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Comparison of Endoscopic Injection of Vantris and Gil-Vernet surgery in the Treatment of Primary Vesicoureteral Reflux (VUR)

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Abstract

Purpose: Vesicoureteral Reflux (VUR) is the most common urologic condition in pediatric population, affecting almost 1% of children. The present study aims to compare outcomes of an open surgical technique (Gil-Vernet), an old-fashioned method still performed in some centers, and the endoscopic correction using Vantris as a preferred less invasive method in children with VUR.

Materials and methods: In this randomized clinical trial, a total of 61 children with VUR of grades I-IV underwent either open surgical repair using the Gil-Vernet approach (30 patients, 50 renal refluxing units), or endoscopic repair using Vantris as the bulking agent (31 patients, 49 renal refluxing units). The change in VUR grade before and after operation was compared between the two groups.

Results: The Vantris group comprised 5 males and 26 females with the mean age of 6.15±2.26 years (range, 1-10) versus the Gil-Vernet that included 9 males and 21 females with the mean age of 5.23±2.05 years (range, 1-10) (p=0.20 and 0.21, respectively). The VUR grade decreased significantly in both groups after operation (p<0.001), but despite a better improvement in the Vantris patients the inter-group analysis missed a statistically significant level in a marginal fashion (p=0.07). The rate of improvement and full improvement was 98% and 81.6% in the Vantris group vs. 94% and 86% in the Gil-Vernet group, respectively (p=0.62 and 0.56, respectively).

Conclusion: Although postoperative improvement in VUR grade was better in the Vantris® group than that in the Gil-Vernet group, the difference was not statistically significant. Both methods of treatment were safe and with a high rate of success. Nevertheless, lesser manipulations performed in Vantris® makes it favorable comparing with open Gil-Vernet method.

Abbreviations

VUR: Vesico-Ureteral Reflux

Introduction

Vesicoureteral Reflux (VUR), the return of the urine from bladder to the ureter, is an anatomic or functional abnormality [1]. The treatment goal is to preserve renal function by reducing the risk of infection and renal scarring [1,2]. But desirable treatment of VUR is controversial. Open anti-reflux surgery is the treatment of choice for severe cases [3]. Gil-Vernet Open surgery is an intravesicular surgical procedure, in which the intramural length of ureter is increased with medial advancement and increasing the muscle support [4]. This technique is performable in unilateral and bilateral cases [5], is simple, and is associated with few complications [6]. It seems that Gil-Vernet trigonoplasty is one of the open procedures, which is less invasive, simple, has a high success rate, has the advantage of feasibility of future ureteroscopy with less problems, and is also performable on outpatient basis [5]. The advantages of endoscopic methods include the feasibility to be performed on outpatient basis, short duration of the procedure, short hospital stay, low cost, minimally invasiveness and lack of common complications of open surgery [3]. Various substances have been proposed to be injected, including Teflon, collagen, patient's own fat (autologous), poly-di-methylene silocan, silicon, chondrocytes and deflux (dextranomer/hyaluronic acid solution). In the meantime, the best results have been reported in Teflon injection, but because of the small size of the particles and concerns about displacement and migration of particles to the neighboring areas and other organs, such as lungs, brain, and heart complications, its use has not been confirmed in children [7]. Polyacrylate-Polyalcohol Copolymer (PPC, Vantris) is the most recent industrial biocompatible material from the acryl family that is used to correct VUR [2]. The size of Vantris particles are at a level, which allows local and remote migration and therefore do not lose their stability, after injection, over time. It seems that Vantrisis eligible as the most ideal material for these cases, but few studies have addressed this issue [1]. This study aimed to compare the results of Gil-Vernet surgical treatment and endoscopic method using Vantris in patients with VUR.

Materials and Methods

In this clinical trial study, 61 children with a diagnosis of VUR selected from consecutive children who attended a tertiary outpatient urology referral center and divided by simple randomization into two groups of Gil-Vernet open surgery or endoscopic surgery during 30 months and the results were compared.

