

FORMULATION OF CLOBETASOL AND TACROLIMUS URETHRAL SYRINGES AND EFFICACY IN BALANITIS XEROTICA OBLITERANS: A CASE REPORT

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Background and importance

Balanitis xerotica obliterans (BXO) is a chronic inflammatory disease that affects gland skin and the foreskin. It is characterized by sclerotic and atrophic lesions, leading to stenosis of the urethra. Pharmacological treatment consists in topical corticosteroids or calcineurin inhibitors.

Aim and objectives

To describe the formulation of clobetasol and tacrolimus urethral syringes and to relate our experience in the treatment of BXO.

Material and methods



The patient

- ▶ A 12 year old child
- ▶ Operated for scrotal hypospadias
- ▶ Developed a BXO on foreskin donor skin

✗ The urethral mucosa was sclerosed and whitish, with an atrophic aspect.

✗ The basal flux was 5 ml/s

- A bibliographical search was carried out (Pharmacopeia and PubMed) about clobetasol and tacrolimus urethral syringes.
- Galenic validation included:
 - ✓ Organoleptic characteristics evaluation
 - ✓ pH and microbiological control.



Treatment efficacy was assessed by skin symptom resolution and increased voiding flow.

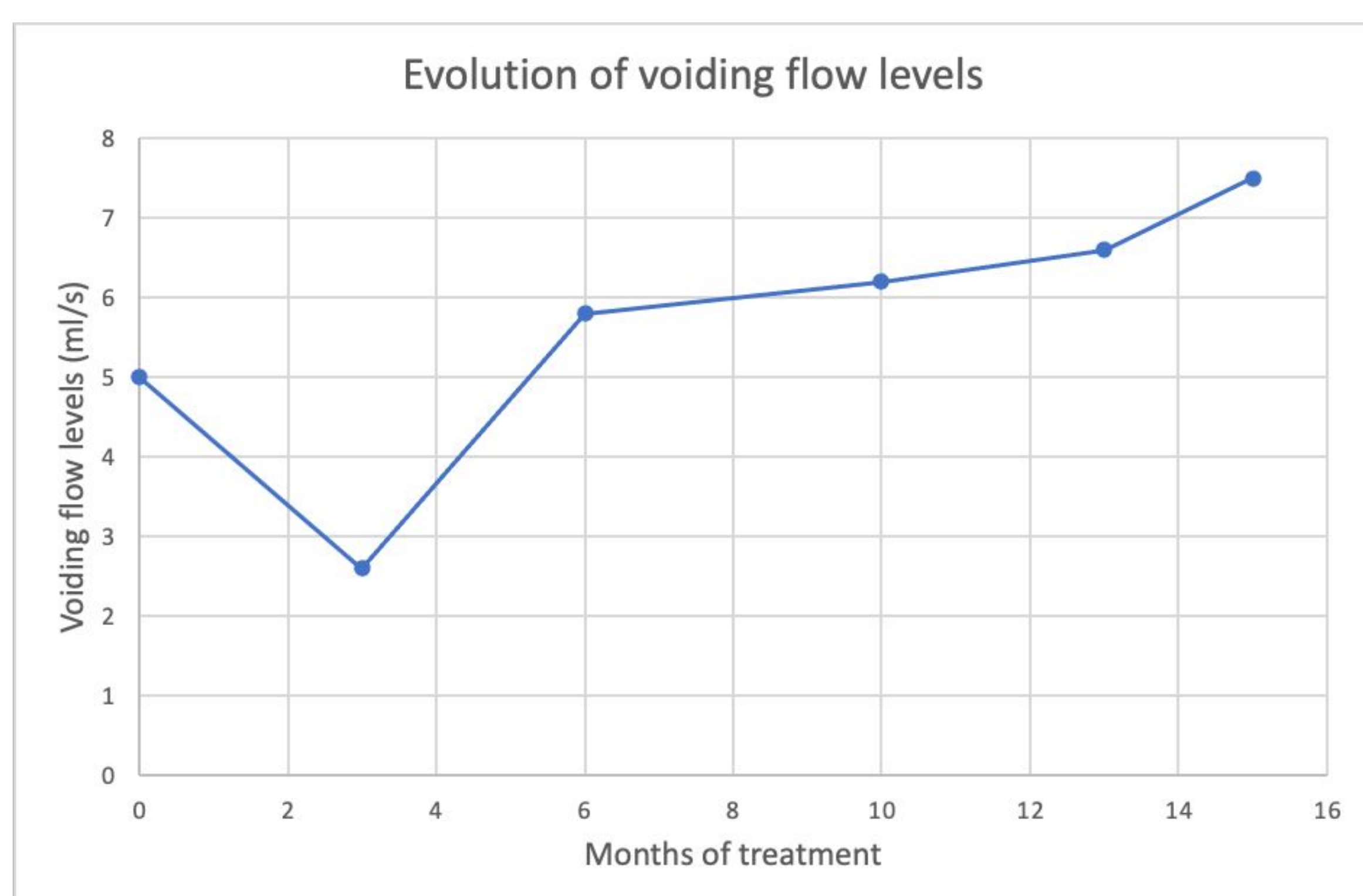
Results

Modus operandi for clobetasol 0.05% urethral syringe 3 mL in a laminar flow cabinet:

1. Weigh 1.5 mg of clobetasol product.
2. Add a small portion of urological lubricant (OneGel®) and mix.
3. Repeat step 2 to a total volume of 3 ml.
4. Repack in an urethral syringe.

For tacrolimus 0.03% urethral syringe, the same steps should be followed as above, weighing a quantity of 0.9 mg of tacrolimus product.

The given expiry date was 30 days at ambient temperature and protected from light.



The patient started with daily clobetasol and improved

↓ + 3 months

Reduced to every 48 h (worsening → resuming daily dosing)

↓ + 6 months (Asymptomatic and recovered flow)

Alternate with tacrolimus

↓ + 10 months

2 days of clobetasol and 4 of tacrolimus per week

↓ + 13 months

2 days of clobetasol and 3 of tacrolimus per week

↓ + 15 months

1 day of clobetasol and 3 of tacrolimus per week

Conclusions and relevance

Both magistral formulations were validated and proved to be effective in the treatment of BXO through resolution of symptoms and progress in urodynamic testing.

