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Robotic versus open pediatric ureteral reimplantation: Costs and complications from a nationwide sample

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Summary

Introduction
We sought to compare complications and direct costs for open ureteral reimplantation (OUR) versus robot-assisted laparoscopic ureteral reimplantation (RALUR) in a sample of hospitals performing both procedures. Anecdotal reports suggest that use of RALUR is increasing, but little is known of the outcomes and costs nationwide.

Objective
The aim was to determine the costs and 90-day complications (of any Clavien grade) in a nationwide cohort of pediatric patients undergoing OUR or RALUR.

Methods
Using the Premier Hospital Database we identified pediatric patients (age < 21 years) who underwent ureteral reimplantation from 2003 to 2013. We compared 90-day complication rates and cost data for RALUR versus OUR using descriptive statistics and hierarchical models.

Results
We identified 17 hospitals in which both RALUR and OURs were performed, resulting in a cohort of 1494 OUR and 108 RALUR cases. The median operative time was 232 min for RALUR vs. 180 min for OUR ($p = 0.0041$). Incidence of any 90-day complications was higher in the RALUR group: 13.0% of RALUR vs. 4.5% of OUR (OR = 3.17, 95% CI: 1.46–6.91, $p = 0.0037$). The difference remained significant in a multivariate model accounting for clustering among hospitals and surgeons (OR, 3.14; 95% CI, 1.46–6.75; $p = 0.0033$) (Figure). The median hospital cost for OUR was $7273 versus $9128 for RALUR ($p = 0.0499$), and the difference persisted in multivariate analysis ($p = 0.0043$). Fifty-one percent (55/108) of the RALUR cases occurred in 2012–2013.

Discussion
We present the first nationwide sample comparing RALUR and OUR in the pediatric population. There is currently wide variation in the probability of complication reported in the literature. Some variability may be due to differential uptake and experience among centers as they integrate a new procedure into their practice, while some may be due to reporting bias. A strength of the current study is that cost and 90-day postoperative complication data are collected at participating hospitals irrespective of outcomes, providing some immunity from the reporting bias to which individual center surgical series' may be susceptible.

Conclusions
Compared with OUR, RALUR was associated with a significantly higher rate of complications as well as higher direct costs even when adjusted for demographic and regional factors. These findings suggest that RALUR should be implemented with caution, particularly at sites with limited robotic experience, and that outcomes for these procedures should be carefully and systematically tracked.

90-day complications	Univariate analysis		Multivariate analyses*	
	Odds Ratio (95% CI)	*p*-value	Odds Ratio (95% CI)	*p*-value
RALUR vs OUR	3.17 (1.46, 6.91)	0.0037	3.14 (1.46, 6.75)	0.0033
Female gender	1.05 (0.69, 1.61)	0.8156	-	-
Age (years, increasing)	1.01 (0.94, 1.08)	0.7625	-	-
Absence of comorbidity	0.34 (0.18, 0.66)	0.0014	0.34 (0.19, 0.62)	0.0004

*Multivariate model is adjusted for propensity score

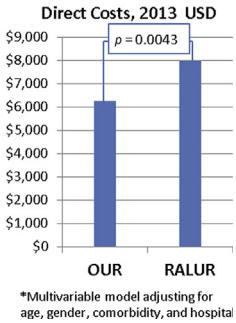

Figure Left: Univariate and multivariate odds of 90-day complication comparing open ureteral reimplantation (OUR) and robotic-assisted laparoscopic ureteral reimplantation (RALUR). Right: Comparison of OUR and RALUR direct costs in 2013 USD.

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Introduction

Although open ureteral reimplantation (OUR) has long been the gold standard for surgical correction of vesicoureteral reflux (VUR), laparoscopic approaches for VUR have been reported as far back as 1993 with a description of laparoscopic correction of VUR in a porcine model [1]. A robot-assisted approach was first described in 2004 [2,3], and subsequent reports suggest that robot-assisted laparoscopic ureteral reimplantation (RALUR) is rising in popularity [4,5]. While broad, multi-institutional data regarding outcome and cost have been reported for robotic pyeloplasty [6] the same is not true for ureteral reimplantation. Currently, the published data are conflicting regarding the complication profile of RALUR [7–10] with multi-institutional pooled data demonstrating high rates of persistent reflux and reoperation [10], whereas a large prospective single-surgeon series reported no complications [11]. This exists in comparison to OUR, which has a robust literature of favorable short and long-term outcomes and low complication rates [12,13]. Similarly, direct costs have increased with use of robot-assisted technology [6]. As such, we sought to compare 90-day complications and direct costs for OUR versus RALUR in a large national sample of hospitals performing both procedures. We hypothesize that RALUR would be associated with higher rates of complications and higher direct costs than OUR.

