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Review Article

The use of polyacrylate-polyalcohol copolymer hydrogel in the endoscopic treatment of primary vesicoureteral reflux in children

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ABSTRACT

Background/purpose: It is still under discussion which is the best tissue augmenting substance for the endoscopic treatment of children with vesicoureteral reflux (VUR). We describe our preliminary experience (September 2009–November 2011) with polyacrylate-polyalcohol copolymer hydrogel (PPCH).

Methods: This is an observational, descriptive, prospective study which included 81 female and male patients (age 1–14 years) diagnosed with unilateral (n = 45) and bilateral (n = 36) primary VUR comprising a total of 117 refluxing renal units (RRU). Complex cases were excluded from the study. All patients were clinically and radiologically evaluated and those who met the inclusion criteria were treated endoscopically with a single subureteral injection of PPCH by a single surgeon. 11 patients (13.5%) had a pathological 99mTc-DMSA before treatment. The volume of injected product was measured in all cases. Results were considered successful if 6 months postinjection, conventional voiding cystourethrogram (VCUG) revealed VUR was cured (Grade 0). Follow-up ranged from 7 to 32 months.

Results: The overall resolution rate based on the number of RRUs studied was 92.3% (108/117). The mean injected volume of PPCH per patient was 0.6 ml. One patient with obstructive anuria required vesicoureteral reimplantation. Other complications were persistent, self-limiting hematuria (n = 2); lumbar pain (n = 4) and urinary tract infection with normal VCUG (n = 4).

Conclusions: Our short term data show PPCH provides a high level of reflux resolution in selected patients. Long term follow-up is required.

Vesicoureteral reflux (VUR) is characterized by backflow of urine from the bladder toward the kidney, increasing the risk of infection of the upper urinary tract, renal scarring and in the long-term, kidney damage and hypertension [1].

Since the introduction of STING two decades ago and US FDA approval in 2001 of dextranomer hyaluronic acid (Dx/HA) (Deflux®, Q-Med Scandinavia, Uppsala, Sweden) as a tissue augmenting substance for subureteral injection, the endoscopic treatment of VUR has become a widely accepted, first line therapy in numerous centers worldwide [2,3].

However, despite the overall high success rates reported by different authors, there are concerns about the short term follow-up of most series, in addition to recently intriguing data regarding the very high incidence of VUR recurrence following successful Dx/HA treatment. These results led us to investigate whether another tissue augmenting substance could achieve long term efficacy, or in other words, definitive correction of VUR [4].

In 2008, the emergence of a new tissue-augmenting substance, polyacrylate-polyalcohol copolymer hydrogel (PPCH), was published in *Archivos Españoles de Urología*. The characteristics of this biocompatible, synthetic, nonbiodegradable, easy to inject product were described [5].

Namely, Vantris® (Promedon, Córdoba, Argentina) belongs to the family of acrylics: particles of polyacrylate-polyalcohol copolymer immersed in a glycerol and physiological solution carrier (40%), which is eliminated by the reticular system through the kidneys without being metabolized. It has a pH of 6 and a very high molecular mass. When injected into soft tissues, it produces a bulkiness that remains stable through time. Once implanted, the particles are covered by a fibrotic capsule of up to 70 μm. Since particles are anionic with high superficial electronegativity, a low cellular interaction and fibrotic growth are promoted. Also since particles are highly deformable by compression, the material can be injected using a 23-Gauge needle [5].

In 2010, the same authors published their experience with PPCH in a multicenter prospective study including 83 patients with 88.6% efficacy (78 renal units) and an overall success rate of 83.6% [6].

The general objective of this study is to present our preliminary experience with PPCH and to evaluate its efficacy in the management

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of primary VUR in children. The specific objectives are: to report VUR resolution rates (according to radiological criteria) and the complications associated to its application.

1. Patients, materials and methods

This is an observational, descriptive, prospective study reviewed and approved by the institution's Research and Ethics Committee, which included 81 pediatric patients diagnosed with unilateral (n = 45) and bilateral (n = 36) primary VUR comprising a total of 117 refluxing renal units (RRUs). Signed informed consent was obtained from the parents or guardians of all of the patients.

Complex cases were excluded from the study (see list of exclusion criteria below) because this was the authors' first experience with the product; eventual and undesirable complications, as for example, the development of an obstruction in a patient with ureterohydronephrosis wanted to be prevented.

25 patients were male and 56 were female. The mean age at treatment was 4.95 years (range 1–14 years).

All patients were clinically and radiologically evaluated. Those who met the inclusion criteria were treated endoscopically with a single subureteral injection of PPCH.

