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Incontinence

Repeat Retrourethral Transobturator Sling in the Management of Recurrent Postprostatectomy Stress Urinary Incontinence After Failed First Male Sling

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Abstract

Background: A failure rate between 20% and 45.5% after retrourethral transobturator sling (RTS) is reported. Recommendations for the management of persistent or recurrent postprostatectomy stress urinary incontinence (SUI) after failed male sling do not exist.
Objective: The aim of this study was the prospective evaluation of the efficacy of repeat RTS (RRTS) in patients after failed first RTS.
Design, setting, and participants: Between March 2007 and August 2009, 35 patients with mild to severe SUI after failed first RTS were treated with a second AdVance sling (American Medical Systems, Minnetonka, MN, USA).
Measurements: Preoperative and postoperative evaluation included daily pad use, 1-hr pad test, postvoiding residual (PVR) urine, uroflowmetry, and quality-of-life (QoL) scores.
Results and limitations: After 6 mo, 45.5% (15 of 33 patients) showed no pad use; 30.3% (10 of 33 patients), one dry "security" pad; 3% (1 of 33 patients), one wet pad; 6.1% (2 of 33 patients), two pads; 3% (1 of 33 patients), pad reduction $\geq$50%; and 12.1% (4 of 33 patients), treatment failure. After 16.6 mo, 34.5% (10 of 29 patients) showed no pad use; 37.9% (11 of 29 patients), one dry "security" pad; 3.4% (1 of 29 patients), one wet pad; 3.4% (1 of 29 patients), two pads; 10.3% (3 of 29 patients), pad reduction $\geq$50%; and 10.4% (3 of 29 patients), treatment failure. Daily pad use and pad weight decreased significantly. PVR and uroflowmetry results showed no significant change. QoL improved significantly. Postoperative acute urinary retention was observed in 23.6% of patients.
Conclusions: RRTS is an effective and safe treatment option for the management of SUI after failed first RTS.
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1. Introduction

After Berry [1] introduced fixed urethral compression in 1961, different sling systems to treat postprostatectomy stress urinary incontinence (SUI) began to be developed. Although the artificial urinary sphincter (AUS) still remains the established standard for SUI treatment [2], the first results of male slings evaluated in clinical trials show promising success rates [3,4]. Almost all male slings currently available induce a compressive effect on the bulbar urethra [5,6]. Described first by Rehder and Gozzi [7], the retrourethral transobturator sling (RTS) (AdVance, American Medical Systems, Minnetonka, MN, USA) is a therapeutic approach with functional impact [7,8]. Urodynamic studies have confirmed its nonobstructive mechanism [7,8]. Recently published 6-mo and 1-yr follow-up data of RTS showed overall success rates that ranged from 54.5% to 77.1% and 80% [3,4,9]. However, a failure rate between 20% and 45.5% after RTS resulted in persistent or recurrent SUI. The selection of patients with only mild and moderate SUI has been discussed to increase its efficacy [3,4]. However, recommendations for the management of patients with persistent or recurrent SUI after failed male sling do not exist. To our knowledge, only one study has reported experiences of AUS placement after a failed bone-anchored male sling [10]. There are no data concerning the use of repeat sling implantation after first sling failure. The aim of this study was the prospective evaluation of the efficacy of repeat RTS (RRTS) in patients after failed first RTS.

2. Material and methods

Between March 2007 and August 2009, 35 consecutive patients 49 to 83 yr of age (mean: 68.4 yr) were treated with RRTS after failed first RTS in a sequential clinical cohort observational study with a prospective design.

All patients were recruited from our outpatient office and consecutively included if they had a history of first RTS failure defined as the presence of persistent or recurrent SUI with a positive "repositioning test" and they requested further treatment. Exclusion criteria were fixed or scarred external urethral sphincter (EUS) with a negative "repositioning test" during urethrocystoscopy [3,11], postvoid residual (PVR) urine >60 ml, urethral stricture, bladder neck stenosis, adjuvant radiotherapy (AR) during the preceding 6 mo, detrusor sphincter dyssynergia (DSD), or detrusor overactivity (DO). One failed patient of the previous study reported by our group [3] fulfilled the inclusion criteria for RRTS but refused further treatment.

All patients completed the appropriate consented forms. The data were collected according to the database approved by the local institutional review board.