Materials and methods

Study cohort assembly

The Premier hospital database (Premier, Inc., Charlotte, NC, USA) is an inpatient dataset created for national quality and utilization benchmarking and includes approximately 20% of inpatient discharges from non-federal institutions in the United States comprising over 700 hospitals [14]. In addition, it provides a unique patient identifier key that allows tracking of an individual across encounters.

We extracted hospital discharge data for pediatric patients (age $<$ 21 years) with an International Classification of Diseases, Ninth Revision (ICD-9-CM) procedure code for ureteroneocystostomy (ICD-9 56.74) between January 1, 2003, and December 31, 2013, from the Premier Hospital Database. From these, we selected patients with ICD-9 diagnosis codes for VUR (593.7), and excluded patients with diagnosis codes indicative of secondary VUR (e.g., neurogenic bladder, exstrophy, ureterocele, posterior urethral valves), as previously described [15]. Absence of comorbidity was defined as a Charlson Comorbidity Score of zero [16]. This study was exempt from institutional review board approval, due to the de-identified nature of the data.

We further classified patients by surgical approach. Patients with code for a robot-assisted procedure (ICD-9 17.42 or 17.44 introduced in October 2008, Healthcare Common Procedure Coding System [HCPCS] Current Procedural Terminology [CPT] Code S2900 introduced in July 2005) or a recorded charge code for robotic instrumentation were classified as RALUR. The charge codes for robotic instrumentation were obtained through a thorough review of the charge description master for each patient specifically identifying supplies unique to robotic procedures, via a combination of flagging every item in the EndoWrist Instrument and Accessory Catalog from Intuitive Surgical and manual review, similar to the methodology described previously [17].

Perioperative outcomes

The primary outcome was 90-day complications after reimplantation. We identified all grades (I–V) of postoperative Clavien–Dindo complications using ICD-9 codes, as previously described [18,19]. Complications occurring during the index hospitalization and/or rehospitalization within 90 days were included, even if not occurring during the initial admission. Secondary outcomes included length of stay (LOS) and costs. LOS was determined by calculating the difference between admission and discharge dates and was reported in days.

Cost calculations

The Premier database enumerates both charges and direct costs (only costs were used in this analysis) of individual billing items for a hospitalization. Total direct cost was calculated by summing the cost of all individual billing items provided in the charge master for each procedure. Costs were tabulated for the 90 days following ureteral reimplantation to include the medical expenditures associated with postoperative complications requiring readmission to a Premier Hospital. These costs were further subdivided into operating room use, operating room supplies, room and board, and other (including laboratory, radiology, pharmacy, and miscellaneous non-categorizable items). The proportion of overall cost attributable to each category was calculated. Fixed costs, including capital costs, annual maintenance fees and professional fees for surgical assistants, were not included. All costs were adjusted to 2013 US dollars using the medical component of the Consumer Price Index. Costs were not available for 17 subjects and whose data was excluded from costs' comparisons.

Statistical analysis

Descriptive statistics were used to characterize the cohort. Continuous variables were expressed as median with interquartile range (IQR). Categorical variables were presented as counts and percentages. To account for RALUR versus OUR procedure type selection, a propensity score was built based on gender, age, and absence of any comorbidity. The association of complications with RALUR versus OUR, adjusting for comorbidity, was investigated. Associations of costs (total, OR, room and board, supply, pharmacy, and other) with procedure type, absence of comorbidities, age, and gender were investigated. All multivariate models were propensity score adjusted. All analyses were performed using generalized estimating equations with identical and logit links for continuous and binary outcome variables, respectively. All of the analyses accounted for clustering of the data by a physician within a

center. Functional forms of continuous covariates were investigated to ensure satisfaction of model assumptions. Costs were log-transformed. Sensitivity-to-outliers analyses were performed satisfactorily. All statistical tests were two-sided and a $p < 0.05$ was used as the threshold of significance. Analyses were performed using SAS v9.4 (SAS Institute Inc., Cary, NC, USA.)

Results

Across the 11-year study period from 2003 to 2013, there were 4284 patients undergoing OUR and 113 undergoing RALUR. Limiting the sample to the 17 centers performing both OUR and RALUR yielded a cohort of 1494 patients undergoing OUR and 108 undergoing RALUR. Fifty-one percent (55/108) of the RALUR cases occurred in 2012–2013.

