

Effectiveness and cost analysis of different methods of anti-refluxive operations in VUR grade 3 in a single institution

Evi Comploj¹, Michael Mian², Mark Koen³, Tanja Becker³, Christoph Berger³, Marcus Riccabona³

¹Department of Urology, General Hospital of Bolzano, Italy

²Department of Hematology, General Hospital of Bolzano, Italy

³Department of Pediatric Urology, Krankenhaus der Barmherzigen Schwestern, Linz, Austria

KEY WORDS

vesicoureterorenal reflux grade 3 ► clinical outcome ► cost analyses

ABSTRACT

Introduction. In the ongoing debate for an optimal management, cost effectiveness has become an important factor. Independent of the different health care systems, treatment efficacies versus their expenses is vocalized worldwide. To determine the cost-benefit ratio between the different types of open surgeries, we performed a retrospective single institution analysis.

To compare the clinical outcomes and costs of different operative techniques in children with vesicoureterorenal reflux grade 3 (VUR G3).

Patients and methods. We retrospectively reviewed the medical records of 401 patients [514 RU (renal units)] previously treated conservatively, but unsuccessfully elsewhere and therefore admitted to our institution. Three therapeutic options were offered and, according to parents' decisions, the patients were subdivided in three groups: group 1 - transvesical ureter reimplantation (Politano or Cohen), group 2 - extravesical technique (Lich-Gregoir), and group 3 - endoscopic injection. The average costs of the treatments and re-interventions were calculated according to the initial diagnosis, hospital stay, operating theater, and controls.

Results. Group 1 procedures were performed successfully in 98 children (152 RU) and no re-interventions occurred. In Group 2, 132 children (136 RU) underwent extravesical surgery with one re-intervention (0.7%). In Group 3, 171 children (226 RU) underwent endoscopic injection. After the first injection, 69% (157/226) were successfully treated. In 12 RU, a second injection was applied and the cure rate increased to 167/226RU (74%). In the 59 remaining refluxive RUs, open reconstruction was now performed and was successful in: 36 RU by the Lich-Gregoir-, 16 RU by the Cohen-, and 7RU by the Politano-Leadbetter technique.

In unilateral VUR G3, the extravesical procedure turned out to be the treatment of choice due to the high success and low recurrence rates.

Conclusions. For counseled parents who consented that their children be treated for VUR G3 by open surgery, despite being more expensive, benefited from a significantly higher cure rate than endoscopic injection.

INTRODUCTION

At present, children affected by vesicoureterorenal reflux grade 3 (VUR G3) have different treatment options available to them. Several factors have to be considered when determining the best approach for a child affected by VUR. The most important are the grade of the VUR, unilateral vs. bilateral placement, anatomical variations, and the compliance of the patient and parents. The initial success rate and the final outcome are as important as the number of recurrences and the best way to handle them. The preferences of each parent as well as the risks and complications need to be discussed. The same is true for the total expenses and the cost effectiveness of each treatment.

In the ongoing debate for an optimal management, cost effectiveness has become an important factor. Independent of the different health care systems, treatment efficacies versus their expenses is vocalized worldwide. To determine the cost-benefit ratio between the different types of open surgeries, we performed a retrospective single institution analysis.

PATIENTS AND METHODS

We retrospectively reviewed the medical records of 401 patients (514 renal units (RU)) who had been admitted to our institution for treatment of primary VUR G3 between 1993 and 2009. Children with VUR due to a neurogenic bladder, outlet obstruction, or other anatomical abnormalities such as ureteroceles were excluded from the study.

The indication to open surgery was based on recurrent high febrile urinary tract infections (UTIs) that had been treated conservatively elsewhere without success.

Initially, all children underwent a complete diagnostic work-up including: LA (laboratory examinations, i.e., urine analysis and culture), USG (ultrasonography), VCUG (voiding cystourethrogram), and Technetium-99m-dimercaptosuccinic acid (DMSA) renal scintigraphy. These costs are considered as "sunk costs", with no valuable differences among them.

The different kinds of treatments were chosen in accordance with the parents counseling and consent, and preference was given to the surgeon for the technique itself when considering factors such as unilateral vs. bilateral VUR.

The patients were divided into three groups: group 1 (G1) consisted of patients who underwent open transvesical reconstruction according to either Politano-Leadbetter's or Cohen's technique, group 2 (G2) was treated with the extravesical Lich-Gregoir technique, and group 3 (G3) underwent the less invasive endoscopic injection.

The kind of re-operation was chosen after considering the parents' counseling and consent.

All operations were performed following the so-called "Golden standard procedures" without modification. Training operations were performed under supervision.

The hospital stay (HS) was nine days for G1, five days for G2, and three days for G3. HSs were in accordance with the Austrian national health system and are therefore not comparable with shorter HSs in other countries.

