



# Hospital volume in ureterorenoscopic stone treatment: 99 operations per year could increase the chance of a better outcome—results of the German prospective multicentre BUSTER project

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## Summary

**Background** Despite the high utilisation of ureterorenoscopy (URS) in interventional stone treatment, there is little evidence of any link between annual hospital volume and outcome.

**Methods** From January to April 2015, data from 307 URS patients were prospectively recorded in the multicentre observational **BUSTER-Trial** (**B**enchmarks of **u**reterorenoscopic **s**tone **t**reatment-**r**esults in terms of complications, quality of life, and stone-free rates). The best threshold value for annual hospital volume with an independent effect on the outcome (measured on stone-free and complication rates) of our study group was established with logistic regression.

**Results** In 38.4% of cases of renal and 61.6% of ureteral stones, median stone size was 6 mm with an interquartile range (IQR) of 4–8 mm. The annual URS rate in the 14 participating hospitals ranged from 77 to 333 (median 144; IQR 109–208). The binary endpoint as a combination of completely stone-free or residual fragments small enough to pass spontaneously and a maximum complication severity of Clavien–Dindo grade 1 was attained in 234/252 (92.9%) cases with a hospital volume of  $\geq 99$  URS compared with 43/55 (78.2%) in  $< 99$  URS ( $p = 0.002$ ). Adjusted for patient-, stone- and physician-related factors, an annual hospital URS volume of  $\geq 99$  increases the chance of an optimum outcome (OR = 3.92; 95% CI 1.46–10.51;  $p = 0.007$ ).

**Conclusions** An independent effect of URS hospital volume on outcome quality in the 14 participating hospitals was demonstrated. Threshold values for annual case numbers should be scientifically established irrespective of the considered procedure.

**Keywords** Urolithiasis · Ureterorenoscopy · Hospital volume · Annual caseload · Cut-off · Threshold

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## Introduction

Depending on geographical region, age and sex, recent decades have seen a rise in the prevalence of urolithiasis from 4.0 to 10.1% in the European population [1–3].

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Significant improvements in endoscopic instruments and laser technology have made significant changes to stone treatment: the increasing use of URS and steady rate of percutaneous stone removal (PCNL) have seen a continuous decline of extracorporeal shock wave lithotripsy (ESWL) and open stone surgery [4]. Depending on the surgeon's preference and health insurance reimbursement, URS currently accounts for up to 70% of interventional stone treatments [2].

The link between hospital volume and outcome quality is considered well established for various urological procedures [5–7].

Despite the high utilisation, there is only little information available on this link for URS. A PubMed search on this link yielded 23 hits, of which three publications had three different categorisations for hospital volume with reference to outcome quality [8, 9].

Kandasami et al. selected the median of annual case numbers of all 114 hospitals observed, specifically a case number of  $n = 67$ , to differentiate between low- and high-volume centres. In this prospective, multicentre study of consecutively recorded URS, high-volume centres had a significantly higher stone-free rate and significantly lower complication rate [10].

Rob et al. arbitrarily defined  $< 25$ ,  $25–49$  or  $\geq 50$  procedures per hospital per year as the threshold for low-, medium- and high-volume centres for URS in adolescents (age  $\leq 18$  years) [11]. With low-volume centres excluded, this systematic review of stone-free and complication rates showed no significant differences between medium- and high-volume centres.

In a retrospective review of insurance data from 93,523 interventional stone treatments (URS, ESWL, PCNL), Scales et al. defined the 90th percentile of all annual case numbers as threshold for a high-volume centre based on all interventional stone treatments, so that is not referring specifically to URS, and the threshold value was not specified as such [12]. In a high-volume centre there was a 20% lower risk of treatment-related complications requiring emergency medical services or readmission to hospital within 30 days of stone treatment (OR 0.8; 95% CI 0.74–0.87;  $p < 0.001$ ). The stone-free rate was not explored in this study.

In summary, despite the high utilisation of URS, there is little evidence of any link between hospital volume and outcome quality.

This study explores, based on multicentre prospectively collected data, whether the stone-free and complication rates depend on annual URS hospital volume and if so, whether a justified threshold value can be defined to differentiate between low- and high-volume centres.

## Materials and methods

### Data collection

The multicentre observational **BUSTER-Trial** (**B**enchmarks of **u**reterorenoscopic **s**tone **t**reatment-**r**esults in terms of complications, quality of life, and stone-free rates) was conducted from January to April 2015. In this period, 587 URS treatments were performed in the 14 participating German urological clinics. All patients who consented to complete a questionnaire regarding their course 30 days after hospital discharge were enrolled. The study group totalled 307 patients whose pre-, intra- and postoperative data were prospectively recorded based on a standardised protocol.

