

VUR Overview for Caregivers

What is VUR?

It's actually the most common congenital urinary defect in children, affecting 1% of the children in the U.S.

Normally in the urinary system, the kidneys produce urine which flows down to the bladder where it's stored until the child urinates.

Vesicoureteral reflux (ves-ih-koe-yoo-REE-tur-ul re-flux), commonly known as VUR, is a condition in which urine from the bladder backs up into the ureters. This backed-up urine can carry bacteria which can cause urinary tract infections (UTIs), kidney infections and potentially long-term kidney damage.

If your child experiences frequent urinary tract infections with fever (called "febrile UTIs"), you may want to talk to your child's doctor about the possibility of VUR, and a referral to a pediatric urologist (a doctor that specialized in the treatment of fUTI and VUR).

Testing for VUR

Your doctor will diagnose your child based on an evaluation that may include a test called a voiding cystourethrogram, or VCUG. A VCUG takes an x-ray image of the bladder and ureters while your child is urinating (also called voiding) to show anything unusual in the bladder and ureters.

VUR can be very mild, requiring little treatment, or it can be severe.

VUR is graded I-V, with V being the most severe. The higher the grade of VUR, the greater the chance that kidney damage will result—and the less likely your child is to outgrow it.

When your child is diagnosed with VUR, your doctor will let you know what grade VUR is present. If your doctor doesn't inform you of the grade, ask. Treatment for VUR is usually determined by the grade, so this is important to know.

There is Help for VUR

It's critical to treat febrile UTIs and VUR to prevent possible infection and long-term kidney damage. There are four ways your child's pediatric urologist or doctor may decide to treat your child, depending on the severity of your child's VUR:

- **Watchful waiting** may be an option if your child has a milder case of VUR (grade I). This means that you will need to watch for signs of a urinary tract infections with fever (called a febrile UTI). With mild cases, children sometimes outgrow VUR.
- **Antibiotics** are used to treat UTIs associated with VUR. Antibiotics are used until the child outgrows VUR, this may take several years and require long periods of antibiotic prescriptions. Occasional tests are required to monitor for UTI recurrence and VUR. Antibiotics are most suitable for milder grades of VUR. However, long-term treatment with antibiotics may cause the bacteria to become resistant, leading to more infections.¹
- **Endoscopic treatment**, Deflux, is a treatment option for children with VUR grades II-IV. Deflux is a natural gel made of two sugars that is injected where the ureter joins the bladder. The treatment is minimally invasive with no cuts or incisions, and children may go home the same day.
- **Open Surgery** is most suitable for the most severe cases. General anesthesia is used while an incision is made in the lower abdomen, through which the pediatric urologist repairs the bladder defect. Your child will need to stay in the hospital for a few days.

The Deflux Advantage

Deflux works well to stop VUR in children. Most children have success after one injection, while some may need more injection procedures. A recent study shows Deflux was proven effective in up to 93% of children, with no febrile UTIs after one injection.²

Deflux is placed where the ureters meet the bladder. The treatment takes about 15 minutes and allows children to go back to normal activities the next day. There's minimal pain and no scarring. However, your child may feel some stinging during the first few times he or she urinates.

In a survey of 91 families, 60% of parents preferred treatment with Deflux if they knew prolonged antibiotic therapy had to continue for 3-5 years or when operative treatment was required.³

1. Selekmán RE, Shapiro DJ, Boscardin J. Uropathogen resistance and antibiotic prophylaxis: A meta-analysis. *Pediatrics*. 2018;142(1):e20180119

2. Kalisvaart JF. Intermediate to long-term follow-up indicates low risk of recurrence after double hit endoscopic treatment for primary vesicoureteral reflux. *J Ped Urol*. 2012;8(4):359-365.

3. Ogan K, Pohl HG, Carlson D, Belman AB, Rushton HG. Parental preferences in the management of vesicoureteral reflux. *J Urol*. 2001;166(1):240-243.

The Deflux Procedure

First, the pediatric urologist examines the bladder with a lighted tube, called a cystoscope, which is inserted into the urethra. Then he or she will inject Deflux, a hyaluronic acid (HA) gel containing dextranomer beads, around the ureter that may help the valve between the bladder and ureter close properly. Hyaluronic acid is a naturally-occurring material, and the HA in Deflux has been used for over two decades in more than 40 million procedures worldwide⁴, often as a dermal filler for wrinkle correction.

There is usually no pain after the procedure. Your child may feel some stinging during the first few times he or she urinates. Be sure to call your pediatric urologist if your child cannot urinate, feels pain in his or her tummy, or has a fever after returning home.

After the procedure, your pediatric urologist will determine what type of follow-up is needed and if additional treatment is required. If necessary, another VCUG is performed a few months after the procedure to see if the reflux remains.

Deflux - Safe & Effective

Since 2001, in the U.S., Deflux has been used to treat VUR grades II-IV in children. Deflux is made of hyaluronic acid (HA) and dextranomer beads, both are sugar-based and are similar to the natural starches, sugars and tissues in the body.

A recent study shows Deflux was proven effective in up to 93% of children, with no fUTIs after one injection.⁵

Treatment with Deflux has some potential risks. There is a small risk of infection and bleeding from the procedure. Although rare, the gel might block the ureter and cause the urine to back up in the kidney. You should ask your pediatric urologist about these potential side effects.

4. Data on file.

5. Kalisvaart JF. Intermediate to long-term follow-up indicates low risk of recurrence after double hit endoscopic treatment for primary vesicoureteral reflux. *J Ped Urol.* 2012;8(4):359-365.

Important Safety Information about DEFLUX

Patients should not receive DEFLUX® (hyaluronic acid/dextranomer) if they have any of the following conditions: kidneys that don't work (non-functional kidney[s]), bulging or herniation in the skin of the bladder (hutch diverticulum), swelling at the bottom of the ureter (ureterocele), a disorder in eliminating urine (active voiding dysfunction), and ongoing urinary tract infection.

Safety and efficacy of treatment in children under 1 year of age have not been established.

Safety and efficacy of treatment of duplex kidney systems have not been established.

There is a risk of infection and bleeding that is associated with the cystoscopy procedure used to inject DEFLUX.

Talk to your doctor if your child has ureters with grossly dilated orifices before receiving DEFLUX treatment.

DEFLUX should only be administered by qualified surgeons experienced performing urologic procedures.

In clinical studies, the most common side effects associated with DEFLUX were: urinary tract infection (UTI), ureteral dilation, and nausea/vomiting/abdominal pain.

The following adverse events have been reported with DEFLUX (occurring $\leq 1\%$): blockage of the ureters (some cases require temporary placement of a ureteric stent), painful urination, blood in the urine, urgency of urination, frequency of urination, swelling of the kidneys, inflammation of the kidneys, urinary tract infection, foreign body reaction, calcification, and fever.

You are encouraged to report negative side effects of DEFLUX to the FDA. Visit fda.gov/medwatch, or call 1-800-FDA-1088.

For product information, adverse event reports, and product complaint reports, contact:

Palette Life Sciences

Medical Information Department

T: 844.350.9656

F: 510.595.8183

E: palettemc@dlss.com

For more information about Deflux, please visit deflux.com.



Follow us on:



APM022C

Deflux is a registered trademark of Nestlé Skin Health S.A. used under license.
© 2019 Palette Life Sciences. All rights reserved.