There were no differences between OUR and RALUR in the presence of any preoperative comorbidity, or gender distribution (Table 1). The number of procedures performed per year is shown in Fig. 1. The median age was slightly higher in the RALUR group at 5 versus 4 years ($p = 0.005$), and LOS was shorter ($p = 0.002$). The median operative time for RALUR was 232 min (IQR, 188–270) versus 180 min for OUR (IQR, 140–225, $p = 0.004$). The majority (51%, 55/108) of robotic cases were performed in 2012 or 2013. Median total cost was substantially higher in the RALUR group ($9128 vs. $7273, $p = 0.05$). We considered the frequency of additional procedures. Examining retrograde pyelograms, only 2.01% (30/1492) of the OUR cohort and 1.85% (2/108) of the RALUR had these performed; the percentage did not differ between the groups ($p = 0.91$). Examining cystoscopy, a large proportion of the OUR cohort had this performed: 38.6% (576/1492). The RALUR cohort had this performed far less frequently: 13.9% (15/108); in this the groups differ statistically ($p < 0.0001$).

The 90-day complications analyzed are shown in Table 2, inclusive of multiple complications when occurring in the same patient. Most complications (95.1%, Clavien 1–2) were relatively minor. However, it is notable that patients with complications had a highly significant probability of longer hospital stay (median 3 vs. 2 days, $p < 0.0001$), higher total costs (median $10,883 vs. 7,224, $p < 0.001$), and longer operative time (219 vs. 180 min, $p < 0.0001$).

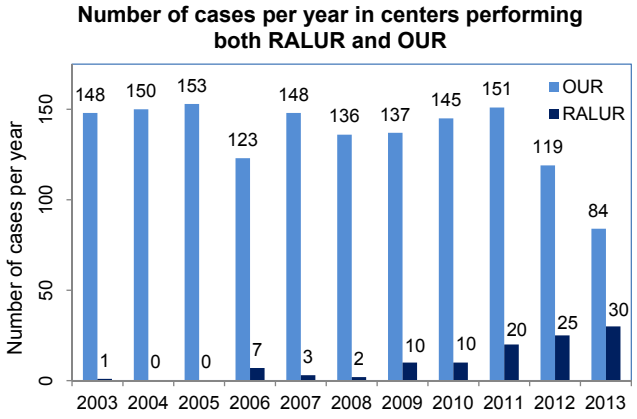

Figure 1 Annual number of cases stratified by surgical modality.

Longer operative time is associated with higher probability of complication in each procedure type ($p < 0.0001$). Fourteen of 108 patients undergoing RALUR (13.0%) experienced a total of 21 complications; 67 of 1494 patients undergoing OUR (4.5%) experienced a total of 97 complications ($p = 0.004$). Using propensity score-adjusted multivariate analysis (Table 3), the probability of any complication remained higher with RALUR ($p = 0.0033$); odds of complications were also higher if any comorbidity was present ($p = 0.0004$). Gender and age were tested in the model, but were excluded from the final model, given absence of univariate relationships (as shown in Table 3).

A multivariate, propensity score-adjusted analysis of cost found that RALUR did increase total costs by 18.07% (95% CI, 5.35–32.34; $p = 0.0043$). Unadjusted median costs are shown in Fig. 2; statistical tests in this figure are from the multivariate analysis. A subcomponent analysis of total cost revealed that the room and board costs were lower in RALUR by 43.0% (95% CI, 18.2–60.3; $p = 0.023$), and pharmacy costs were also lower by 40.8% (95% CI, 9.8–61.1; $p = 0.015$). Supply costs for RALUR that were 86.7% higher (95%CI, −11.7 to 294.5; $p = 0.10$) and OR costs that were 24.4% higher (95% CI, −3.7 to 60.6; $p = 0.09$) likely contributed to the significantly higher total costs for RALUR, but did not individually cross the threshold of significance.

Table 1 Univariate association of RALUR and OUR with demographic factors and the outcomes of OR time, LOS, total cost, and probability of any 90-day event.