The study was conducted between September 2009 and November 2011. The median follow-up term was 14 months (7–32 months).

The demographic data and patient characteristics are presented in Table 1.

1.1. Clinical and radiological evaluation

All patients underwent the following tests before and after the endoscopic procedure:

1. Renovesical ultrasound to measure prevoid and postvoid residual urine (the latter, for continent patients).
2. Conventional voiding cystourethrogram (VCUG). VUR was classified into Grades I to V, following the International Classification System (International Reflux Study Committee).
1. Renal scintigraphy using technetium 99m–dimercaptosuccinic acid (99mTc-DMSA). This was performed 6 months after the last febrile UTI to assess renal scarring before treatment, and 1 year after treatment. 50% (±5%) of relative renal function (RRF) per renal unit was considered normal. The objective presence of scarring and/or loss of RRF below 40% were considered pathological. Renal units with relative uptake between 40 and 45% were considered normal.
1. Urodynamic/video-urodynamic studies were indicated only in the case of patients with symptoms of bladder and/or voiding dysfunction (n = 7). Only 2 of these 7 patients (28.6%) were included in the protocol as they only had noninhibited contractions treated with anticholinergics.

Table 1
Demographic data and patient characteristics.

Male	25
Female	56
Mean age (years)	4.95 (range: 1–14 years)
Primary VUR cases (RRUs)	117
Unilateral VUR	45
Bilateral VUR	36
VUR Grade (RRU)	
II	14 (11.97%)
III	67 (57.26%)
IV	30 (25.64%)
V	6 (5.13%)
Indications for surgery	
Breakthrough UTI	75 (92.6%)
High grade VUR	5 (7.4%)
Abnormal 99mTc-DMSA	11 (13.5%)
Mean injected volume of PPCH (ml) per patient	0.6 ml (range: 0.3–1.5 ml)
Follow-up (months)	14 (range: 7–32 months)

1.2. Inclusion criteria

1. Pediatric patients with diagnosis of unilateral or bilateral VUR Grades II–V (Table 1) and:
   a. A history of recurrent, breakthrough febrile UTIs;
   b. Adequate bladder and urethral voiding;
   c. Absence of hydronephrosis or ureterohydronephrosis;
   d. RRF per renal unit >15% measured by renal scintigraphy (99mTc-DMSA);
   e. Absence of concomitant pathologies;
   f. Normal renal function;
   g. Antibiotic prophylaxis: use of nitrofurantoin until resolution of VUR.
   h. Nephrological examination.

1.3. Exclusion criteria

1. VUR Grade I;
2. Anatomical anomalies of the urinary tract: double urinary collecting system, ectopic ureter, posterior urethral valve;
3. Hydronephrosis or ureterohydronephrosis/uronephrosis;
4. History of urinary tract surgery;
5. Alterations in bladder dynamics: voiding dysfunction as evidenced on urodynamic or video-urodynamic studies;
6. Neurogenic bladder;
7. Patients with bowel dysfunction;
8. No consent to participate in the study.

1.4. Technique

A single injection of PPCH was administered by a single surgeon. The STING procedure was performed in 79 patients whereas the HIT (hydrodistention injection technique) was carried out only in the first and second patients. In all cases, the volume of injected PPCH was measured.

For the STING procedure, patients received general anesthesia and were placed in the lithotomy position. A right-angled 9.5 Fr cystoscope was used to facilitate the procedure. A metallic needle with a lateral orifice was inserted tangentially to a depth of 2–3 mm, just below the ureteral orifice (6 o'clock position), for injection of the product, until the creation of a prominent bulge. The distal ureter and the ureteral orifice were uplifted, increasing the submucosal length of the ureter.

The HIT procedure was performed similarly to the STING but with the following changes. Pressurized irrigation (hydrodistention) of the ureter was used to facilitate correct positioning of the needle. 0.1 ml of PPCH was injected into the distal ureteral submucosa (6 o'clock position) to confirm implant location. Once confirmed, hydrodistention was stopped and the needle inserted to a depth of 4 mm. The product was then injected until complete coaptation of the ureter was achieved.

1.5. Analysis of results

The endoscopic procedure was considered successful if 6 months postinjection, VCUG revealed VUR was cured (Grade 0). If VUR could not be resolved or was solely downgraded, it was considered a failure. The resolution rate (according to radiological criteria) was calculated for each VUR grade based on the number of RRUs and patients. The overall failure rate was calculated too. The intraoperative and postoperative complications were finally assessed.

2. Results

Before injection of PPCH, VUR Grade II was diagnosed in 14 RRUs, Grade III in 67, Grade IV in 30, and Grade V in 6 (Table 1).