Parents of all patients signed written informed consent. This study was approved by the Ethics Committee of Tabriz University of Medical Sciences. The clinical trial was submitted at the Iranian Registry of Clinical trial (IRCT) by ID number: 2015022321211N1, IRCT is under supervision of the World Health Organization (WHO). Inclusion criteria included patients age between one and ten years, having reflux grade II to IV, occurrence of symptomatic urinary tract infection (such as fever, dysuria, failure to thrive, poor nutrition or new renal scarring, in spite of previous antibiotic treatment or bilateral reflux or drug intolerance or unwillingness of parents and high grades (III - IV); and exclusion criteria include dreflux grade I with no complication and V, history of surgery or endoscopic procedures on bladder or ureter, anatomic urinary tract

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Table 1: Demographic characteristics and variables associated with patients' history between Vantris and surgical group.

Variable	Vantris (31 cases)	Open surgery (30 cases)	P Value*
Sex:			
male	5 (16.1)	9 (30)	0.2
female	26 (83.9)	21 (70)	
Age (years)	6.15±2.26 (1-10)	5.23±2.05 (1-10)	0.21
Height (Cm)	119.73±17.79 (77-157)	110.93±22.32 (69-151)	0.11
Weight (Kg)	24.90±10.38 (9.5-54)	23.73±11.27 (8-48)	0.68
Age at primary diagnosis	3.08±0.56 (0-10)	2.99±0.43 (0-8)	0.9
History of prophylactic antibiotics	29 (93.5)	27 (90)	0.67
Age at prophylactic antibiotics	2.84±0.57 (0-9)	2.28±0.44 (0-7)	0.24
History of UTIs despite prophylactic antibiotics	14 (45.2)	10 (33.3)	0.34
Causative germ			
E. Coli	12 (85.7)	10 (100)	0.49
Pseudomonas	2 (14.3)	0 (0)	
Primary presentation			
UTI	29 (93.5)	25 (83.3)	
Prenatal hydronephrosis	1 (3.2)	3 (10)	
Enuresis	1 (3.2)	2 (6.7)	
Comorbidities			
Absent	24 (77.4)	22 (73.3)	
Prenatal hydronephrosis	1 (3.2)	4 (13.3)	
Growth retardation	1 (3.2)	2 (6.7)	
Seizure	0 (0)	2 (6.7)	
Enuresis	2 (6.5)	0 (0)	
Prenatal hydronephrosis + Growth retardation	1 (3.2)	0 (0)	
Prenatal hydronephrosis + horseshoe kidney	1 (3.2)	0 (0)	
Prenatal hydronephrosis + Growth retardation + vaginal atresia	1 (3.2)	0 (0)	
Familial history in siblings	1 (3.2)	1 (3.3)	0.75

The data is shown as frequency (%) and (maximum-minimum) mean±standard deviation/standard error.
P-value≤0.05 was considered statistically significant.

malformation, including obstruction or full duplicated pielocalicial system, suspected or proven voiding dysfunction through clinical findings, including abnormal neurological examination or intestinal dysfunction or obstructive-stimulatory LUTS, confirmed by VCUG or sonographic evidence of irregular bladder wall or diverticulum or trabeculation, low bladder volume and neurogenic bladder. 61 patients (100 renal units) with Vesicoureteral reflux were included based on pre-determined inclusion and exclusion criteria, after proving their reflux and the disease grade by VCUG. After explaining the study terms and conditions, the children were categorized into one of the groups of Vantris endoscopic injection (Promedone, Cordoba, Argentina) or Gil-Vernet open surgery. All operations were done by a single attending pediatric urologist who was trained with more than 10 years of performing experience for endoscopic injection. In patients undergoing endoscopic injection (31 patients, 50 renalunits), the Vantris bulking material was sub mucosally injected through the compact cystoscope with 6-French size and 23-gauge needles under the intramural ureter at 6 o'clock position of the ureteral orifice (STING method). In patients with higher grades of reflux and very loose ureteral orifice, it was injected inside the ureter. Volume of injection varied from 0.2 to about 2 cc, depending on the patient. The patients were discharged the same day of surgery with oral antibiotics for a week. Finally, follow-up was not feasible on one renal unit because Left the trial after surgery and 49 renal units were investigated in this group. In the Gil-Vernet antireflux surgery group (30 patients, 50 renal units), patients underwent classic Gil-Vernet antireflux surgery. In this technique, in cases of unilateral reflux, both sides underwent surgery to prevent reflux in the opposite side due to trigone instability. These patients were discharged after two days. Patients had no Foley catheter after surgery and were discharged with antibiotics for one week. All patients underwent ultrasonography two weeks after surgery for hydronephrosis (as a complication). Three months postoperatively, VCUG (voiding cysto-ureterography) was performed to follow-up of reflux. The reporters of the VCUG images were unaware of the type of the treatment. Treatment success was defined as eliminating or reducing the severity of reflux.

