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Long-term Outcomes of Two Dextranomer-based Bulking Agents (Dexell vs. Deflux) in the Endoscopic Treatment of Vesicoureteral Reflux

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What's known on the subject? and What does the study add?

Vesicoureteral reflux (VUR) is a common urological condition observed in approximately 30-40% of pediatric patients presenting with urinary tract infections (UTIs). The primary objective in the management of VUR is to prevent febrile infections and subsequent renal damage, thereby reducing the morbidity associated with both the condition and its treatment. Endoscopic treatment of VUR is typically employed prior to major surgical interventions such as ureteroneocystostomy in patients who continue to experience febrile UTIs despite observation or antibiotic prophylaxis. Although a variety of bulking agents have been utilized in this procedure, the most commonly used substance is the dextranomer/hyaluronic acid (Dx/HA) copolymer. Deflux consists of dextranomer microspheres with a mean diameter of 80-250 µm, suspended in a sodium hyaluronic acid solution. In a recent study, a positively charged dextranomer product, Dexell-which comprises positively charged dextranomer microspheres with a smaller average diameter of 80-120 µm-was compared with Deflux. Previous studies have evaluated and published data on different Dx/HA copolymers in an effort to determine whether variations in microsphere size impact complication rates or success rates. However, these studies have predominantly focused on short-term outcomes. Therefore, the aim of the present study was to compare the long-term outcomes of Dexell (Istem Medical, Türkiye) and Deflux (Valeant Pharmaceuticals North America, LLC). In conclusion, no significant differences were observed between the two materials in terms of complication rates or treatment success, despite the variations in microsphere diameter.

Abstract

Objective: This study aimed to compare the clinical and radiographic success rates of endoscopic treatment for vesicoureteral reflux (VUR) using two different formulations of dextranomer microspheres.

Materials and Methods: This retrospective study included 119 children treated endoscopically for VUR between 2015 and 2020 at a single tertiary center. Subureteric injections were performed using either Dexell (n=61) or Deflux (n=58) by a single surgeon applying the hydrodistention implantation technique. Clinical data, including demographics, VUR grade, voiding status, injection volume, and complications, were collected from medical records. Treatment success was defined as the resolution of reflux on voiding cystourethrogram at 3 months, and the absence of febrile urinary tract infections during the 2- and 5-year follow-ups. Statistical analyses included chi-square and Mann-Whitney U tests, and logistic regression was used to identify predictors of treatment failure.

Results: The mean follow-up durations were 75.9 months in the Dexell group and 78.2 months in the Deflux group, with comparable baseline demographic and clinical characteristics between groups. The short-term success rates at 3 months were 83.6% for Dexell and 84.5% for Deflux (p=0.896). Long-term success rates remained similar at both 2 years (80.3% vs. 81.0%, p=0.922) and 5 years (72.1% vs. 74.1%, p=0.805). Postoperative obstruction occurred in 3 patients in the Dexell group and 2 patients in the Deflux group, all of which resolved conservatively. Multivariable analysis revealed no independent predictors of treatment failure.

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Conclusion: Our analysis showed that the diameter of dextranomer microspheres, frequently utilized for the endoscopic treatment of pediatric VUR, did not affect the short-term or long-term success rates of the procedure. Therefore, Dexell may be considered a cost-effective alternative to Deflux in clinical practice. However, multicentric, randomized, prospective trials with long follow-up durations are necessary.

Keywords: Dextranomer/hyaluronic acid, vesicoureteral reflux, subureteric injection, michrospheres

Introduction

Vesicoureteral reflux (VUR) is a prevalent urologic anomaly (1). It is observed in 1%-2% of the pediatric population and in 30-40% of children with urinary tract infections (UTIs) (1,2). Reflux nephropathy is a common etiology of hypertension in children, potentially resulting in growth retardation and renal insufficiency (3). The objective of managing reflux is to prevent febrile infections and kidney damage, thereby reducing the morbidity associated with both the disease and its treatment. Conservative treatment is often the preferred option in patients diagnosed with VUR. Nonetheless, a subset of the population with recurrent febrile UTI despite antibiotic prophylaxis, who are unlikely to experience spontaneous resolution and possess renal scarring, necessitates interventional treatment options (4). Previously, the primary treatment included medical therapy and open surgical correction of reflux. However, in 1981, Matouschek (5) described the subureteral implantation of Teflon as a bulking agent for the treatment of vesicoureteral reflux. Subsequently, O'Donnell and Puri (6) published the initial clinical series in 1984. Despite the use of many injection materials, including Teflon, bovine collagen, and macroplastique, questions regarding their efficacy and safety have emerged; thus, Vantris and dextranomer/hyaluronic acid (Dx/HA) copolymer are being used for endoscopic treatment (7-10).