The evaluation of patients was performed before and after RRTS at follow-up visits in a standardized procedure by two independent investigators who did not perform the RRTS implantations. Preoperative workup included assessment of urine analysis, urodynamics (to exclude DO or DSD), cough stress test, uroflowmetry, PVR, daily pad use, 1-hr pad test, urethrocystoscopy, and micturition cystography (MCU). The EUS function and mobility of the posterior (membranous) urethra were verified, and erosion of the first sling was excluded during urethrocystoscopy. Sling function was simulated by the "repositioning test" [3,11]. Immobility of the bladder and bladder neck was excluded during MCU. The impact of SUI on quality of life (QoL) was assessed using the Incontinence Quality of Life (I-QOL) and the International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-UI SF) questionnaires. The degree of incontinence was defined as mild (one to two pads per day), moderate (three to five pads per day), or severe (six or more pads per day).

At follow-up visits, evaluation of daily pad use, 1-hr pad test, PVR, uroflowmetry, and I-QOL and ICIQ-UI SF questionnaires were performed. All patients were available after 6 mo, 24 patients after 1 yr, 9 patients after 18 mo, and 5 patients after 24 mo. The mean follow-up was 16.6 mo (range: 6–32 mo).

The primary study outcome was the objective success rate based on number of pads used per day. The success rate was achieved if patients were either cured (no pad use or one dry "security" pad) or improved (one to two pads or pad reduction ≥50%) [3]. All other cases were defined as failure. The secondary study outcome was the quantitative assessment of the 1-hr pad test and the impact of SUI on QoL.

2.1. Surgical technique

RRTS were implanted by one experienced surgeon (CG) using spinal or general anesthesia. For RRTS implantation we performed a few minor modifications of the previously described surgical technique [3,7] to provide better sling fixation. In all cases, the first failed sling was not removed because its position was not a hindrance for optimal RRTS implantation. This fact may indicate slippage of the first sling from its initial correct position. Correct RRTS placement was controlled by urethroscopy after mobilization of the urethral bulb. Positioning and tension of RRTS continued until the surgeon visualized a complete passive contraction of the EUS. In all patients, a nonrepositioned posterior urethra and no obstruction after the second sling positioning were found during urethroscopy. To prevent sling slippage, which was assumed to be a main reason for previous failure, RRTS was fixed at its middle part by five to six nonresorbable sutures along the midline of the perineal body to the urethral bulb instead of long-term resorbable sutures at the distal border and the middle part as reported previously [3,7] (Fig. 1).

2.2. Statistical analysis

Sample size was calculated considering the success rate of 80% for RRTS as a secondary procedure due to previous reported data for RTS as the primary approach [3,4]. The "proportion" (result) of 60%, a type 1 error ($p < 0.05$), and a power of 0.8 required 34 patients.

SPSS statistical software for Windows (v.17.0, SPSS Inc, Chicago, IL, USA) was used for data analysis. The number of daily pads used, uroflowmetry, PVR, 1-hr pad test, and QoL scores were analyzed by the

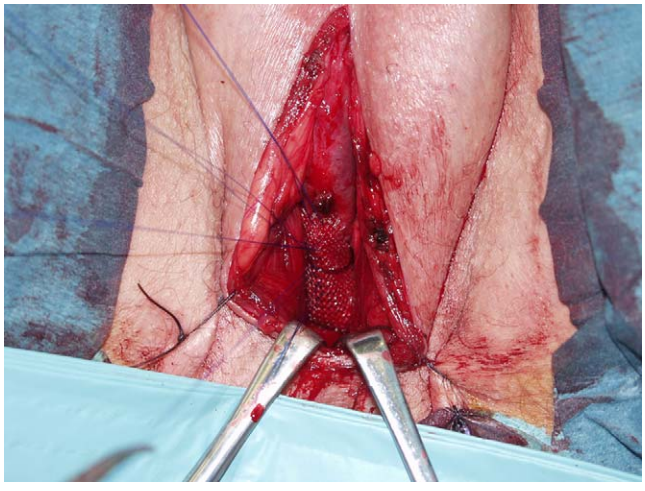

Fig. 1 – Technique of repeat retrourethral transobturator sling placement with special attention to sling fixation.