Statistical analysis

The data was reported by mean±standard deviation, or standard error (if necessary), and frequency (%). Statistical software SPSS™

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Table 2: Pre-operational Clinical findings, lab data in Vantris and open surgery groups.

	Gil-Vernet surgery (30 cases)	Vantris (31 cases)	P Value*
Clinical symptoms			
Asymptomatic	21(70)	22(71)	
Obstructive/irritative LUTS	3(10)	1(3.2)	
Constipation	3(10)	2(6.5)	
Enuresis	0(0)	3(9.7)	
Obstructive/irritative LUTS+constipation	2(6.7)	0(0)	
Obstructive/irritative LUTS + urinary incontinence	0(0)	1(3.2)	
Obstructive/irritative LUTS+recurrent fever	0(0)	1(3.2)	
Constipation + Urinary Incontinence	1(3.3)	0(0)	
Obstructive/irritative LUTS+constipation+Enuresis	0(0)	1(3.2)	
(Blood Pressure) mmhg			
Systolic	117.00±6.75 (100-120)	111.15±16.85 (80-120)	0.31
Diastolic	69.00±3.16 (60-70)	65.00±11.90 (40-80)	32
Circumcision	2(6.7)	3(9.7)	0.52
Lab Data			
Creatinine	0.58±0.16 (0.15-.084)	0.67±0.23 (0.35-1.4)	0.15
Urine Analysis:			
Unremarkable	22(73.3)	23(74.2)	
Protein+	5(16.7)	2(6.5)	
Bacteriae+	1(3.3)	0(0)	
Nitrite+	0(0)	1(3.2)	
Protein & Bacteriae+	0(0)	1(3.2)	
Protein & Bacteriae& Nitrite+	2(6.7)	4(12.9)	
Positive urine culture	0(0)	3(9.7)**	0.24
Ultrasonography:			
Unremarkable	8(26.7)	7(22.6)	
Unilateral Hydronephrosis	6(20)	7(22.6)	
Bilateral Hydronephrosis	6(20)	5(16.1)	
Renal Scarring	3(10)	3(9.7)	
Bladder Trabeculation	3(10)	0(0)	
Renal Atrophy	0(0)	1(3.2)	
Hydronephrosi & Renal Scarring	0(0)	1(3.2)	
Hydronephrosi & Bladder Trabeculation	1(3.3)	7(22.6)	

The data is shown as frequency in number (and percent) and (maximum-minimum) mean±standard deviation/standard error.
*P-value≤0.05 was considered statistically significant.
**E. Coli was observed in all three cases

(version 16) was used. Normal distribution of quantitative data was confirmed by Kolmogorov-Smirnov test. To compare variables between the two groups, t-test and for independent groups, chi-square test or Fisher's exact test (depending on conditions) were used. Repeated measures test was used to assess between-group and inter-group analysis to assess the changes in disease grade. P<0.05 was considered statistically significant.

Results

Demographic characteristics and variables associated with history of patients in both groups are summarized in (Table 1). Accordingly, the two groups were similar. Clinical symptoms, laboratory examination results of both groups are summarized in (Table 2). In these cases, there was also no significant difference between the two groups. It should be noted that neurologic examination revealed no cases of mental retardation, impaired gait and spina bifida/spinal dysraphism. In Vantris group, VUR was on the right in 5 cases (16.1%), on the left in 8 cases (25.8%), and bilateral in 18 cases (58.1%). VUR in the surgical group was on the right in 6 patients (20%), on the left in 4 cases (13.3%) and bilateral in 20 cases (66.7%) and there was not a statistically significant difference in this respect between the two groups (P=0.47). In Vantris group, the baseline

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Table 3: The improvement rate based on the initial Grade of VUR in two groups.