As an observational trial, the protocol did not affect treatment decisions made by individual centres or surgeons.

The stone-free rate was determined endoscopically and by means of retrograde ureteropyelography (rUPG) by the surgeon at the end of the URS (stone-free, residual fragments small enough to pass spontaneously, re-intervention required, unclear). Postoperative complications were standardised as defined by Clavien and Dindo [13].

The pseudonymised patient data were sent to the coordinating centre where they were transferred to a database.

As well as operation and course-related patient data, total annual URS case volume was also recorded for participating hospitals.

The ethics committee of the Regional Medical Association Brandenburg gave a positive approval (AS 136(bB)/2014). The study was registered at the German Clinical Trials Register (DRKS-ID: DRKS00007668) and the WHO International Clinical Trial Registration Platform (ICTRP) [14, 15].

### Statistical analysis

Metric variables were stated as median and interquartile range (IQR), ordinal and nominal data as whole numbers and percentages.

Stone-free and complication rates should be considered as key criteria for assessing the outcome of URS. Thus, the combination of completely stone-free or residual fragments small enough to pass spontaneously and a maximum complication severity of Clavien–Dindo grade (CD grade) 1 was defined as binary endpoint of this study.

The direct correlation between annual hospital volume and endpoint attainment was reviewed using Spearman's rank correlation.

Receiver operating characteristic (ROC) analysis was used to establish the threshold of annual case volume

using coordinate points of the ROC curve based on the highest value for the Youden index (sensitivity + specificity – 1) which makes it more likely to attain the specified endpoint.

The use of this threshold would require no significant differences in any of the criteria affecting treatment outcomes of the participating hospitals. This was tested using one-way analysis of variance for metric data and chi-squared test for nominal data.

The case volume was then integrated as continuous and dichotomised variable into binary logistic regression models and adjusted for patient-, stone- and physician-related factors. It was dichotomised for all reported annual case volumes from participating hospitals ( $n = 14$ ). Patient-related factors were age, sex, body mass index (BMI) and the American Society of Anesthesiologists score (ASA; dichotomised to ASA 1–2 and 3–4); stone-related factors were stone size, location (kidney or ureter) and preoperative placement of an ureteral stent; physician-related factors were years after board certification and the indication for URS as a first-line treatment according to the German S2 k-guideline for diagnosis, therapy and metaphylaxis of urolithiasis [16].

The model accuracy was specified with Nagelkerke's  $R^2$ , the effect size as Cohen's  $f$  ( $f = R^2/1 - R^2$ ), whereby  $f \geq 0.10$  equates to a small,  $f \geq 0.25$  to a medium and  $f \geq 0.40$  to a large effect.

The internal validation of the binary logistic regression model was performed with bootstrapping based on 1000 resamples.

Given hospital-specific characteristics, such as standard operating procedures or the instruments used, a hospital-specific clustering of data affecting the results of the binary logistic regression could not be ruled out. Therefore, also a marginal regression model was created with patients modelled as 'repeated measures' within the hospitals to balance the possibly clustered structure of the data.

Data were analysed with SPSS 24.0 (IBM Corp, released 2016, IBM SPSS Statistics for Windows; Armonk, NY, USA). The defined  $p$  values were always two sided and the significance level was considered statistically significant for all tests at  $p < 0.05$ .

## Results

### Description of the study group, treatment and treatment results

80.5% of URS were elective. During surgery 117 stones (38.4%) were situated in the kidney and 188 (61.6%) in the ureter. Laser disintegration was required in 136 cases (44.3%), in 134 cases (43.6%) fragmentation was unnecessary, and in 205 cases (66.8%) stones or fragments were

extracted with a basket and in 60 (19.5%) cases with grasping forceps (Table 1).

The annual URS rate in the 14 participating hospitals ranged from 77 to 333 (median 144; IQR 109–208) (Table 2). 211 patients (68.7%) were completely stone free, in 69 (22.5%) the surgeon estimated only residual fragments small enough to pass spontaneously, in 22 (7.2%) re-intervention was probable, and in 5 (1.6%) it was not possible to reliably assess if the patient was stone free.

During hospitalisation, complications grade 0, 1, 2 and 3 as defined by Clavien and Dindo were observed in 274 (89.2%), 30 (9.8%), 2 (0.7%) and 1 (0.3%) cases, respectively.

