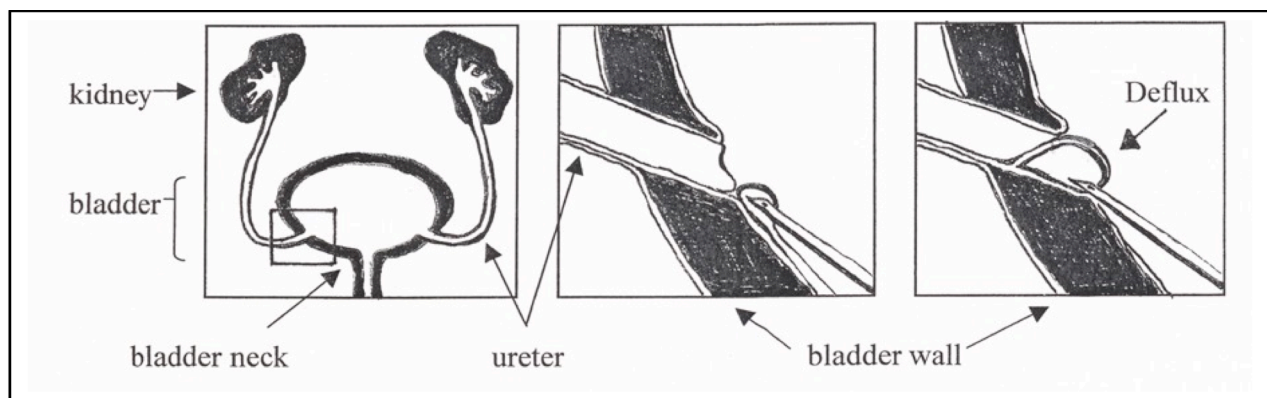


Child and Family Information Material

Endoscopic Treatment of Vesicoureteral Reflux Original

What is endoscopic treatment of vesicoureteral reflux (VUR)?

In endoscopic treatment of VUR, the doctor uses a special viewing device, called a cystoscope, to see inside the bladder. The cystoscope is inserted through the urethra, which is the opening through which urine leaves the body. During the procedure, a small amount of an injectable substance is introduced into the wall of the bladder near the opening of one or both ureter(s) (the tubes that carry urine from the kidney to the bladder). This creates a bulge in the tissue, making it harder for the urine to flow back up the ureter and to the kidneys. There are no incisions made in the abdomen for this procedure.



The injectable substance eventually breaks down, leaving a bulge of tissue in its place. This occurs because the hyaluronic acid part of the injectable substance is a chemical that naturally occurs in the body, and is broken down. Then, the dextranomer part remains, and is slowly replaced by the body's own tissues. So, a little bulge of tissue is formed, which makes it harder for the urine to flow backwards up the ureter and to the kidney. The bulge stays in place permanently and corrects the reflux.

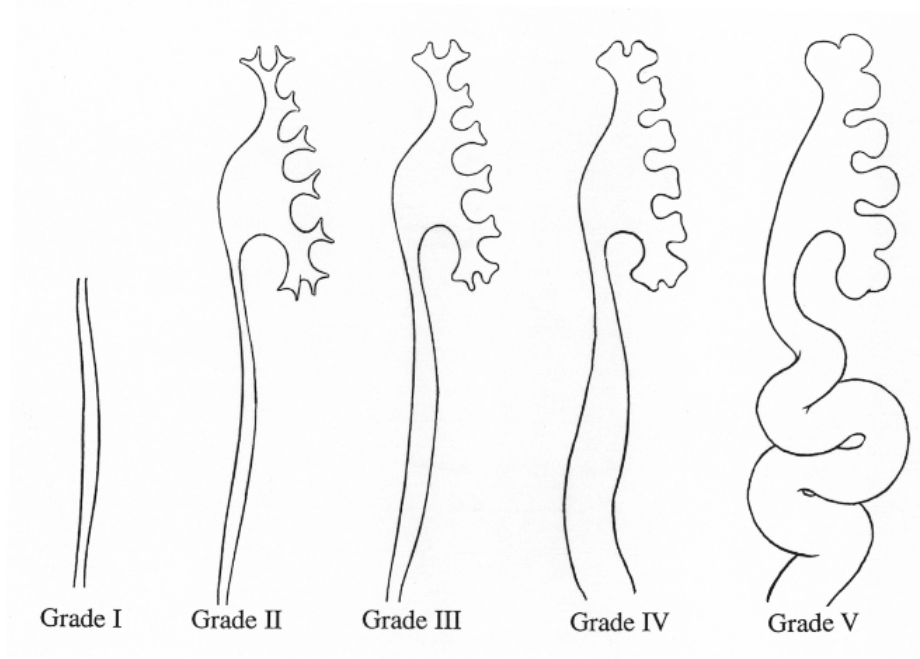
What are the side effects of the injectable substance?