Supportive care consisted of antibiotic prophylaxis for three weeks following the procedure. In order to evaluate the outcome of the treatment and to identify possible recurrences in G1 and G2, USG was performed one to three months postoperatively. In G3, due to the high risk of recurrences, a VCUG was also performed three months after discharge.

All children were further followed in our outpatient department after 12 months and later every two years by USG to monitor the growth of the kidneys. In cases of endoscopic correction, the size of the subureteral implant was also determined.

The average costs of the transvesical, extravesical and endoscopic mono- or bilateral interventions and the follow-up investigations were grouped as follows: first, the sunk costs (LA, US, VCUG and DMSA) with no valuable differences among them; second, the average costs of the different operative procedures calculated according to the actual total expenses (i.e., social insurance reimbursement) of the following: a) the operation theater (OR), b) the anesthesia, and c) the hospital stay (in accordance with the Austrian national health system); and third, the follow-up controls.

RESULTS

We evaluated the medical records of 401 children (284 girls and 117 boys), with $n = 514$ RU and a mean age of 42 months (5 months – 15.8 years), who underwent different treatment modalities and were available for a complete follow-up investigation in our outpatient department. The mean follow-up was 42 months (3 months – 14.7 years).

In G1, a transvesical operation was performed in 98 children ($n = 22$ RU Politano-Leadbetter and $n = 130$ RU Cohen) at a mean age of 47 months (6 months – 15 years) without severe complications or re-operations. G2 ($n = 132, 136$ RU) underwent the Lich-Gregoir procedure at a mean age of 43 months (5 months – 15.8 years) with VUR recurrence in one girl (1 RU) who was successfully treated later by a Cohen procedure. In G3 ($n = 171, 226$ RU), at a mean age of 38 months (5 months – 13.5 years), endoscopic injection was performed. In 157/226 RU (69%) the VUR was cured, while in 12 RU a second injection was necessary. Thereafter, the cure rate increased to 74% (167/226 RU). Of the remaining 59 refluxive RUs; 36 RUs were successfully corrected by Lich-Gregoir-, 16 RU by Cohen-, and 7 RU by the Politano-Leadbetter technique. None of the patients experienced a ureteral obstruction. Overall, the cure rate at the first intervention was 100% in G1, 99% in G2, and only 69% in G3.

The average cost distributions per child/RU for the first treatment controls (LA, USG with or without VCUG) as well as the repeat treatments were calculated and are as follows:

The average cost per child in G1 was ~16,000 € at one year of follow-up. In G2, for the first successful intervention the average cost was ~10,000 €. In one RU (0.7%), a repeat was performed by a Cohen procedure (at ~16,000 €) and increased the cost after one year to ~26,360 €. In G3, the average cost of the first endoscopic injection (RU 157) was ~6,360 € per RU, however, the costs increased in the cohort after VUR recurrences to ~12,720 € when a second injection was applied (which was again unsuccessful in 2 RUs, who were treated now a third time by a Lich-Gregoir to increase the expenses up to ~23,000 €).

DISCUSSION

Since 1981 [1], endoscopic injections with different implant materials have been the most popular first-line treatment of VUR G3. In comparison to open surgery, the advantages are a shorter hospital stay, less pain, and a quicker recovery.

Nevertheless, these advantages have been outweighed by:

1. shorter long-term effectiveness;
2. a higher relapse rate;
3. the need for frequent postoperative controls, which lead to an increased burden for children and parents; and
4. the greater expenses in case of VUR recurrences.

In 2001, Läckgren G et al. [2] found a success rate following the first endoscopic injection in VUR G3 of 70%, which is comparable with the 69% in our series. However, in comparison to open surgery, success rates are much higher when performed as a first-line treatment [5, 6, 7, 8]. The same is true for VUR recurrences found in 23-29% of such-treated RUs when an endoscopic injection was repeated [2, 3, 9, 10]. Thus, the initially attractive and also "less expensive" endoscopic injection dampened our initial enthusiasm with its frequent need for repeat procedures. As shown in our single institution, the highest treatment success was at 99-100% with the open anti-refluxive surgery. The costs of ~16,000 € in G1 and ~10,000 € in G2 were nearly twice the endoscopic procedure, which had a cost of ~6,360 € but a success rate of only 69%.

To achieve the therapeutic goal of reflux freedom in G3 the costs of a repeated endoscopic injection doubled the cost to ~12,720 € and, if required, the open procedure increased costs to ~23,000 €. For comparison, if a Lich-Gregoir had been used to correct the first unsuccessfully applied endoscopic injection, the total cost per child would be ~16,400 € and ~22,400 € in the 22 RUs treated by a transvesical procedure.

The low cost of the first endoscopic injection is outweighed by the 31% reflux persistency and the associated disadvantages of repeated anesthesia and higher costs.

