Journal of Pediatric Urology (2013) 9, 878—883

Journal of Pediatric urology

Bladder augmentation with small intestinal submucosa leads to unsatisfactory long-term results

M. Schaefer [a,*], A. Kaiser [b], M. Stehr [a], H.J. Beyer [a]

[a] *Department of Pediatric Surgery and Urology, Cnopf'sche Kinderklinik, St.-Johannis-Mühlgasse 19, 90419 Nuremberg, Germany*
[b] *Department of Pathology, Klinikum Nürnberg, Prof. Ernst-Nathan-Str. 1, 90419 Nuremberg, Germany*

Received 2 September 2012; accepted 5 December 2012
Available online 16 January 2013

KEYWORDS
Urinary bladder;
Microbladder;
Bladder exstrophy;
Vesico-ureteral reflux;
Cloacal malformation;
Enterocystoplasty;
Bladder augmentation;
Small intestinal submucosa

Abstract *Purpose:* To evaluate the use of small intestinal submucosa (SIS) for bladder augmentation in a series of select patients.
Material and methods: Six patients (age 6.5—15.4, mean 9.8 years) underwent bladder augmentation with SIS: one after a cloacal exstrophy repair, one after multiple surgery of the bladder because of vesicoureteral reflux, two with spina bifida, two after bladder exstrophy repair. All suffered from a microbladder with a mean volume of 61.5 ml (range 15—120, 7—36% of expected bladder capacity for age). Preoperative bladder compliance ranged from 1.0 to 3.3 (mean 1.3) ml/cmH_2O.
Results: Follow-up time ranged from 4.6 to 33.5 (mean 24.4) months. An increase of bladder volume was achieved in four patients (53—370 ml, 16—95% of expected bladder capacity for age). Bladder compliance postoperatively ranged from 0.9 to 5.6 (mean 3.0) ml/cmH_2O. Histological examinations showed a complete conversion of SIS, leaving irregular urothelial lining and bladder wall containing muscular, vascular and relatively thick connective tissue in four patients and regular urothelium in two patients. Major complications were bladder stones in two patients and a bladder rupture in one patient.
Conclusion: Bladder augmentation with SIS in humans failed to fulfill the hopes raised by animal studies. Due to the insufficient increase in bladder compliance and therefore failure to accomplish sufficient protection of the upper urinary tract, bladder augmentation with SIS cannot be recommended as a substitute for enterocystoplasty.

* Corresponding author.
E-mail addresses: mattias.schaefer@email.de, mattias.schaefer@diakonieneuendettelsau.de (M. Schaefer).

1477-5131/$36
http://dx.doi.org/10.1016/j.jpurol.2012.12.001

Introduction

Reconstruction of the human bladder remains one of the major surgical challenges both in adult and pediatric surgery [1]. The use of small bowel segments is widely accepted as standard procedure [2]. However, the use of bowel is associated with major complications such as stone and mucus formation, metabolic acidosis due to reabsorption of ammonia (especially relevant in patients with impaired renal function), urinary tract infections, intestinal obstruction and carcinogenesis [3,4].

Several attempts have been made to find different materials to replace the use of bowel, but so far all efforts that have included the use of biodegradable materials such as pericardium, amniotic sac, human dura mater or placenta, or the use of synthetic materials such as polypropylene, have been discouraging [5]. The same applies to the use of autoaugmentation techniques [6]. Only for seromuscular colocystoplasty have improved medium-term results been reported, although strict patient selection is necessary [7,8].

The ideal procedure for bladder augmentation would be a primary extraperitoneal procedure without the use of bowel, easy to perform and guaranteeing good functional results [9]. The main goal is to reduce high pressure in bladders to protect the upper urinary tract, and then to increase bladder capacity and quality of life due to longer dry periods or continence.

Small intestinal submucosa (SIS) is an acellular collagen based material derived from porcine small intestine. It is commercially available (SURGISIS® ES Soft Tissue Graft, Cook Biotech Inc., West Lafayette, USA) and has been approved as a soft tissue implant for human use according to EC Directive 93/42/EEC on medical devices (certificate no. G7 10 12 39164,060, TÜV Süd, Germany).