Dx/HA copolymer, approved by the Food and Drug Administration in 2001, is among the most widely used materials globally. Deflux consists of dextranomer microspheres averaging 80-250 µm, suspended in a sodium hyaluronic acid solution. The positively charged dextranomer (Dexell), employed for comparison with Deflux in the recent study, consists of dextranomer microspheres averaging 80-120 µm in diameter (11). Previous studies have compared and published findings on two Dx/HA copolymers to see whether there are differences in complication rates and success rates related to varying microsphere diameters. These studies indicated that similar results were observed in the context of the employed diagnostic or treatment methods (Dx/HA); however, they only included short-term outcomes. Therefore, we aimed to compare the long-term effects of Dexell (Istem Medical, Türkiye) and Deflux (Valeant Pharmaceuticals North America, LLC).

Materials and Methods

This study was conducted as a retrospective comparative analysis of two dextranomer-based bulking agents, Dexell (Istem Medical, Türkiye) and Deflux (Valeant Pharmaceuticals North America, LLC), used in the endoscopic treatment of VUR. The availability of these materials in our clinic depended on institutional purchasing policies, local supply conditions, and periodic procurement schedules, which might vary over time and are not under the direct control of the surgical team.

One hundred nineteen patients who were included in the study were treated at our clinic between 2015 and 2020. In our series, 61 patients underwent subureteral injection with Dexell, and 58 patients were treated with Deflux. The numbers of renal units with VUR were 82 and 76 in the Dexell and the Deflux groups, respectively. Patients with grade V reflux, duplex systems, paraureteral diverticula, or refractory lower urinary tract symptoms (LUTS) and patients who do not attend regular follow-up were excluded. The main goal was to evaluate whether one agent had a clear advantage over the other in terms of treatment success, safety, and associated clinical outcomes. Data were collected from patients' medical records, which included demographic information, clinical presentation, treatment details, and follow-up data. This study was conducted in accordance with the ethical principles outlined in the Declaration of Helsinki.

Demographic characteristics such as age, gender, and VUR grade were documented. Treatment details included the volume of injection material used, the presence of any intraoperative or postoperative complications, and the duration of follow-up. The primary outcomes were treatment success (defined as the absence of reflux on follow-up imaging) and postoperative complications, particularly the development of obstruction.

The resolution rate was determined by voiding cystourethrogram (VCUG) at the third postoperative month. We stated that the long-term success rate is defined by the absence of UTIs with fever in patients after two and five years. In cases where patients presented with a UTI accompanied by fever, an additional VCUG was performed.

All surgeries were performed by a single surgeon using a Karl Storz pediatric cystoscope with a 5 Fr working channel, and the

hydrodistention implantation technique (HIT), approach was applied using a metal injection needle.

Statistical Analysis

The statistical analysis included both categorical and continuous variables. Categorical variables were analyzed using chi-square tests to determine any significant differences between groups, while continuous variables were analyzed using either the t-test or Mann-Whitney U test, depending on the normality of the data distribution. Correlations between the volume of injection material and postoperative obstruction were analyzed using point-biserial correlation. This study was approved by the Ankara University Human Research Ethics Committee (approval no.: 2022000257-3, date: 27.04.2022).

Results

A total of 119 children were assessed, including 61 in the Dexell group and 58 in the Deflux group (Table 1). No statistically significant difference was observed between the two groups regarding the male-to-female ratio. The mean follow-up duration (75.90 and 78.21 months, respectively) and the mean age of the children (66 and 67 months, respectively) also showed no statistically significant differences between the Dexell and Deflux groups. Additionally, 14 children in the Dexell group and 13 children in the Deflux group were not toilet-trained at the time of treatment.

In the Dexell and Deflux groups, right-sided reflux was observed in 21 and 22 patients, left-sided reflux in 19 and 18 patients, and bilateral reflux in 21 and 18 patients, respectively. The differences between the two groups were not statistically significant. Additionally, multiple injection sessions were required in 11 patients (11.48%) in the Dexell group and 7 patients (15.52%) in the Deflux group. VUR grades were categorized into three groups: Grades 1-2, grade 3, and grade 4. In the Dexell and Deflux groups, the distribution of grades was as follows: Grades 1-2 in 14 and 13 patients, grade 3 in 33 and 34 patients, and grade 4 in 14 and 11 patients, respectively. Among patients with bilateral VUR who received injections on both sides, the contralateral reflux grades were as follows: Grade 1-2 in 9 patients in the Dexell group and 10 patients in the Deflux group, grade 3 in 10 patients in the Dexell group and 7 patients in the Deflux group, and grade 4 in 2 patients in the Dexell group and 1 patient in the Deflux group. No statistically significant difference was seen between the two groups regarding the presence of voiding