	RALUR ($n = 108$)	OUR ($n = 1494$)	p
Age, Median (IQR)	5 (2–8)	4 (2–6)	0.005
Gender, %female (n)	75.9% (82)	74.3% (1110)	0.50
Presence of any comorbidity,%(n)	6.5% (7)	5.5% (82)	0.84
OR time, minutes median (IQR)	232 (188.4, 270)	180 (140, 225)	0.004
Length of Stay, Days, Median (IQR)	2 (1–2)	2 (1–3)	0.001
Total cost, 2013 USD, median (IQR)	9128 USD (5,711, 11,604)	7273 USD (5,115, 9610)	0.049
Presence of any complication, % (n)	13.0% (14)	4.5% (67)	0.004

IQR = interquartile range; LOS = length of stay; OR = m operating room; OUR = open ureteral reimplantation; RALUR = Robot-assisted laparoscopic ureteral reimplantation.

Table 2 All 90-day complications experienced.

	Open (n = 97)[a]	Robotic (n = 21)[a]
Genitourinary	Urinary retention (5), postoperative hydronephrosis (5), obstruction of ureter or kidney (5), oliguria/anuria (2), acute kidney injury, hematuria (8), urinary extravasation, other urinary complications	Urinary retention (2), postoperative hydronephrosis (4), other ureteral abnormalities, oliguria/anuria, urinary frequency, complications of cystotomy, hematuria
Infection	Urinary tract infection (9), wound infection (4), other	Urinary tract infection (2)
Cardiovascular and respiratory	Tachycardia, dysrhythmias (2), pneumonia (4), asthma flare (3), bronchospasm, other	Tachycardia, pulmonary collapse, hypoxemia, asthma flare (2)
Hematologic	Anemia (2), hemorrhage complicating a procedure	
Gastrointestinal	Nausea/vomiting (14), paralytic ileus (5), constipation (7), abdominal pain (2), intestinal perforation	Constipation, abdominal pain

[a] Some patients in each group experienced multiple complications.

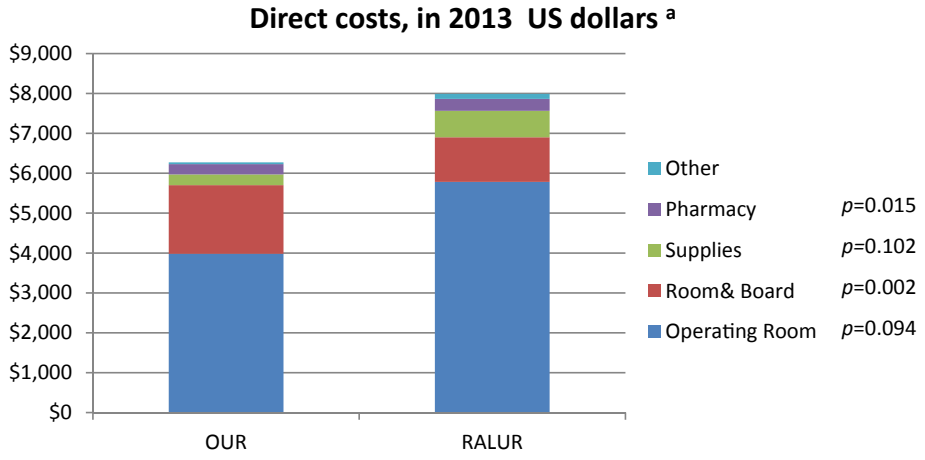

Figure 2 Comparison of direct costs between open ureteral reimplantation and robot-assisted laparoscopic ureteral reimplantation. [a]Comparisons performed with a multivariable model adjusting for age, gender, presence of comorbidity, and hospital.

Table 3 90-day complications. Univariate and multivariate Models for odds of 90-day postoperative complication.

	Univariate analysis		Multivariate analyses[a]	
	Odds ratio (95% CI)	p-value	Odds ratio (95% CI)	p
RALUR vs. OUR	3.17 (1.46, 6.91)	0.004	3.14 (1.46, 6.75)	0.003
Female gender	1.05 (0.69, 1.61)	0.8156	—	—
Age (years, increasing)	1.01 (0.94, 1.08)	0.7625	—	—
Absence of any comorbidity	0.34 (0.18, 0.66)	0.001	0.34 (0.19, 0.62)	0.0004

[a] Multivariate model is adjusted for propensity score.

Comment

We present the first nationwide sample comparing RALUR and OUR in the pediatric population. There is currently wide variation in the probability of complication reported in the literature. Some of this variability may be due to differential uptake and experience among centers as they integrate a new procedure into their practice, while some may be due to reporting bias. A major strength of the current study is that cost and 90-day postoperative complication data are collected at participating hospitals irrespective of outcomes, providing some immunity from the reporting bias to which individual center surgical series may be susceptible.

