Beyond Beauty: Botulinum Toxin Use in Anal Fissure

Dear Editor

I read with interest the article on use of Botox in Anal fissure, *Beyond Beauty: Botulinum Toxin Use in Anal fissure* MJAFI 2009;65:213-5. I have following observations regarding the methodology employed and the conclusions drawn. The patients in the ibid study continued to be on standard conservative regime for chronic anal fissure (High roughage diet and topical 2% Lignocaine jelly) even after they received Botox injection. Therefore, the pain relief reported by the author cannot be solely attributed to injection Botox. This conclusion would have been valid if there had been a control group in the study which had solely received the conservative regime.

Author has not mentioned how he measured the pain relief. Pain relief is a highly subjective event open to numerous external biases. Objective parameters (e.g. anal manometry) need to document actual reduction in anal tone. Further, it is well documented that chronic anal fissure results from a combination of multiple events, out of which anal spasm is just one [1]. With this background, the role of Botox injection in the present study remains a conjecture.

Cost effectiveness of injection Botox remains in question. Given the scenario that LIS can be performed under local block as a daycare procedure, LIS may not be as expensive as the author claims. Additionally, Injection Botox has higher rates of recurrence on the long term [2]. One needs to consult an excellent Cochrane review by Nelson [3] in which the author concludes that "medical therapy

(including inj Botox) for chronic anal fissure, acute fissure and fissure in children may be applied with a chance of cure that is marginally better than placebo and for chronic fissure in adults, far less effective than surgery.

The conclusion by the author seems to suggest that injection Botulinum Toxin is recommended in anal fissure as it offers an outpatient alternative to surgical therapy in view of 'heavy' OPD load. In view of weight of published evidence over precisely this issue, this conclusion perhaps needs a rethink.

References

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3. Nelson RL. Non surgical therapy for anal fissure. *Cochrane database of systematic reviews* 2006; 3.CD003431.DOI: 10.1002/14651858.

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Reply

I would like to thank the reader for his astute comments for which I offer the following clarifications.

The onset of action of botulinum toxin is by the third day and is fully manifested by about two weeks. Patients were kept on conservative regimes only to cover this window period. As mentioned in the article, all patients in the study had already been on conservative treatment with varying relief and had desired alternative treatment approach of Botox because of dissatisfaction with the earlier modality. Relief of pain after Botox despite little improvement with conservative regimes already used by the patients correlates with its muscle paralytic action and is logically due to its physiological effect. As has been mentioned in the conclusion a controlled trial would be needed to establish the fact but was beyond the purview of this clinical study.

Pain relief was measured by the patient's subjective assessment as reflected in Table 2, from less than 50%, to increasing fractions between 50-75%, greater than 75% or complete relief. Reduction in anal tone itself does not always correlate with pain relief and is not accepted as a criteria for successful treatment as per Nelson [1]. Botox addresses not only the anal spasm but ischemia as well due to its vasodilatory action, both major etiopathologic reasons for fissure onset and persistence.

Evaluation of anal fissure management garnered from three Command Hospitals and a dozen peripheral service hospitals where I had occasion to work formed the basis of my study. Prevailing anal fissures surgical management requires investigations, pre

anaesthesia evaluation, admission prior to surgery, operation under spinal/general anaesthesia and 2-3 day hospitalization which is material and manpower intensive. Day care surgery, though desirable, and attempts by many, has not proved feasible in our setting due to service constraints. With progressive lower cost price Botox is presently available for hospital supply at less than Rs 12,000/ for 100 units which amounts to even lesser than Rs 4000/- per case as mentioned in the article. Surgical approach with additional loss of man hours is definitely more costly to the organisation than a single injection in the OPD with no interruption of patient's routine duties. Interestingly, Lord's dilatation though contraindicated in the Cochrane review by Nelson because of high risk of life style modifying incontinence is still practiced in many service hospitals. Patients are often also given sick leave after fissure surgery, mainly from field hospitals, thereby burdening the system more than necessary.

In the Cochrane review by Nelson the author's final conclusion is that Botox without the side effects of NTG or calcium channel blockers might be used in individuals wanting to avoid surgical therapy, with surgery being reserved for treatment failures. Nelson admits to the disparity between the reported 8% incontinence rates following sphincterotomy and the incongruous quality of life assessments despite the high level of faecal leak. He offers no explanation for the same.

My conclusions of Botox use as an OPD alternative are based on ascertainable facts prevalent in our setting and not any idealized scenario. Patients with fissure in ano are usually relegated to