A total of 277/307 (90.2%) patients attained the relevant endpoint (Table 2).

Table 3 shows the characteristics of the covariates used.

The questionnaires regarding their course 30 days after hospital discharge were completed by the patients within 31 days (median; IQR 27.5–35.0) and subsequently sent to the study centers.

### Establishing the threshold of annual case volume by ROC analysis

The ROC analysis showed a non-random correlation between annual hospital volume and endpoint attainment with an AUC of 0.622 ( $p = 0.028$ ). A threshold of  $< 144$  vs.  $\geq 144$  URS/year was established using coordinate points of the ROC curve based on the highest value for the Youden index (sensitivity + specificity – 1) which makes achieving the endpoint more likely.

The use of this threshold would require that there are no significant differences between the criteria affecting treatment outcome in the participating hospitals—this was statistically tested for all covariates and was not the case (data not shown).

### Establishing the threshold of annual case volume by binary logistic regression

Although there was a tenuous but significant correlation between hospital volume and outcome quality (Spearman's  $r = 0.13$ ;  $p = 0.027$ ), its continuous inclusion into the logistic regression model had no independent effect on endpoint attainment (OR = 1.00; 95% CI 0.99–1.01;  $p = 0.259$ ).

After dichotomising the hospital volume at the threshold value established in the ROC analysis to  $< 144$  vs.  $\geq 144$  URS/year, it had an independent effect on endpoint attainment (OR = 2.73; 95% CI 1.09–6.86;  $p = 0.033$ ). Nagelkerke's  $R^2$  was 0.255, whereby a Cohen's  $f$  of 0.58 yielded a large effect size.

The greatest model accuracy and effect size, however, after dichotomisation of all annual case numbers in our

**Table 1** Types of ureterorenoscopes, methods of stone disintegration and stone removal

	Kidney		Ureter		Total <sup>a</sup>	
	(n)	(%)	(n)	(%)	(n)	(%)
Type of ureterorenoscope						
Semirigid	36	30.8	161	85.6	197	64.6
Flexible with access sheath	39	33.3	3	1.6	42	13.8
Flexible without access sheath	10	8.6	3	1.6	13	4.2
Combined	32	27.3	21	11.2	53	17.4
Total	117	100	188	100	305	100
Method of stone disintegration						
None	42	35.9	90	47.9	132	43.3
Laser	60	51.3	76	40.4	136	44.6
Pneumatic	8	6.8	14	7.4	22	7.2
Mechanic with forceps	1	0.9	2	1.1	3	1.0
Others	6	5.1	6	3.2	12	3.9
Total	117	100	188	100	305	100
Method of stone removal						
None	11	9.4	20	10.6	31	10.2
Forceps	8	6.8	52	27.7	60	19.7
Basket	95	81.2	110	58.5	205	67.2
Combined (forceps and basket)	2	1.7	2	1.1	4	1.3
Others	1	0.9	4	2.1	5	1.6
Total	117	100	188	100	305	100

<sup>a</sup>In two patients, the stone location was not reported in the CRF. Therefore, the table describes only 305 out of 307 patients

**Table 2** Annual case volume of URS at the participating hospitals, proportion of study patients and patients who attained the endpoint

Annual URS hospital volume in 2015	Patients in the study	Endpoint attained	
		(n)	(%)
77	16	12	75.0
87	15	11	73.3
95	24	20	83.3
99	13	11	84.6
109	26	25	96.2
136	16	15	93.8
142	18	14	77.8
144	26	25	96.2
151	9	9	100.0
153	6	6	100.0
185	19	19	100.0
198	20	19	95.0
208	40	39	97.5
333	59	52	88.1
Total	307	277	

study, were seen for the model with a threshold value of <99 vs. ≥99 URS/year ( $R^2=0.27$ ; Cohen's  $f=0.61$ ; OR = 3.92; 95% CI 1.46–10.51;  $p=0.007$ ). The regression model was

internally valid for the dichotomised hospital volume and all covariates.

At an annual hospital volume of ≥99 URS, the endpoint attainment was significantly more frequent with 234/252 (92.9%) cases compared to 43/55 (78.2%) cases at <99 URS ( $p=0.002$ ). In the marginal model balancing the influence on logistic regression from possibly hospital-related clustered data structure, hospital volume dichotomised to <99 vs. ≥99 URS/year also had an independent effect on endpoint attainment (OR = 3.78; 95% CI 3.06–4.55,  $p<0.001$ ).