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Also, before injection 11 patients (13.5%) had an abnormal DMSA scan result. This was associated to episodes of pyelonephritis the patients had before the endoscopic treatment.

A mean of 0.6 ml (range: 0.3–1.5 ml) of PPCH was injected to the 81 patients. Only 4 of these patients (4.76%) were lost to follow-up after the second VCUG.

Six months postinjection VUR was resolved in 13 RRUs with VUR Grade II, in 65 RRUs with VUR Grade III, in 27 RRUs with VUR Grade IV and in 3 RRUs with VUR Grade V (Table 2).

The overall resolution rate based on the number of RRUs studied was 92.3% (108/117).

The overall resolution rate based on the number of patients studied was 93.82% (76/81).

VUR was downgraded in 7 RRUs (5.98%), in 4 patients (4.93%). VUR was not resolved in 2 RRUs (1.71%), in 1 patient (1.23%). There were no patients with VUR graded worser than baseline.

The overall failure rate based on the number of RRUs studied was 7.69% (9/117).

The overall failure rate based on the number of patients studied was 6.17% (5/81).

There were no significant differences regarding RRF before and after treatment. There were no complications associated with the endoscopic procedure.

Postoperatively, a 9 years old, female patient (case #2) evolved with obstructive oligoanuria postinjection. Authors used the double HIT technique in this case and the amount of PPCH injected per ureter was 1.2 ml. The patient required vesicoureteral reimplantation using the Politano–Leadbetter technique, after a failed attempt to place a stent. There was great difficulty to perform a dissection owing to an aggressive inflammatory response, which led the ureterovesical junction to behave in the same fashion as a pelvic floor tumor. Authors could not determine the degree in which the ureteral lumen was affected, the extent of inflammatory compression or whether there was an excessive angulation. The histopathological report determined a 'tumor-like' inflammatory reaction with presence of abundant giant cells.

Two patients (2.4%) had persistent self-limiting hematuria; 4 patients (4.9%) presented lumbar pain, treated with oral analgesics; 3 patients (3.7%) showed nonfebrile UTI with a normal postoperative VCUG, and 1 patient (1.23%) had a febrile UTI with a normal postoperative VCUG.

3. Discussion

Since Matouschek's initial description of the subureteral injection technique in 1981 [7] and the first clinical series reported by O'Donnell and Puri in 1984 and 1986 [8,9], the technique has evolved into a therapeutic alternative to open surgery. The concept is based on the creation of a solid support underneath the intravesical portion of the ureter.

The endoscopic injection of bulking agents has revolutionized the management of patients with VUR, since it is a simple, less time-consuming therapy with resolution rates around 80%, according to the different series published worldwide.

Stredele RJ et al reported in 2013 their experience with different substances in 229 RRUs (VUR Grades II–IV) in 135 children. They injected collagen in 98 RRUs; polydimethylsiloxane in 32 RRUs, and Dx/HA in 99 RRUs [10]. Of the 135 children studied, 127 underwent a VCUG (radiologic or nuclid) 3 months after the first injection, and 88 children a second VCUG (nuclid) 37 months, also after the first injection. Resolution rates with collagen, polydimethysiloxane and Dx/HA were 52%, 55% and 81.5% respectively. Repeated injections were successful in only 21% (collagen) to 42% (Dx/HA). Of the 88 patients with a second VCUG, 48.5% of the initially reflux-free children developed relapse VUR after collagen, 45.5% after polydimethylsiloxane and 21.5% after Dx/HA injection. Clinically, there was a significant difference in postoperative UTI occurrence in favor of the Dx/HA group.

Table 2
Radiological resolution rates 6 months postinjection in 117 RRUs according to VUR grade.

VUR grade	RRU	Resolved VUR
II	14	13 (92.8%)
III	67	65 (97%)
IV	30	27 (90%)
V	6	3 (50%)

However, despite Dx/HA is the product that commonly exhibits the best results, giving better protection against UTIs and a higher VUR resolution rate, there is no consensus yet as to which bulking substance is the best in terms of morbidity, long-term results (at least 5 years postinjection), or whether all the products or only one of them is useful to treat VUR in patients with anatomical defects (as paraureteral diverticulum or complete double urinary collecting systems). Last but not least there is no consensus on which is the most effective product to treat patients with postinjection residual VUR.

Except for various prospective studies aimed at evaluating the efficacy of PPCH in terms of resolution of VUR in children [11–14], most of the published material regarding bulking substances are series of cases analyzed retrospectively [10,15–18]. Clearly, it is necessary to count on randomized prospective studies designed to evaluate the efficacy of bulking substances compared with open reimplantation, the use of antibiotic chemoprophylaxis, and the usefulness of keeping a vigilant attitude. Some authors still recommend endoscopic injection as first-line treatment though [19].