Table 1. Preoperative and perioperative clinical features

	Dexell (80-120 µm)	Deflux (80-250 µm)	p-value
Age, months, mean ± SD	66.11±29.79	67.05±30.45	0.81[b]
Follow-up duration, months	75.90±11.70	78.21±11.62	0.28
Gender			>0.906[a]
Male	28	26	
Female	33	32	
Reflux side			0.902[a]
Right	21	22	
Left	19	18	
Bilateral	21	18	
Grade of the main injection side			0.845[a]
Grade 1-2	14	13	
Grade 3	33	34	
Grade 4	14	11	
Grade of the other injection side			>0.709[a]
Grade 1-2	9	10	
Grade 3	10	7	
Grade 4	2	1	
Voiding dysfunction presence	18	16	0.977[a]
Circumsized boys, n	25	24	0.702[a]
Success rate of 3 months	83.6%	84.5%	0.896[a]
Success rate after 2 years	80.33%	81.03%	0.922[a]
Success rate after 5 years	72.13%	74.14%	0.805[a]
Postoperative obstruction, n	3	2	0.690[a]

[a]: Chi-square test, [b]: Mann-Whitney U test, SD: Standard deviation

dysfunction. The number of circumcised boys does not differ between the two groups. VCUG was obtained at postoperative 3 month. The success rates after subureteral injection at the third month (83.6% and 84.5%) were not statistically different.

We introduced success criteria indicating the absence of a UTI with fever as well as the absence of reflux. We established equivalent criteria for success rates in the second and fifth years. If patients experienced a UTI accompanied by fever, a new VCUG was conducted. The success rates over a two-year period following subureteral injection were 80.33% and 81.03%, with no significant difference seen. The differences in the success rates after subureteral injection over a five-year period (72.13% and 74.14%) were statistically insignificant.

When obstruction rates post-surgery were compared based on the volume of injected material between the two groups, point-biserial correlation analysis showed no substantial differences (n=3 for Dexell group, n=2 for Deflux group) (p=0.94). The correlation coefficient between the 2-year success rate and the presence of voiding dysfunction was found to be r=0.074, with a p-value of 0.42. Similarly, the correlation coefficient between the 5-year success rate and voiding dysfunction was r=0.089, with a p-value of 0.33. In both cases, the correlation is very low and not statistically significant (p>0.05), indicating that there is no meaningful relationship between voiding dysfunction and success rates at both time points.

In addition, a multivariable logistic regression analysis was performed to identify predictors of unsuccessful cases. In the univariate analysis, age [p=0.007, odds ratio (OR): 0.97, 95% confidence interval (CI): 0.96-0.99], a history of prior endoscopic treatment (p<0.001, OR: 6.13, 95% CI: 2.0-18.7), and grade 4 reflux on the dominant side (p<0.001, OR: 14.22, 95% CI: 3.33-60.0) were found to be significant predictors. However, none of these variables remained statistically significant in the multivariate analysis (Table 2).

Discussion

While several studies on dextranomer microspheres exist in the literature, they have predominantly focused on short-term outcomes. Although short-term success rates and postoperative complication outcomes appear similar among these materials, the long-term differences in success rates, recurrence risk, and complication profiles have not been well established. In the present study, no differences were observed between the two materials in terms of long-term success rates or complication outcomes, which makes our findings noteworthy. Although Dexell and Deflux are theoretically and legally considered equivalent dextranomer-based bulking agents, minor differences in microsphere diameter and manufacturing processes may influence their clinical behavior. Deflux is produced by a global manufacturer and is used worldwide, whereas Dexell is currently manufactured and distributed locally in Türkiye. Demonstrating comparable outcomes between these two agents is therefore valuable, as it supports the use of Dexell as a locally available and potentially more cost-effective alternative.