In addition, hospital volume, sex, pretested URS and stone size were independent factors affecting endpoint attainment. Women had a 3.9 times higher chance of an optimum outcome compared to men as well as a 3.9 times higher chance of success in the case of pretested URS, while each millimetre of stone size reduced the chance of an optimum outcome by 10.4% (Table 4).

## Discussion

Based on prospectively collected data, we found that thresholds could be statistically established for the effect of annual hospital volume on outcome quality following URS. Comparative data were not found in the current literature [8, 9].

**Table 3** Data from the study group ( $n = 307$ ) used in the logistic regression models as covariates

Variable	Median (IQR)	Proportion [%]
1 Age <sup>a</sup> (a)	54.4 (44.4–65.8)	–
2 BMI <sup>a</sup> (kg/m <sup>2</sup> )	27.5 (24.3–30.9)	–
3 Sex (male/female) <sup>b</sup>	–	65.5/34.5
4 ASA (1–2/3–4) <sup>b</sup>	–	79.9/20.1
5 Stone size <sup>a</sup> (mm)	6 (4–8)	–
6 Stone location (Kidney/Ureter) <sup>b</sup>	–	38.4/61.6
7 Prestented URS <sup>b</sup> (yes/no)	–	70.0/30.0
8 Years after board certification <sup>a</sup> (a)	6 (1–14)	–
9 URS as the first-line treatment <sup>c</sup> (yes/no) <sup>b</sup>	–	82.3/17.7

1–4: Patient-related variable, 5–7: Stone-related variable, 8–9: Physician-related variable

BMI Body Mass Index, ASA American Society of Anesthesiologists physical status

<sup>a</sup>Metric variable

<sup>b</sup>Nominal variable

<sup>c</sup>As defined by the German S2 k-guideline on the diagnosis, therapy and metaphylaxis of urolithiasis [16]

**Table 4** Result of the binary logistic regression, annual URS hospital volume dichotomised to  $< 99$  and  $\geq 99$ 

Variable	OR	95% CI	$p$	$p^{\text{bootstrap}}$
<i>Dichotomised annual URS hospital volume (Ref. <math>&lt; 99</math>)</i>	3.92	1.46–10.51	0.007	0.009
Age (continuous, per year)	0.99	0.96–1.02	0.540	0.586
BMI (continuous, per kg/m <sup>2</sup> )	0.96	0.90–1.01	0.132	0.174
Sex (Ref. male)	3.96	1.19–13.16	0.025	0.019
ASA dichotomised (Ref. 1–2)	3.93	0.87–17.69	0.075	0.065
Stone size (continuous, per mm)	0.90	0.83–0.96	0.003	0.016
Stone location dichotomised (Ref. ureter)	0.97	0.37–2.55	0.949	0.961
Prestented URS (Ref. no)	3.86	1.55–9.66	0.004	0.007
Years after board certification (continuous, per year)	1.04	0.98–1.10	0.199	0.143
URS as a first-line treatment <sup>a</sup> (Ref. no)	0.31	0.08–1.29	0.108	0.107

Italics represents variable with independent effect on the outcome quality ( $p < 0.05$ )

$p^{\text{bootstrap}}$   $p$  value 1000-fold bootstrap-corrected

<sup>a</sup>As defined by the German S2 k-guideline on the diagnosis, therapy and metaphylaxis of urolithiasis [16]

Thresholds specified by Rob et al./Kandasami et al. to differentiate between low- and high-volume centres of 50 or 67 URS/year were arbitrary [10, 11]. The lowest annual URS hospital volume in our study was  $n = 77$ . Applying these thresholds, all the hospitals in our study were high-volume centres which is intuitively improbable. The cited thresholds, therefore, cannot be practically applied to an existing study group from 14 German hospitals of different treatment levels.

The best option to assess stone clearance is non-contrast computer tomography (nCT). No postoperative nCT was required in our non-interventional study for radiation-protection reasons. However, complete stone clearance is often overestimated based on endoscopic and conventional radiological findings at the end of the URS [17]. It, therefore, seemed feasible to include residual fragments the surgeon believes can pass spontaneously. Furthermore, rUPG was considered acceptable also in other studies and publications

for the assessment of stone-free rates [18]. As CD grade  $\geq 2$  complications only arose in three patients and CD grade 1 complications hardly affected the patients and could be easily symptomatically treated, complications of maximum CD grade 1 were also considered acceptable outcomes. The combination of these aspects seemed important and so complete stone removal or residual fragments small enough to pass spontaneously and a maximum complication severity of CD grade 1 were defined as binary endpoint of this study.