Initial VUR Grade	Result	Gil-Vernetsurgery (50 renal units)	Vantris (49 renal units)	
		(%)Frequency	(%)Frequency	P.V*
I-II	Complete correction	11 (78.6)	1 (100)	0.8
	Overall improvement	14 (100)	1 (100)	As above
III	Complete correction	12 (80)	21 (87.5)	0.66
	Overall improvement	12 (80)	23 (95.8)	0.73
IV	Complete correction	20 (95.2)	18 (75)	0.1
	Overall improvement	21 (100)	24 (100)	As above

*P-value≤0.05 is considered statistically significant.

VUR grade was II in one case, III in 24 cases, and IV in 24 cases and in the surgical group was I in 2 cases, II in 12 cases, III in 15 cases, and IV in 21 cases. The post-surgical VUR grade was I in 3 cases, and III in 4 cases. VUR grade significantly decreased in both groups after treatment (P<0.001), however, a significant difference was not observed between the two groups (P=0.07).

The mean duration of follow-up in Vantris group was 8.81±1.65 months (1 to 22) and in the surgical group was a 7.57±0.89 months (3 to 26). There was no statistically significant difference in this respect between the two groups (P=0.47). Recovery and non-recovery after treatment in the Vantris group, was 48 (98%) and 1 (2%), respectively, and in the surgical group was 47 (96%) and 3 cases (4%). There was no significant difference in this respect between the two groups (P=0.62). Full recovery after treatment in the Vantris group was observed in 40 cases (81.6%) and in the surgical group, in 43 cases (86%). There was no statistically significant difference in this respect between the two groups (P=0.56). After treatment, VUR occurred in the opposite side in the Vantris group in one case (3.2%) and in the surgical group in two cases (6.7%). There was no significant difference in this respect between the two groups (P=0.61). Symptomatic urinary tract infection after treatment, during follow-up, occurred in the Vantris group in one case (3.2%), while there were no cases in the surgical group. There was no significant differences between the two groups (P=0.51). Urine analysis or culture was positive after treatment of VUR, during follow-up, in the Vantris group in two cases (6.5%), while there were no cases in the surgical group. There was no significant differences between the two groups (P=0.49). According to the ultrasonography findings after treatment, during follow-up, in the Vantris group, 24 cases (77.4%) were normal, renal hydronephrosis was recorded in 4 cases (12.9%), renal stone, atrophy, and scar, each in 1 case (3.2%) and in the surgical group 22 cases (75.9%) were normal, and renal hydronephrosis occurred in 5 cases (17.2%), and renal scar in 2 cases (6.9%). The results of treatment in two groups, based on the initial severity of VUR, is summarized and compared in (Table 3). There was no statistically significant difference between the two groups. Two cases had severe hydronephrosis, one of those accompanied by scarring. The remainder of hydronephrotic cases were of mild hydronephrosis. For those with severe hydronephrosis, IVP was done which revealed ureteral stenosis. The atrophic and stone cases and the open surgery cases with scarring were free of considerable hydronephrosis/obstruction.The two cases with severe persistent hydronephrosis underwent extravesical ureteral reimplantation.

Discussion

In the current study, the success rate of endoscopic treatment of VUR after the first injection of Vantrisin patients with severity of grade II to IV was investigated and the results were compared with those treated with Gil-Vernet open surgery methods. Duration of follow-up was, on average, 8 months in both groups. Accordingly, complete remission and overall recovery was observed in 81.6% and 98% in the Vantris group and in 86% and 94% in the open surgery group, respectively (no significant difference). Although the decrease in the severity of disease was non-significant in the Vantris group, it was at borderline more than other groups.