The potential advantages of a robotic approach to ureteral reimplantation have been previously described. Smith et al. [7] reported a 12% longer operative time, but this was offset by a shorter LOS and lower pain medication use in 25 patients undergoing RALUR than in 25 patients undergoing OUR. Schomburg et al. [9] echoed these findings in a

retrospective review comparing 20 RALUR and 20 open procedures, with decreased morphine requirements in the RALUR group, but longer operative times, and similar complication rates. Also, several series have reported excellent functional results with RALUR. Kasturi et al. [11] reported on 150 patients who underwent bilateral extravesical reimplants. In this prospectively assembled series, there were no complications (0/150) and reflux resolved in 99.3% (149/150) of cases. Similarly, Silay et al. [20] recently reported a large series in which reflux resolved in 97.9% (89/91) of cases and the complication rate was low at 2.7% (2/71).

Concerns have been raised about RALUR as an alternative to OUR. Grimsby et al. [10] published a two-institution experience with 61 patients. The authors reported complications in 10% of the cohort, and a 23% rate of persistent vesicoureteral reflux. Akhavan et al. [8] reported a 10% (5/50) rate of complications including a case of ureteral injury. Marchini et al. [21] reported a 30% (6/20) complication rate for RALUR, including two postoperative ureteral leaks.

The findings of this paper suggest higher cost and higher rates of 90-day complications with RALUR than open procedures. Costs were higher in the RALUR group despite cystoscopy being performed less frequently than with OUR. This complex procedure involves new risks and new equipment, and centers embarking on a program of RALUR would be well advised to examine their outcomes accordingly. As shown nationally in parallel circumstances in other specialties, concentration of activity in centers and surgeons with more exposure to the procedure may mitigate this problem [22], especially in the case of minimally invasive procedures [23]. The role of surgeon, center, and the technical components of RALUR which may increase the risk of complications are important topics of future research. While the complications seen in this cohort were relatively minor (95.1%, Clavien 1–2; 4.9%, Clavien $>$ 2), we should not assume that this means they had no impact. The median LOS and total direct costs among patients with complications (of any severity) were 50% greater than that among those without complications. This suggests that even these seemingly minor complications would translate to substantially higher costs and morbidity if scaled up to large numbers.

There are several limitations in our study inherent in the design. As with all administrative databases, Premier relies on diagnostic and procedural coding to classify patients and clinical events, and so is subject to concerns including misclassification, clerical error, and omission, all of which would tend to bias our estimate of complications toward the null. We are unable to control for procedure laterality or the details of the procedure itself (e.g., intravesical vs. extravesical approaches) due to limitations of the source database. This could result in bias in selection: for example, if the robotic group included more bilateral cases and therefore exposed more ureters to potential complications. Potential benefits to patients of RALUR such as avoiding a Pfannenstiel incision and possibly decreased pain are not captured. The role of a learning curve is important in new procedures, and was not investigated here; it is possible that as experience increases and operating teams "work out the kinks," outcomes will improve. A majority of RALUR cases in this sample were performed in 2012–2013; the surgical technique for RALUR had been well described by this time period, the individual centers may have been early in the learning curve of that particular surgical team. The outcomes assessed here are limited to those associated with this inpatient dataset; we are unable to assess complications that were managed entirely in the outpatient setting, or at non-Premier hospitals. Furthermore, we are not able to analyze the rates of postoperative reflux resolution. Importantly, this is also a limitation found even in directed single-surgeon series, as postoperative cystography is not universally obtained [9]. In our analysis of cost, we excluded indirect costs such as the amortized purchase cost of the robotic platform or associated annual maintenance fees; these would be expected to be associated exclusively with RALUR, and thus true overall cost of RALUR is likely higher than the direct costs reported herein.

Conclusions

Compared with OUR, RALUR was associated with a significantly higher rate of complications as well as higher direct costs even when adjusted for demographic and regional factors. These findings suggest that RALUR should be implemented with caution, particularly at sites with limited pelvic robotic experience, and that outcomes for these procedures should be carefully and systematically tracked.

Conflict of interest

None.

