergic for Fecal Incontinence (in Spinal Cord Injury)

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See “Topical oxymetazoline for fecal incontinence in patient with spinal cord injury: a double-blind randomized controlled crossover study,” by Barak et al., on page 234.

Wherever people with chronic spinal cord injury (SCI) gather in veterans and civilian centers, colon and rectal surgeons are called as consultants to create colostomies for intractable constipation and/or incontinence¹ and to treat the hemorrhoids that follow years of mechanically stimulated defecation.² Occasionally, we are asked to comment on SCI bowel care, more commonly to manage slow-transit constipation and/or functional outlet obstruction.³ However, for some people with SCI, especially those with lower levels of injury (paraplegia rather than tetraplegia) and lower motor neuron dysfunction, fecal incontinence is a prominent feature of their neurogenic bowel. This may be managed by medical and mechanical bowel programs that replace the vagaries of spontaneous defecation with scheduled, stimulated evacuation, and by such surgical techniques as sacral nerve stimulation⁴ and antegrade irrigation via appendicostomy or cecostomy.⁵ A Cochrane review⁶ finds little compelling evidence for most current treatments and no way to compare them. This would suggest caution to enthusiasts of one or another treatment—and the more invasive the treatment, the more caution is advised.

Into this still-nascent, underresearched field comes a modest new medical entrant, the topical α -agonist oxymetazoline. The study published in this issue⁷ has what

Funding/Support: None reported.

Financial Disclosure: None reported.

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Dis Colon Rectum 2019; 62: 137–138
DOI: 10.1097/DCR.0000000000001264
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DISEASES OF THE COLON & RECTUM VOLUME 62: 2 (2019)

Cochrane evaluators would call high risk for bias because it is funded by a drug company and first authored by an employee and stockholder. That company, RDD Pharma (Tel Aviv, Israel), describes a business model of “repurposing drugs...that are already approved for other indications,”⁸ for anorectal disease. Readers may be familiar with oxymetazoline as the active agent in over-the-counter nasal decongestants (eg, Afrin, Bayer Consumer Health, Whippany, NJ), over-the-counter antiredness eye drops, and prescription topicals for rosacea.

Risk for bias notwithstanding, the study is a randomized crossover study of methodologically sound design in which 2 tetraplegics and 17 paraplegics, all of whom had significant incontinence as part of their neurogenic bowel pattern, were divided into 2 groups. The groups used 1% oxymetazoline gel or placebo gel intra-anally once a day for 4 weeks. After a 2-week washout, the 2 groups crossed over, each getting the other treatment. With each patient as his or her own control, resting anal pressure was higher and episodes of incontinence (gas and nongas) were fewer with oxymetazoline. Overall formal incontinence scores were not changed significantly.

A lingering concern about this study is the heterogeneous nature of the SCI patients, who had injuries at various levels, from differing etiologies, with differing levels of completeness of injury, and with (in all likelihood) widely differing, quite individual patterns of neurogenic bowel dysfunction. A randomly selected group of fecally incontinent people without SCI might well be more homogeneous than the SCI group tested here. This raises the question of why this study was performed in the SCI population. Is this a case of a therapy tailored specifically for people with SCI but that might later be of service to the general population? I do not see anything particularly SCI specific about the drug or mode of delivery. Alternatively, given their avowed penchant for repurposing, might RDD Pharma be angling for the general population, using the SCI indication as an easier route to regulatory approval? I will happily admit ignorance of how regulatory sausages are made, and the Talmudic principle of *דן לכף זכות* (*judge favorably* or give the benefit of doubt)⁹ certainly applies here. People with SCI can use help with the incontinence

aspect of their neurogenic bowel, and topical oxymetazoline might be of service. Absent scientific guidance, practitioners of the art of SCI bowel care—people with SCI and their caregivers—need more tools to supplement their currently meager toolkit.

In his novel about how sausages were made, Upton Sinclair figuratively “aimed for the public’s heart, and... hit it in the stomach.”¹⁰ Similar statements may be made literally by the inventors of surgical robotics, who aimed for the heart and hit the prostate, among other noncardiac targets. Likewise, today’s fissure drugs, purposed for heart, blood vessels, and extraocular muscles, later trickled down to the anus, and the original synthesizers of oxymetazoline in the 1960s probably did not envision the *anal Afrin* described here. However, people on the front lines do whatever works with the materials at hand. Repurposed tools are more than welcome.

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