The duration of the follow-up period (>5 years) should be further addressed too. The radiological evaluation is generally performed at a mean of 3 months in most patients. Only a few studies evaluate long-term results. Lee EK et al [20], for instance, reported an overall 1-year success rate of 46% with Dx/HA, and Lackgren G et al [21] showed a high recurrence rate in a long-term follow-up with the same product. On the other hand, Chertin B et al evaluated prospectively the efficacy of Vantris in children with complex cases of VUR. VCUG was performed in 11 (73.3%) of 15 children who completed 1 year and in 3 (33.3%) of 9 who completed 3 years of follow up as a part of the routine protocol. None showed VUR recurrence. Ultrasound scans also demonstrated normal appearance of kidneys in all patients [13]. According to Sharifiaghdas F et al study, a single Vantris injection provides a high level of efficacy and safety in the treatment of primary G I–IV VUR in young girls, at 2 years' prospective follow-up [11].

Clinical efficacy versus radiological efficacy is another topic of discussion by many authors. In 2012, Dr. Kaye J et al [22] concluded that clinical success is more meaningful to the patient, and that initial radiological success could be followed by UTI necessitating further intervention. They also questioned the need for routine postoperative VCUG. We believe long-term randomized prospective studies are needed to determine the best criteria for success following endoscopic VUR surgery. Besides, routine postoperative VCUG, unlike clinical evaluations, enables the detection of patients in whom the VUR grade is only downgraded and not cured.

In Europe there are studies that consider VUR Grade I as 'cured' and these patients are included within the overall success rate. We disagree with this concept because the 5-year spontaneous resolution rate for these children is roughly 90%, and thereby a small minority of them would be expected to have persistent VUR over time [23].

In our experience the outcome of using PPCH in patients with VUR was good in terms of efficacy. We believe our successful resolution rate (according to radiological criteria) of more than 90% was directly associated with the adequate selection of patients, the use of a standardized injection procedure (STING technique instead of double HIT, which was solely used in the first 2 patients) and a low volume of injection (mean of 0.6 ml with STING in contrast to >1 ml with double HIT). The fact the bulking substance was not injected in dilated distal ureters in which ureteral obstruction could occur additionally contributed to the good outcome. Kirsh AJ et al for instance also

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concluded there is a definite learning curve with injection therapy and that the location of injected material and experience with the technique appear to correlate with the outcome of the procedure [18].

In our case, regarding the injection procedure, double HIT was employed in the first 2 patients whereas the STING technique in the remaining 79. We decided not to use the double HIT from the third patient onwards, particularly because in children with bilateral ureteral obstruction, a lower volume of PPCH can be used with STING and both RRUs can be treated with a single syringe (thus operative costs are reduced). We believe that the serious complication observed in the 9 year old girl who required bilateral vesicoureteral reimplantation (because urinary diversion with a double J catheter could not be achieved) was the result of carrying out a double HIT and the high dose of PPCH (>1 ml) administered. Although a postoperative ureteral obstruction refractory to stenting is rare, there has been an account of its occurrence published by Alizadeh F et al in 2012 [24].

In our opinion, what makes the use of PPCH a novel therapy can be summarized as follows: its physiochemical properties; high efficacy (at least in the short term); rapid learning curve; better bulking effect than other biodegradable products as Dx/HA; the low dose required; optimization of injection with the use of a metallic needle with a lateral orifice.

This study is not without limitations though. We present only technical data regarding the short-term efficacy of PPCH as a tissue-augmenting substance, and we have demonstrated outcome regarding VUR radiological resolution 6 months postinjection in a relatively small group of patients. Despite the high reflux resolution success, we had a relatively high rate of postoperative complications as well, one of them very serious. We do not have data on the characteristic appearance of the product on computed tomography but know that it can be barely demonstrated on renovesical ultrasound. Finally, we do not know the recurrence rate of using this product in the long-term or whether it will be difficult to place a stent or perform a ureteric reimplantation in patients following failure of VUR correction with PPCH.

4. Conclusions

PPCH provides a short-term, high level of reflux radiological resolution (>90%) in selected patients (especially intermediate VUR grades). According to our experience the low volume of bulking substance administered using the STING technique is the most suitable procedure to treat these patients, though time will tell. We believe it would be useful to continue the follow-up of these patients to obtain long-term results and to use this protocol with other bulking substances to obtain comparative results with the same variables under study.

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