Vantris was introduced for the first time in 2008, as a bulking material, in Argentina by Ormaechea and colleagues [8]. After that some study is done with low included patients but in all of these overall recovery were more than 80% to near 90% for one injection [9-12]. In a multicenter comprehensive study, carried out by Kocherov and colleagues (2014), the results of endoscopic treatment of VUR using Vantris were studied. In this study, a total of 611 pediatric patients were studied at seven different centers. Follow-up duration ranged from 6 to 54 months and more than half of patients had VUR with grade III. After the first treatment course, VUR was fully recovered in 93.8% of patients. Finally, it was concluded that this treatment modality is simple, safe and effective and can be used in all grades of VUR [13]. In the study by Corbetta and colleagues (2015), the results of endoscopic treatment using Vantris were evaluated in 81 children with VUR (117 renal units). The overall recovery rate in this study was 92.3%. Finally, it was concluded that this therapy has a high efficiency [14]. It has been pointed out in the conclusion of the study results that the success rate (total or complete) ranged from 71% to 98.1% in similar investigations; accordingly, the results of the present study is also within this range and is in a high level. It should be noted that success rate of endoscopic treatment of VUR using different bulking materials have been reported at 70 to 80% [15-17]. In a study by Abdullaev et al. (2013) on 4000 cases of VUR treated with endoscopic treatment using a variety of bulking materials, it was concluded that the best material is Vantrisin this regard [18]. Vantrisis a non-biodegradable synthetic material; that is why it creates fibrotic capsule at the injection site that leads to stability, continuity, and survival in place for a long time. This material belongs to the Acrylics family, in which the polyacrylate polyalcohol copolymer particles are floating in a physiologic carrier solution. The high molecular weight of the material causes it to last for a long time after injected in the place, through creating a mass status. The used carrier contains 40% glycerol solution that is absorbed by the reticular system after injection and is excreted through the kidneys without being metabolized. Since Vantris contains anionic particles with high surface electron negativity, it induces little cell

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response and fibrotic growth. Studies have shown that this material is not mutagenic and toxic. In addition, histological examination of the animal organs with this material has shown that it does not cause particle migration. Thus, Vantrisis considered one of the best bulking materials in endoscopic treatment of VUR [8]. However, some studies have reported the major limitation of the endoscopic treatment of VUR as its high degree of inefficiency in severe cases of the disease [19].

Meanwhile, Dogan et al. (2015) found no significant relationship between initial severity of the disease and the success rate of endoscopic method, in their study [20]. In the present study, the success rate of this treatment are reported separately, based on the severity of VUR (Table 3). Accordingly, the overall success rate was high in all the investigated severities (100% in group I-II and IV, and 80% in group III). However, it is recommended that future studies examine this treatment in severe cases with grade V with sufficient sample size in each group. It should be noted that this study is the first clinical comparing the results of using Vantris with the results of Gil-Vernet open surgery. In all of other study there were not any comparisons with gold standard. Gil-Vernet open surgical procedure is considered an intravesical method, where medial ureter is displaced. Among open surgical procedures, this method is very simple, and fast and is associated with high success rates. Based on previous studies, the success rate of this method is usually more than 90% and in some cases 100% [21-23]. For example, in the study by Basiri et al. (2008) in Iran, 96 patients with VUR (150 renal units) underwent Gil-Vernet surgery with a recovery rate of 92% [24]. The study by Mirshemirani et al. (2010) in Iran, also, investigated the results of Gil-Vernet open procedures in 72 patients with VUR. The mean duration of follow-up in this study was 48 months. Full recovery following this surgery was reported 96.2% [5]. As evident, the results of our study are consistent with previous studies regarding the efficiency of this procedure. However, it should be noted that endoscopic treatment has more advantages over open surgery. The benefits of endoscopic vs. surgical methods include less complications, cost, and no scarring on the skin surface. In addition, unlike open surgery, endoscopic procedures can be done on outpatient basis and do not require hospitalization [18].

Conclusion

According to this study, the results of the endoscopic treatment with Vantris in short follow-up period is similar to the open surgery with Gil-Vernet technique. With respect to the superiorities of Vantris over Gil-Vernet such as short hospital stay and an early recovery, we recommend it for VURs with severities less than V.

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