Table 1 – Characteristics of patients with failed first sling ($n = 35$)

Variable	Data
Mean ± SD age, yr (range)	68.4 ± 6.8 (49–83)
Mean ± SD body mass index, kg/m^2 (range)	26.1 ± 2.3 (22–30)
Prostate surgery, No. (%)	
Retropubic RP	35 (100)
Pelvic irradiation after RP	7 (18.9)
Mean ± SD time between slings, mo (range)	8.1 ± 3.9 (3–22)
Hospital where the first sling was implanted, No. (%)	
Dept. of Urology, LMU Munich	28 (80.0)
Other hospitals	7 (20.0)
Type of anesthesia for the RRTS*, *No. (%)*	
General anesthesia	12 (35.3)
Spinal anesthesia	22 (64.7)

RP = radical prostatectomy; RRTS = repeat retrourethral transobturator sling; SD = standard deviation.
* RRTS sling was implanted by surgeons trained in one of the AMS training centers or who had taken part in a workshop in our clinic.

Table 2 – Specific findings of patients in relation to their stress urinary incontinence before and after failed first sling as well as before undergoing the repeat retrourethral transobturator sling ($n = 35$)

Variable	Data
Severity of incontinence before the first sling, No. (%)	
Mild	2 (5.9)
Moderate	19 (55.9)
Severe	13 (38.2)
Mean ± SD pads used per day before first sling (range)	6.2 ± 4.4 (2–24)
Mean ± SD pad test, ml/1 h, before first sling (range)	181.5 ± 116.1 (30–500)
Mean ± SD Q_{max}, ml/s, before first sling (range)	17.6 ± 7.6 (6–39)
No. with recurrent incontinence after the first sling (%)	27 (77.1)
Mean ± SD continence time before recurrence, wk (range)	7.6 ± 1.9 (1–13)
Severity of incontinence before the RRTS, No. (%)	
Mild	10 (29.4)
Moderate	15 (44.1)
Severe	9 (26.5)
Mean ± SD pads used per day before RRTS (range)	4.3 ± 3.0 (1–15)
Mean ± SD pad test, ml/1 h, before RRTS (range)	145.9 ± 126.4 (14–500)
Mean ± SD Q_{max}, ml/s, before RRTS (range)	17.1 ± 7.7 (6–44)

Q_{max} = maximum flow rate; RRTS = repeat retrourethral transobturator sling; SD = standard deviation.

Wilcoxon signed rank test. Univariate analysis was performed by the chi-square test and multivariate assessment by multiple logistic regression. A p value < 0.05 was considered significant.

3. Results

Tables 1 and 2 present the characteristics and specific preoperative data of the patients recruited for RRTS placement after the first failed sling. The assessment of daily pad use was not available from 2 of 35 patients because they used toilet paper instead of pads in everyday life for economic reasons. Preoperatively both of them had a mild incontinence assessed by the 1-hr pad test. After 6 mo follow-up, one of them used toilet paper only for "security" reasons, and the second patient needed no more toilet paper. After a mean follow-up of 16.6 mo, both of them no longer used toilet paper and were complete continent.

After 6-mo follow-up, 45.5% (15 of 33 patients) showed no pad use; 30.3% (10 of 33 patients), one dry "security" pad; 3% (1 of 33 patients), one wet pad; 6.1% (2 of 33 patients), two pads; 3% (1 of 33 patients), pad reduction ≥50%; and 12.1% (4 of 33 patients), treatment failure. In a detailed analysis of the failed patients, in three patients excessive physical activity during the first 3 mo postoperatively seemed to be the reason for failure. At first these patients reported a significant postoperative improvement. However, after heavy physical activity, SUI recurred. All failed patients were successfully treated using the AUS.

After a mean follow-up of 16.6 mo, 34.5% (10 of 29 patients) showed no pad use; 37.9% (11 of 29 patients), one dry "security" pad; 3.4% (1 of 29 patients), one wet pad; 3.4% (1 of 29 patients), two pads; 10.3% (3 of 29 patients), pad reduction ≥50%; and 10.4% (3 of 29 patients), treatment failure. Two of the failed patients were successfully treated by AUS. Only one patient refused AUS placement and performed pelvic floor exercises. No significant worsening of SUI over time was observed.