In 1995 Kropp and his group first presented preclinical studies with the use of SIS as possible bladder augmentation material [10,11]. Subsequently, several studies extensively evaluated this xenograft as a bladder wall substitute in different animal models, such as rabbits [12], dogs [13,14] and pigs [1,10,15]. Apart from the open surgery bladder augmentation with SIS, which showed encouraging results, two studies also evaluated a laparoscopic approach and their results were not fully satisfying [16] or discouraging [17]. SIS has also been used in humans in several urological [18–21] and other surgical indications such as hernia repair [22,23] and congenital diaphragmatic hernia [24] without major immunogenic side effects.

At our center we had experienced good results after the use of SIS in the repair of abdominal wall defects, encouraging us to use it in bladder augmentation in selected patients.

Material and methods

We report on the retrospective analysis of six patients who received bladder augmentation with SIS (Table 1). In one case bladder augmentation with small bowel was not possible (patient A), and in the other cases the patients and parents had profound objections and strongly refused to allow bladder augmentation with the use of bowel segments. Detailed informed consent both from patients and parents regarding the experimental nature of the individualized treatment trial was obtained.

Surgical technique: The bladder dome was incised in a cranio-caudal direction through a primarily extraperitoneal approach. Ureteral reimplantation or other necessary procedure (e. g. Monti stoma, bladder neck plasty) was performed at the same time when necessary. A 7 × 10 cm four-layered SIS graft was cut into shape at the edges and sutured into the bladder wall, which was divided between (thick) muscle and mucosa layers. To ensure watertight anastomosis the sutures were covered with fibrin glue and the bladder was covered with Tachosil® (Nycomed, Konstanz, Germany).

A 10 or 12 F transuretheral catheter was inserted and left for two or three days. An 8 or 10 F suprapubic catheter was left in for 12–30 days and removed before discharge. A perivesical safety drainage was left in situ for 4–10 days. Full dose antimicrobial therapy was given in the first two weeks and then low-dose prophylaxis was administered for three months.

Patient follow-up included regular ultrasound, voiding cystourethrograms (VCUGs), cystometry and renal scans. Preoperative and postoperative bladder capacity as the percentage of expected capacity for age was calculated using the equation (age + 1) × 30 (in ml) for expected capacity. Biopsies were taken at the middle of the bladder dome in the augmented area only when a consecutive procedure (e. g. cystoscopy) was performed.

Cystometry was performed with warm saline solution using MMS Solar Silver® (Medical Measurement Systems, Bottrop, Germany). Bladder compliance was calculated as bladder volume/leak point pressure or bladder volume/pressure at beginning of uneasy feeling, which ever occurred earlier. Bladder capacity was obtained through both cystometry and VCUG.

Biopsies were fixed in 4% buffered formalin and standard HE staining was performed.

Results

Patient A was a 6-year-old girl with a cloacal malformation, caudal regression syndrome and syringomyelia, and bipartite bladder which had been treated by bladder fusion at the age of 3 years, including vaginoplasty. A posterior sagittal anorectoplasty was impossible because of a hypoplastic colon. The child was provided with a right-sided ileostoma and was incontinent regarding urine. An amount of small bowel had already to be used for the Monti stoma because of the absence of an appendix necessary for a Mitrofanoff stoma, so enterocystoplasty was felt to be impossible because of the risk of causing short bowel syndrome.

Patient B was a 15-year-old girl who originally suffered from bilateral vesicoureteral reflux IV–V° and had undergone several surgical procedures, including unsuccessful subureteral collagen injections and Lich-Gregoir anti-reflux surgery. She then developed left postoperative prevesical obstruction, had temporarily a ureterostoma, and finally underwent a psoas-hitch procedure on the left side. When the girl was referred to our centre she had developed an iatrogenic microbladder and was incontinent regarding urine.