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References

[1] Atala A, Kavoussi LR, Goldstein DS, Retik AB, Peters CA. Laparoscopic correction of vesicoureteral reflux. J Urol 1993;150:748–51.
[2] Peters CA. Laparoscopic and robotic approach to genitourinary anomalies in children. Urol Clin N Am 2004;31:595–605.
[3] Peters CA, Woo R. Intravesical robotically assisted bilateral ureteral reimplantation. J Endourol 2005;19:618–21. discussion 621–2.
[4] Weiss DA, Shukla AR. The robotic-assisted ureteral reimplantation: the evolution to a new standard. Urol Clin N Am 2015;42:99–109.
[5] Bowen DK, Faasse MA, Liu DB, Gong EM, Lindgren BW, Johnson EK. Use of pediatric open, laparoscopic and robot-assisted laparoscopic ureteral reimplantation in the United States: 2000 to 2012. J Urol 2016;196:207–12.
[6] Varda BK, Johnson EK, Clark C, Chung BI, Nelson CP, Chang SL. National trends of perioperative outcomes and costs for open, laparoscopic and robotic pediatric pyeloplasty. J Urol 2014;191:1090–5.
[7] Smith RP, Oliver JL, Peters CA. Pediatric robotic extravesical ureteral reimplantation: comparison with open surgery. J Urol 2011;185:1876–81.
[8] Akhavan A, Avery D, Lendvay TS. Robot-assisted extravesical ureteral reimplantation: outcomes and conclusions from 78 ureters. J Urol 2014;10:864–8.

[9] Schomburg JL, Haberman K, Willihnganz-Lawson KH, Shukla AR. Robot-assisted laparoscopic ureteral reimplantation: a single surgeon comparison to open surgery. J Pediatr Urol 2014;10:875—9.
[10] Grimsby GM, Dwyer ME, Jacobs MA, Ost MC, Schneck FX, Cannon GM, et al. Multi-institutional review of outcomes of robot-assisted laparoscopic extravesical ureteral reimplantation. J Urol 2015;193:1791—5.
[11] Kasturi S, Sehgal SS, Christman MS, Lambert SM, Casale P. Prospective long-term analysis of nerve-sparing extravesical robotic-assisted laparoscopic ureteral reimplantation. Urology 2012;79:680—3.
[12] Hubert KC, Kokorowski PJ, Huang L, Prasad MM, Rosoklija I, Retik AB, et al. Clinical outcomes and long-term resolution in patients with persistent vesicoureteral reflux after open ureteral reimplantation. J Urol 2012;188:1474—9.
[13] Kennelly MJ, Bloom DA, Ritchey ML, Panzl AC. Outcome analysis of bilateral Cohen cross-trigonal ureteroneocystostomy. Urology 1995;46:393—5.
[14] Premier Research Services, Premier, Inc, www.premierinc.com/wpdm-package/research/. [Accessed 2016].
[15] Routh JC, Nelson CP, Graham DA, Lieu TA. Variation in surgical management of vesicoureteral reflux: influence of hospital and patient factors. Pediatrics 2010;125:e446—51.
[16] Deyo RA, Cherkin DC, Ciol MA. Adapting a clinical comorbidity index for use with ICD-9-CM administrative databases. J Clin Epidemiol 1992;45:613—9.
[17] Wright JD, Ananth CV, Lewin SN, Burke WM, Lu YS, Neugut AI, et al. Robotically assisted vs laparoscopic hysterectomy among women with benign gynecologic disease. JAMA 2013;309:689—98.
[18] Dindo D, Demartines N, Clavien PA. Classification of surgical complications: a new proposal with evaluation in a cohort of 6336 patients and results of a survey. Ann Surg 2004;240:205—13.
[19] Leow JJ, Reese SW, Jiang W, Lipsitz SR, Bellmunt J, Trinh QD, et al. Propensity-matched comparison of morbidity and costs of open and robot-assisted radical cystectomies: a contemporary population-based analysis in the United States. Eur Urol 2014;66:569—76.
[20] Silay MS, Baek M, Koh CJ. Robot-assisted laparoscopic extravesical ureteral reimplantation in children: top-down suturing technique without stent placement. J Endourol 2015;29:864—6.
[21] Marchini GS, Hong YK, Minnillo BJ, Diamond DA, Houck CS, Meier PM, et al. Robotic assisted laparoscopic ureteral reimplantation in children: case matched comparative study with open surgical approach. J Urol 2011;185:1870—5.
[22] Finks JF, Osborne NH, Birkmeyer JD. Trends in hospital volume and operative mortality for high-risk surgery. N Engl J Med 2011;364:2128—37.
[23] Birkmeyer JD, Finks JF, O'Reilly A, Oerline M, Carlin AM, Nunn AR, et al. Surgical skill and complication rates after bariatric surgery. N Engl J Med 2013;369:1434—42.