In the management of VUR in pediatric patients, three principal treatment modalities are available: antibiotic prophylaxis, subureteric injection, and open surgery, which is considered the gold standard (12). In addition, patients may be kept under observation without any treatment. According to the results of the Swedish reflux trial, a randomized prospective controlled study on VUR, the 2-year success rates were reported as 71% in the endoscopic treatment group, 39% in the prophylaxis group,

Table 2. Multivariable logistic regression model for predictors of unsuccessful cases

	Univariate			Multivariate
	p-value	Odds ratio	95% confidence interval	p-value
Type of dextranomer materials	0.805	0.979	0.96-0.99	0.368
Age	0.007	0.979	0.96-0.99	0.205
Gender	0.540	0.776	0.34-1.74	
Reflux side of dominant side Right Left Bilateral	 Ref 0.861 0.212	 0.910 1.848	 0.31-2.61 0.70-4.84	
Reflux grade of dominant side Grade 1-2 Grade 3 Grade 4	 Ref 0.339 <0.001	 1.926 14.22	 0.50-7.38 3.33-60	 0.584
Voiding dysfunction	0.329	0.622	0.24-1.61	
Prior endoscopic treatment history	<0.001	6.136	2.00-18.74	0.99
Circumcision history	0.141	4.154	0.62-27.72	

and 48% in the follow-up group (13). Similarly, Capozza et al. (14) reported a 69% success rate for endoscopic treatment and a 38% success rate for the antibiotic prophylaxis group. Although endoscopic treatment demonstrates increased success rates, prolonged use of prophylactic antibiotics may result in bacterial resistance, treatment non-compliance, and an enhanced risk of breakthrough UTIs. Open surgery presents a success rate of 92-98%, however, its disadvantages encompass invasiveness, prolonged hospitalization, and heightened anxiety for both the patient and their parents (15).

A meta-analysis of endoscopic treatment, encompassing 5,527 patients and 8,101 renal units, indicated that the reflux clearance rate (by ureter) after a single treatment was 78.5% for grades I and II, 72% for grade III, 63% for grade IV, and 51% for grade V (16). Capozza et al. (14) discovered that 80% of parents favored endoscopic treatment over antibiotic prophylaxis and open surgery after being provided with comprehensive information regarding all treatment alternatives. Endoscopic treatment is regarded as safe and minimally invasive, with a brief operating duration and short hospitalization, rendering it an attractive alternative to open surgical repair of reflux. Three procedures have been developed for subureteric injection: STING, HIT and double HIT. In a study conducted by Kirsch and Arlen (17), the overall success rates for patients and ureters were 89% and 92% for the HIT group, in contrast to 71% and 79% for the STING group, showing statistically significant differences.

Additionally, a 93% success rate was recorded in the double HIT cohort. To avoid heterogeneity and ensure a standardized approach, only the HIT technique was administered to all participants, and patients who had undergone STING or Double-HIT were not included in this study.

Many substances have been employed for subureteric injection; however, several have been discontinued due to specific complications and disadvantages (18). Currently, Dx/HA copolymer, launched in 1993, is the predominant injectable material owing to its non-immunogenic, biocompatible, non-allergenic, biodegradable, non-migratory, and durable characteristics (19). Dx/HA possesses many commercial designations based on the dimensions of the microspheres. Deflux comprises dextranomer microspheres of 80-250 µm, whereas Dexell's microspheres range from 80-120 µm. The price of Dexell (€180/cc) is lower to than that of Deflux (€400/cc) (Table 3) (11). A prior retrospective analysis conducted at our clinic revealed no significant difference in success and postoperative complication rates between the two Dx/HA formulations. Likewise, two more studies that evaluated these formulations also revealed no disparities in surgical success rates (7,20). Nevertheless, the duration of follow-up in both our study and the other two trials was short-term. The current study monitored patients over an extended period to assess both short- and long-term success rates and complication rates associated with variations in microsphere size.

In a study by Tekgül et al. (3), patients were divided into two groups: those younger than 54 months and those older than 54 months; with higher success rates observed in the older group. However, when we divided our patients into two groups, under 5 years of age and over 5 years of age, the Pearson correlation analysis showed no clinically significant difference in neither short- or long-term success rates between the two age groups.

Despite patients with voiding dysfunction typically exhibiting reduced success rates following subureteric injections, our study revealed low and statistically insignificant correlation coefficients between voiding dysfunction and 2-year success rates (r=0.074, p=0.42) as well as between voiding dysfunction and 5-year success rates (r=0.089, p=0.33). According to contemporary series and current guidelines, the success rates of subureteric injection are generally thought to be affected by voiding dysfunction. However, the lack of correlation observed in this study may be partially explained by the correction of voiding dysfunction both before and after the subureteric intervention. In addition, to minimize potential misinterpretations due to terminological overlap, it is important to distinguish between refractory LUTS and voiding dysfunction, as these entities may partially overlap although they have different clinical implications. Refractory LUTS refers to persistent LUTS despite appropriate medical and behavioral therapy, whereas voiding dysfunction represents functional abnormalities in the voiding phase that can often be corrected with targeted management. In our cohort, patients with refractory LUTS were excluded to avoid confounding effects on treatment outcomes, while

Table 3. Properties of Dexell and Deflux

	Dexell	Deflux
Dextranomer (mg/mL)	50	50
Hyaluronic acid (mg/mL)	15	17
Osmolality (mOsmol/L)	400	341
pH value	6.2	7.1
Diameter of dextranomer microspheres (µm)	80-120	80-250
Cost (€/cc) in Türkiye	180	400

patients with voiding dysfunction who had been appropriately treated prior to the endoscopic intervention were included. This approach allowed for a more homogeneous study population while reflecting real-life clinical practice.