The mean number of daily pad use was significantly reduced from preoperatively 4.35 ± 3.04 to 1.62 ± 2.78 pads after 6 mo and to 0.89 ± 3.04 pads after 16.6-mo follow-up (Fig. 2).

Table 3 shows the results of the 1-hr pad test, uroflowmetry, and PVR preoperatively after 6-mo follow-up and after a mean follow-up of 16.6 mo.

In a univariate analysis and a multiple logistic regression model, incontinence severity, postoperative acute urinary

Table 3 – Findings of pad test, uroflowmetry, and postvoid residual urine volume before repeat retrourethral transobturator sling (RRTS), 6 mo ($n = 35$) after RRTS, and at mean follow-up of 16.6 mo after RRTS ($n = 31$)

	Before RRTS	After 6 mo	p value*	At 16.6 mo of follow-up time	p value*
Pad test, ml/1 h	145.9 ± 126,4	18.2 ± 48.7	<0.0001	8.5 ± 19.9	<0.01
Q_{max}, ml/s	17.7 ± 7.7	15.4 ± 5.6	0.130	19.0 ± 4.6	0.715
PVR, ml	2.7 ± 8.9	5.3 ± 19.4	0.500	6.9 ± 22.8	0.273

PVR = postvoid residual; Q_{max} = maximum flow rate; RRTS = repeat retrourethral transobturator sling.
Results are represented as mean values with standard deviation.
* The p values for the statistical difference between the findings before RRTS compared with 6 mo follow-up and a mean follow-up of 16.6 mo are given for each time point.

Table 4 – Univariate analysis of outcome for subgroups after 6-mo follow-up ($n = 35$) and after a mean follow-up of 16.6 mo ($n = 31$) regarding severity of stress urinary incontinence before repeat retrourethral transobturator sling (RRTS), evidence of postoperative acute urinary retention after RRTS, and a history of irradiation after radical prostatectomy

	After 6 mo, %	*p* value*	After 16.6 mo, %	*p* value*
Mild/moderate SUI†	**92.0** (48.0 + 44.0)	0.082	**80.0** (70.0 + 10.0)	0.664
Severe SUI	**66.7** (55.6 + 11.1)		**60.0** (50.0 + 10.0)	
AUR†	**87.5** (50.0 + 37.5)	0.157	**71.4** (57.1 + 14.3)	0.278
No AUR	**87.5** (50.0 + 37.5)		**95.0** (50.0 + 45.0)	
Irradiation†	**80.0** (20.0 + 60.0)	0.347	**80.0** (40.0 + 40.0)	0.900
No irradiation	**85.2** (55.6 + 29.6)		**82.6** (52.2 + 30.4)	

AUR = acute urinary retention; RRTS = repeat retrourethral transobturator sling; SUI = stress urinary incontinence.
Figures in bold type represent the success rate; figures in parentheses represent the dry and improvement rate.
* The *p* values for statistical difference between the findings before RRTS compared with 6 mo follow-up and a mean follow-up of 16.6 mo are given for each time point.
† The numbers of patients in each group are given in Table 2 for incontinence severity, in Table 1 for irradiation, and AUR after RRTS was observed in nine patients (23.6%).

Table 5 – Multivariate analysis of risk factors for repeat retrourethral transobturator sling failure after 6-mo follow-up ($n = 35$) and after mean follow-up of 16.6 mo ($n = 31$)

Variable	After 6 mo		After 16.6 mo	
	OR (95% CI)	*p* value	OR (95% CI)	*p* value
Incontinence severity				
Mild/Moderate*	2.83	0.347	2.31	0.426
Severe	(0.32–24.80)		(0.29–18.27)	
AUR				
AUR	0.95	0.974	1.82	0.564
No AUR*	(0.08–11.56)		(0.23–14.21)	
Adjuvant radiotherapy				
Irradiation	†	0.999	†	0.999
No irradiation*				

* Reference outcome.
† No calculable because of low patients number with a history of irradiation.

retention (AUR), and AR showed no negative impact on the success rate (Tables 4 and 5).