The use of this injectable substance has some potential risks. These include mild bleeding, infection, and blockage of the ureter (if too much substance is injected).

About 1 out of 33 children will have his or her ureter enlarged by the procedure, which usually resolves on it's own.

How successful is this procedure?

The first injectable substance, called Deflux, was approved in Europe in 1998 for the treatment of VUR. The U.S. Food and Drug Administration in 2001 approved it for use in the United States. Using Deflux, there is a higher success rate with this procedure for those with lower grades of reflux. Capozza and Caione (2002) reported a 95 percent success rate for grade II reflux, 71 percent success rate for grade III, and 43 percent success rate for grade IV reflux. Similarly, in their study Capozza, Patricolo, Lais, Matarazzo, and Caion (2001) reported a 87 percent success rate for grade II reflux, 75 percent success rate for grade III, and 41 percent success rate for grade IV reflux. In another study, Lackgren, Wahlin, Skoldenberg, & Stenberg (2001) reported a 78 percent success rate for both grades II and III reflux, and 66 percent success rate for grade IV reflux. The success of the procedure is dependent on the individual child and on the physician's technique. In addition, sometimes more than one treatment is needed to build up a bulge large enough to reduce the child's reflux.



Who are candidates for this procedure?

Based on the success rates, this procedure is recommended for use in children with grade II, grade III, and possibly grade IV reflux. This treatment should not be used in patients who have:

- Both kidneys that do not work at all
- An abnormal pouch in the bladder wall
- An extra ureter (tube that carries urine from the kidney to the bladder)
- Active urinary tract infection
- Active voiding dysfunction (abnormal emptying of bladder)

What happens on the day of the procedure?

When you arrive at the hospital, your child will be put to sleep with a general anesthetic for the procedure. The procedure itself takes approximately 30 minutes. However, preparation time for the procedure takes about an hour. After the procedure, additional time will also be required in recovery, during which you will be able to be with your child.

The injectable substance will be given using endoscopic treatment, which means a miniature viewing device, called a cystoscope, will be inserted through the urethra (the opening through which urine leaves the body) to gain access to the bladder. The substance is then injected from a syringe into the lining of the bladder. Since there are no abdominal incisions made for this procedure, the child can go home on the same day.

What can we expect after the procedure?

After the procedure, there may be some blood in your child's urine. Your child may also experience some mild pain when urinating. These are normal findings. However, if your child has any of the symptoms described below, call our office immediately:

- Fever above 100.5°F
- Vomiting
- Severe pain

A follow-up renal and bladder ultrasound will be needed one month after the procedure, and a cystogram may possibly be needed in six months.

References:

- 1) Capozza, N., Patricolo, M., Lais, A., Matarazzo, E., & Caione, P. (2001). Endoscopic treatment of vesico-ureteral reflux: twelve years' experience. *Urologia Internationalis*, 67, 3, 228-231.
- 2) Capozza, N., & Caione, P. (2002). Dextranomer/hyaluronic acid copolymer implantation for vesico-ureteral reflux: a randomized comparison with antibiotic prophylaxis. *Journal of Pediatrics*, 140, 2, 230-234.
- 3) Lackgren, G., Wahlin, N., Skoldenberg, E., & Stenberg, A. (2001). Long-term followup of children treated with dextranomer/hyaluronic acid copolymer for vesicoureteral reflux. *Journal of Urology*, 166, 5, 1887-1892.
- 4) U.S. Food and Drug Administration. (2001). *New device approval: Deflux injectable gel*. Retrieved March 20, 2003, for the FDA Web site: <http://www.fda.gov/CDRH/PDF/P000029.HTML>
Q-Med. (2002). *Deflux*. Retrieved March 20, 2003, from the Q-Med Web site: <http://www.deflux.com>

See the next page for contact information.

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