As shown in our single institution and in accordance with the literature, VUR recurrences occurred in one-third of all children treated with endoscopic injection. Although initially effective, this does not provide parents and children with long-term clinical and cost effectiveness. As also mentioned by Kobelt G et al., the latter plays an increasing role concerning differential indication and decision-making processes. In comparison, the initial success rate of 99 - 100% in VUR G3 treated by ureteral implantation is significantly higher than the endoscopic success rate of 69% [3].

Items 1 and 2 mentioned above are applicable to every institution and are therefore also comparable. However, the burdens on the children and parents (item 3) are variable factors and the total amount of costs (item 4) may differ with regards to different institutions, countries, and health insurance programs.

Open reimplantation, when performed as first-line treatment, is shown to reduce the multiple psychological types of exposure for children and parents. The high success rates not only reduce the number of repeat interventions, but also scheduled and unplanned visits for medical care. This is relevant not only for the child, but also for the parents who require time off from work. Uncertainty for the parents concerning the definitive cure of VUR can also implement limitations for the child.

Although cost effectiveness should not be the primary factor for the decision-making process, the economic impact should also be taken into consideration. Taken together, a permanent correction of VUR G3 should be chosen for the first-line treatment. In our experience, the endoscopic injection therapy was not nearly as effective as open surgery and the rising costs to cure the VUR

recurrences turned out to be substantial. Although this study has several limitations – such as its retrospective design and that the duration of hospitalization in accordance with the Austrian national health system is not comparable with other countries in which the majority of these procedures are performed on an in-and-out-patient basis – the results support our hypothesis that endoscopic injection therapy of VUR G3 is not the best treatment in terms of the success rate and cost effectiveness, particularly when more than one injection is required.

CONCLUSION

The disadvantages of open surgery have to be weighed against the reduced primary cure rate of minimally invasive endoscopic treatment. Costs should be calculated on the basis of the definitive cure rate. For counseled parents who consented that their children be treated for VUR G3 by open surgery, despite being more expensive, benefited from a significantly higher cure rate than endoscopic injection. In unilateral VUR G3, the extravesical procedure turned out to be the most cost-saving intervention due to the low recurrence rate. In bilateral VUR G3, the transvesical procedure seemed to be the most effective when considering the success rate.

REFERENCES

1. Matouschek E: *New concept for the treatment of vesico-ureteral reflux. Endoscopic application of Teflon.* Arch Esp Urol 1981; 34 (5): 385-388.
2. Läckgren G, Wählin N, Sköldenberg E, Stenberg A: *Long-term follow-up of children treated with dextranomer/hyaluronic acid copolymer for vesicoureteral reflux.* J Urol 2001; 166 (5): 1887-1892.
3. Kobelt G, Canning DA, Hensle TW, Läckgren G: *The cost-effectiveness of endoscopic injection of dextranomer/hyaluronic acid copolymer for vesicoureteral reflux.* J Urol 2003; 169 (4): 1480-1484; discussion 1484-1485.

4. Lebowitz RL, Olbing H, Parkkulainen KV et al: *International system of radiographic grading of vesicoureteral reflux. International Reflux Study in Children.* Paediatr Radiol 1985; 15 (2): 105-109.
5. Ehrlich RM: *Vesicoureteral reflux: a surgeon's perspective.* Pediatr Clin North Am 1982; 29 (4): 827-834.
6. Remzi D, Ozen H: *Surgical management of vesicoureteral reflux in children.* Int Urol Nephrol 1983; 15 (4): 323-326.
7. Linn R, Ginesin Y, Bolkier M, Levin DR: *Lich-Gregoir anti-reflux operation: a surgical experience and 5-20 years of follow-up in 149 ureters.* Eur Urol 1989; 16 (3): 200-203.
8. Kennelly MJ, Bloom DA, Ritchey ML, Panzl AC: *Outcome analysis of bilateral Cohen cross-trigonal ureteroneocystostomy.* Urology 1995; 46 (3): 393-395.
9. Kirsch AJ, Perez-Brayfield MR, Scherz HC: *Minimally invasive treatment of vesicoureteral reflux with endoscopic injection of Dextranomer/hyaluronic acid copolymer: the Children's Hospitals of Atlanta experience.* J Urol 2003; 170 (1): 211-215.
10. Capozza N, Caione P: *Dextranomer/hyaluronic acid copolymer implantation for vesico-ureteral reflux: a randomized comparison with antibiotic prophylaxis.* J Pediatr 2002; 140 (2): 230-234.

Correspondence

Evi Compoj
 General Hospital of Bolzano
 Department of Urology
 5, L.- Böhler Street
 39100 Bolzano, Italy
 phone: +39 0471 908 686
 compojjevi94@yahoo.de