3.1. *Quality of life*

The mean I-QOL score increased significantly from 60.6 ± 16.9 to 80.2 ± 20.1 ($p < 0.0001$) after 6 mo and to 88.3 ± 17.8 ($p < 0.0001$) after 16.6 mo (Fig. 3). The mean ICIQ-UI SF score improved significantly from 15.2 ± 4.4 to 9.0 ± 5.2 ($p < 0.0001$) after 6 mo and to 6.6 ± 5.0 ($p < 0.0001$) after 16.6 mo (Fig. 4). In addition, improvement of I-QOL and ICIQ-UI SF scores over time (from 6- to 16.6-mo follow-up) was observed (Figs. 3 and 4). However, this positive trend was not statistically significant.

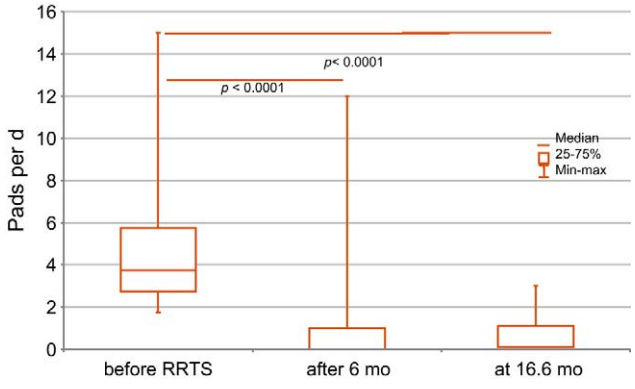

Fig. 2 – Comparison of daily pad use before the implantation of repeat retrourethral transobturator sling (RRTS), after 6 mo, and after a mean of 16.6 mo follow-up.

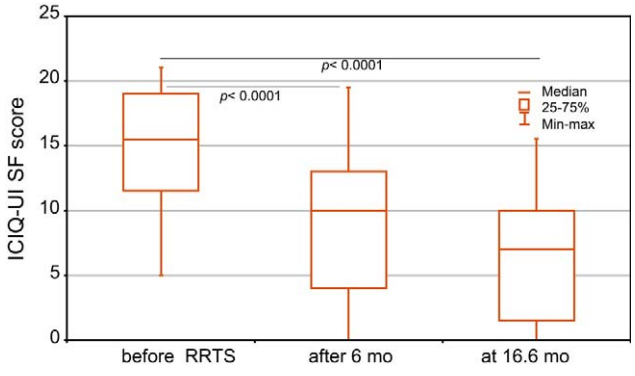

Fig. 3 – Comparison of scores of International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-UI SF) before the implantation of repeat retrourethral transobturator sling (RRTS), after 6 mo, and after a mean of 16.6 mo follow-up.

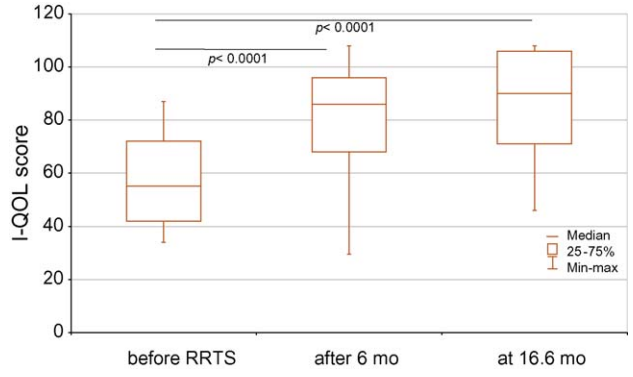

Fig. 4 – Comparison of scores of Incontinence Quality of Life (I-QOL) questionnaire before the implantation of repeat retrourethral transobturator sling (RRTS), after 6 mo, and after a mean of 16.6 mo follow-up.

3.2. *Complications*

One case of a small urethral injury by trocar extraction into the apex of the triangular space between the urethral bulb and the corpus cavernosum occurred at the time of surgery. However, the RRTS placement was continued. In this patient, a cystourethrography was performed after 6 d of transurethral catheterization. No abnormal findings were seen, and the catheter was removed. One patient was successfully treated with oral antibiotics due to postoperative acute urinary infection. No local wound infections or persistent perineal pain were observed.

Postoperative AUR was observed in 23.6% (9 of 35 patients). Patients received either a suprapubic or a transurethral catheter. Seven of nine patients (77.8%) had spinal anesthesia. Catheter removal was performed after 2–15 d without additional treatment. At the time of catheter removal, PVR was $\leq$50 ml.