A meta-analysis has shown that grade 4 reflux is associated with lower success rates compared to grades 1-3. Additionally, it has been reported that the success rates of repeated injections are lower than those of initial injections (16). In our study, younger age, a history of prior endoscopic treatment, and the presence of grade 4 reflux were identified as predictors of unsuccessful outcomes in the univariate analysis; however, none of these variables remained statistically significant in the multivariate analysis. This finding may be attributable to the limited sample size or to our definition of treatment success. If the criteria for defining unsuccessful outcomes had been broadened or if control VCUG had been performed in all patients during follow-up, the results of this analysis might have been different. Additionally, after 5 years of follow-up, 17 patients in the Dexell group and 16 patients in the Deflux group met the criteria for unsuccessful outcomes. In the Dexell group, 12 patients (70.6%) underwent open surgical repair and 5 patients underwent a repeat subureteric injection. In the Deflux group, 10 patients (62.5%) underwent open surgical repair and 6 patients underwent repeat subureteric injection.

Mazzone et al. (21) reported a 5% obstruction rate following subureteric injection. In our study, all patients underwent urinary ultrasound at 1 month postoperatively. In addition to routine ultrasound follow-up, patients presenting with worsening creatinine levels or flank pain underwent additional ultrasound imaging. During follow-up, obstruction was observed in 3 patients in the Dexell group and 2 patients in the Deflux group. However, all cases resolved conservatively without the need for further intervention. Point biserial correlation analysis was used to assess the relationship between injection material and postoperative obstruction, revealing no clinically significant difference (correlation coefficient =0.0069, p=0.94).

The success rate of subureteric injection could have been increased if the double-hit technique had been applied, but the application of the same technique may not have resulted in any discrimination between the two groups.

Study Limitations

This study has certain limitations that should be acknowledged. The first limitation is its retrospective design. Another limitation of this study is that the primary success criterion was defined as the absence of febrile UTIs during follow-up. Although this parameter is widely accepted as a reliable indicator of clinical resolution in current practice, additional factors such as recurrent afebrile UTIs, new scar formation on scintigraphy, decline in renal function, iatrogenic ureterovesical junction stricture, increased hydronephrosis on ultrasound, proteinuria, and hypertension were not systematically assessed due to the retrospective design of the study. In addition, control VCUG was not performed in all patients during follow-up, which could have provided a more objective comparison of anatomical resolution. Although performing VCUG at both baseline and follow-up would be ideal, it is not part of routine clinical practice and would be more feasible within the design of a randomized prospective study. Furthermore, the exclusion of patients with grade 5 VUR might have influenced the overall success rates. However, as these cases are generally associated with lower success rates after endoscopic treatment and are more likely to require surgical correction, we usually prefer open surgical repair for such patients in our daily practice. Their exclusion, therefore, may have reduced heterogeneity and prevented potential confounding in the interpretation of treatment outcomes. Moreover, a notable strength of this study is its provision of long-term outcome data for both Dx/HA materials, thereby addressing an existing gap in the current literature.

Conclusion

Our analysis shown that the diameter of dextranomer microspheres, frequently utilized for the endoscopic treatment of pediatric VUR, did not affect the short-term or long-term success rates of the procedure. Therefore, Dexell may be considered a cost-effective alternative to Deflux in clinical practice. Yet multicentric, randomized, prospective trials with long follow-up durations are necessary.

Ethics

Ethics Committee Approval: This study was approved by the Ankara University Human Research Ethics Committee (approval no.: 2022000257-3, date: 27.04.2022).

Informed Consent: Retrospective study.

Footnotes

Authorship Contributions

Surgical and Medical Practices: Y.T.S., B.B., Concept: M.C.K., Design: M.C.K., E.K., Data Collection or Processing: A.F.Ö., E.K., A.D.G., Analysis or Interpretation: A.F.Ö., A.A., Y.T.S., B.B., Literature Search: A.F.Ö., A.A., Writing: A.F.Ö.

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