The encouragingly low complication density is a limitation to our study because 274/307 (89.2%) patients had no complications during hospitalisation. In this respect, poorly balanced groups may have distorted the findings. The study protocol also allowed an individual procedure in each centre despite prospective and standardised data collection (e.g., instruments, ureteral stenting before and after URS). These differences may have affected the result, especially in terms of stone-free and complication rates but would also enable



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9. NCBI\_NLM\_NIH Pubmed\_2. [https://www.ncbi.nlm.nih.gov/pubmed/?term=\(\(low-volume%5BTitle%2FAbstract%5D\)+OR+high-volume%5BTitle%2FAbstract%5D\)\)+AND+\(\(ureteroscopy%5BTitle%2FAbstract%5D\)+OR+urs%5BTitle%2FAbstract%5D\)+OR+rirs%5BTitle%2FAbstract%5D\)](https://www.ncbi.nlm.nih.gov/pubmed/?term=((low-volume%5BTitle%2FAbstract%5D)+OR+high-volume%5BTitle%2FAbstract%5D))+AND+((ureteroscopy%5BTitle%2FAbstract%5D)+OR+urs%5BTitle%2FAbstract%5D)+OR+rirs%5BTitle%2FAbstract%5D)). Accessed 07 Jan 2018
  10. Kandasami SV, Mamoulakis C, El-Nahas AR, Averch T, Tuncay OL, Rawandale-Patil A, Cormio L, de la Rosette JJ (2014) Impact of case volume on outcomes of ureteroscopy for ureteral stones: the clinical research office of the endourological society ureteroscopy global study. *Eur Urol* 66(6):1046–1051. <https://doi.org/10.1016/j.eururo.2014.06.054>
  11. Rob S, Jones P, Pietropaolo A, Griffin S, Somani BK (2017) Ureteroscopy for stone disease in paediatric population is safe and effective in medium-volume and high-volume centres: evidence from a systematic review. *Curr Urol Rep* 18(12):92. <https://doi.org/10.1007/s11934-017-0742-3>
  12. Scales CD Jr, Saigal CS, Hanley JM, Dick AW, Setodji CM, Litwin MS (2014) The impact of unplanned postprocedure visits in the management of patients with urinary stones. *Surgery* 155(5):769–775. <https://doi.org/10.1016/j.surg.2013.12.013>
  13. Dindo D, Demartines N, Clavien PA (2004) Classification of surgical complications: a new proposal with evaluation in a cohort of 6336 patients and results of a survey. *Ann Surg* 240(2):205–213
  14. DRKS. [http://www.drks.de/drks\\_web/navigate.do?navigationId=trial.HTML&TRIAL\\_ID=DRKS00007668](http://www.drks.de/drks_web/navigate.do?navigationId=trial.HTML&TRIAL_ID=DRKS00007668). Accessed 19 Mar 2018
  15. ICTRP. <http://apps.who.int/trialsearch/Trial2.aspx?TrialID=DRKS00007668>. Accessed 19 Mar 2018
  16. Knoll T, Bach T, Humke U, Neisius A, Stein R, Schonhaler M, Wendt-Nordahl G (2016) S2 k guidelines on diagnostics, therapy and metaphylaxis of urolithiasis (AWMF 043/025): compendium. *Urologe A* 55(7):904–922. <https://doi.org/10.1007/s00120-016-0133-2>
  17. Canvasser N, Lay A, Kolitz E, Antonelli J, Pearle M (2017) MP75-12 prospective evaluation of stone free rate by computed tomography after aggressive ureteroscopy. *J Urol* 197(4):e1007–e1008. <https://doi.org/10.1016/j.juro.2017.02.2160>
  18. Sinha RK, Mukherjee S, Jindal T, Sharma PK, Saha B, Mitra N, Kumar J, Mukhopadhyay C, Ghosh N, Kamal MR, Mandal SN, Karmakar D (2015) Evaluation of stone-free rate using Guy's Stone Score and assessment of complications using modified Clavien grading system for percutaneous nephro-lithotomy. *Urolithiasis* 43(4):349–353. <https://doi.org/10.1007/s00240-015-0769-1>
  19. Lebentrau S, May M, Ziegler H, Werthemann P, Enzmann T, Schostak M, Porsch M, Studiengruppe B (2018) The recommendations of the S2 k guideline for the diagnosis, therapy and metaphylaxis of urolithiasis provide a safe course of action for ureterorenoscopic stone treatment—results of the BUSTER study. *Aktuelle Urol* 49(2):164–170. <https://doi.org/10.1055/s-0043-116859>