4. Discussion

Recent published prospective studies [3,4,9] have confirmed RTS efficacy in the treatment of male SUI. However, a failure rate between 20% [3,4] and 45.5% [9] was reported. Reasons for failure of the primary RTS are still poorly understood and may be related to inappropriate indication or technique of sling placement or sling slippage due to early preoperative increase of intra-abdominal pressure caused by physical activity. However, further studies are needed to evaluate potential risk factors for sling failure such as age, degree of incontinence, preoperative DO or irradiation, type of prostate surgery, and previous invasive SUI treatment [6].

The management of primary RTS failure remains unclear. However, many of these patients request further SUI treatment.

The use of repeat midurethral tapes after its initial failure in female SUI sling surgery has shown a high rate of efficacy [12]. We report on the clinical outcome for a second male sling implantation after a failed first sling with a mean follow-up of 16.6 mo, referring to the good experience for repeat tapes in female sling surgery. In the presented study, 25 of 33 patients (75.8%) and 21 of 29 patients (72.4%) were completely dry or used only one dry "security" pad after the 6-mo and 16.6-mo follow-up, respectively. Moreover, a success rate of 87.9% (defined as no pad or one "security pad" and one to two wet pads or pad reduction $\geq$50) after 6 mo and 89.6% after 16.6 mo follow-up could be achieved. The efficacy after RRTS is comparable with previous reported data [3,4,7,13] and with data for other sling systems [14,15]. We suggest that the achieved success rates by RRTS in this study is due to careful patient selection regarding the exclusion criteria and special attention to RRTS fixation by increasing the number of stitches and the use of nonresorbable sutures. A high failure rate of 45.5% reported recently [9] may be associated with early initiation of physical activity after the first 4 wk postoperatively. Detailed counselling of patients to avoid physical activities in the first 12 wk postoperatively and the focus on better sling fixation may be helpful to achieve success. The fact that the failed RTS was not a hindrance for second sling implantation may indicate sling slippage. A positive "repositioning test" results if sling slippage occurred or a successful repositioning of the posterior urethra was not achieved during the first RTS implantation. The degree of incontinence, postoperative AUR, and irradiation had no negative impact on postoperative results after RRTS. However, the number of patients with AR in this study was too small to find a significant influence of irradiation on postoperative success rates as previously reported [16].

In a study with a follow-up of 14.2 mo concerning the efficacy of the AUS after sling failure, 8 of 11 patients (72.7%) were cured, 2 (18.2%) were improved, and 1 (9%) failed [10]. However, no prospective trial comparing AUS and RTS exists. Considering short- and long-term complications associated with AUS and a revision rate between 65% and 80% at 10 yr [17,18], RRTS appears an attractive approach for the treatment of persisting or recurrent SUI after sling implantation with a low complication rate. In contrast to AUS, for male slings no mental and physiologic ability of the patient is required [19], and costs are comparatively low.

AUR was seen in 23.6% of patients. An argument against obstruction by sling may be made because AUR was resolved without further treatment. These data are in line with prior reported results [3,11]. Significant improvement of QoL after RRTS remained stable over time.

Limitations of the study are a rather small number of patients with only short-term follow-up, the use of a "security" pad as a nonvalidated parameter, no postoperative urodynamic test and MCU, and lack of a detailed analysis of reasons for first sling failure. However, no data concerning repeat use of RTS exist. In addition, the only published study by Fisher et al. [10] dealing with the treatment of patients with the AUS after failed sling implantation covers a smaller number of patients and reports a shorter follow-up period.

5. Conclusions

The findings of our study indicate that RRTS offers an effective and safe minimally invasive treatment option for patients with persisting or recurrent SUI and a positive "repositioning test" after first sling failure. However, a larger clinical multicenter trial for the evaluation of long-term outcome and impact factors for failure is needed.

Author contributions: Irina Soljanik had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Soljanik, Gozzi, Stief.
Acquisition of data: Soljanik, Bauer.
Analysis and interpretation of data: Soljanik, Bauer, Gozzi, Becker, Stief.
Drafting of the manuscript: Soljanik.
Critical revision of the manuscript for important intellectual content: Bauer, Gozzi, Stief, Becker.
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