What do we mean by «stone free», and how accurate are urologists in predicting stone free status following ureteroscopy?

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Abstract

Background and purpose: No consensus exist on how stone free rates (SFR) should be reported after stone treatment. The aim of this study was to assess how accurate urologists predict their patients being stone free after completing ureteroscopy (URS), and to see how various treatment strategies influenced the precision of these predictions. We also wanted to study how different definitions of stone free status (SFS) affected the results and propose a standard definition of «stone free» to be used in future studies.

Materials and methods: A retrospective evaluation of 1019 URS done for stone treatment at Haukeland University Hospital between 2013 - 2018 was performed. Data on pretreatment status, the surgical procedure and follow-up were recorded. SFS was defined as either *no* fragments detected on computed tomography (CT) after 3 months or as *practical stone free status* which also included those with very small residual fragments not needing further treatment. Exact chi-squared and independent-samples *t*-tests were used comparing data between different treatment modalities.

Results: The overall SFR, irrespective of treatment strategy and location of stone, using the *no* residual fragments and practical stone free definitions were 54.2% and 74.7%, respectively. Urologists predicted intraoperatively that 91.0% of their patients treated with fragmentation and extraction would be stone free compared to 76.8% of patients treated with dusting, $p < 0.0001$. At follow-up, the actual SFRs with *no* residual fragments for the two treatment strategies were 68.0% and 35.5%, respectively, $p < 0.0001$. The *practical* SFRs for fragmentation and retrieval was 83.1% and 64.8% for dusting, $p < 0.0001$.

Conclusion: The different definitions of SFS have great impact on SFRs. Urologists are far too optimistic predicting their patient being stone free after URS. SFS should be defined as no fragments detected on CT 3 months after the URS procedure when presented in studies.

Introduction

Worldwide, there has been a trend towards more stone treatment during the last decade, mainly due to an increasing number of ureteroscopic (URS) procedures [1]. Despite this increase, there are significant variations in the reported stone free rates (SFRs) following URS. The variation in SFR is a result of different definitions of stone free status (SFS), variations in the type of imaging modality used to assess the presence of stones postoperatively and the timing of the assessment [2]. No international agreement exists on the definition of SFS after stone treatment. The «term stone free» ranges from the very strict «*no stone or residual fragments detected on computed tomography (CT)*» to the vaguer «*no stones detected on plain radiography or ultrasound*» [3, 4]. Another variant includes endoscopic evaluation by the urologist at the end of the URS [5]. The main problem with not having a consensus of how SFS should be reported, is to compare the results between different studies. In addition, can we really trust the surgeon when he or she reports that the patient is rendered stone free evaluated endoscopically?

The primary aim of this study was to assess how accurate urologists are in their predictions of the patient being «stone free» after completing the URS procedure. In addition, we wanted to study if a stone treatment strategy with fragmentation and retrieval versus dusting affected the outcome of the URS and if the treatment strategies had any impact on the precision of the urologists' predictions of SFS. Furthermore, we wanted to see how different definitions of SFS affected the results.

A secondary aim was to make a proposal of how SFS could be defined and presented in future studies on stone treatment.

Materials and methods

Setting, study population and data collection

Since October 2013, we have performed URS as same day surgery at Haukeland University Hospital (HUH). As part of an internal quality evaluation, every URS for stone treatment in the day-case surgery unit between October 2013 and June 2018 have been reviewed retrospectively and included in this study.

A total of 1019 URS for stones were performed in 725 patients, 289 women and 436 men. At the time of ureteroscopy, the mean age of the patients was 55.5 years (range 4 – 95 years). American Society of Anaesthesiologists Score (ASA-Score) was used assessing the patients' general condition. ASA-Score 2 was the median value.

A low-dose non-contrast CT was performed prior to URS. Stone size was defined as the largest diameter of the stone. In cases with multiple stones, the widest diameter of the biggest stone determined the stated stone size. This definition probably underestimates the total stone burden in cases of multiple stones. Despite this, as most URSs were performed for treatment of a single stone, we consider this definition as appropriate.

The URS procedures were performed using either a semirigid endoscope (8/9.8F tapering shaft, Richard Wolf Medical Instruments Corporation, Vernon Hills, IL), a flexible endoscope (URF-V/V2/V3 or P6/P7, Olympus Corporation, Tokyo, Japan) or both. Access sheaths (UAS) and safety guide wires (SGW) were used only when deemed necessary by the surgeon based on his or her preferences, although a sheath- and wireless procedure is the current standard at HUH. Holmium laser was used for breaking stones. The stones were either fragmented and retrieved with forceps or baskets, or dusted and left in situ for spontaneous passage. If a dusting strategy was decided upon, the standard laser settings were 0.4 Joules at a frequency of 20 Herz. The treatment strategy of choice, depended on the preference and judgement of the urologist in each case. Information of the urologists' prediction of the patients being stone free, was obtained from the patient records.

Follow-up with low-dose non-contrast CT was performed after three months. The patients were considered stone free only if *no* residual fragments were detected on CT. To demonstrate how different definitions of SFS influence the results, another definition, termed *practical stone free status* (PSFS), also included patients with ≤ 3-4 mm residual fragments who received no further treatment.

Statistics

Continuous variables were compared using independent-samples *t*-tests. Exact chi-squared test and Fisher's Exact test were used comparing categorical variables.

IBM SPSS Statistics 25 (IBM, Armonk, NY) was used for statistical analysis. A p value < 0.05 was considered significant.

Ethics

The study was approved by The National Committees for Research Ethics in Norway (ID-no: 2018/2545 REK) and The Data Protection Authorities at HUH (ID-no: 1041).

Results

General

A total of 1019 URSs were performed for treatment of stones. Of all the URSs, 544 cases (53.4%) were done for stones located in the renal pelvis, 358 (35.1%) for ureteral stones and 117 (11.5%) for renal and ureteral stones in combination. In 115 cases (11.3%) neither laser treatment nor extraction of any stones was performed. Of these, no stones were found in 60 patients (52.2%), there was insufficient vision in 13 (11.3%) and no access to the stone due to a narrow ureter, ureteral stricture or excessive edema was registered in 42 patients (36.5%). In cases with insufficient vision or failed access to the stone, a JJ-stent was placed and the patient was scheduled for a subsequent procedure.

Table 1 shows the preoperative stone status and compares patients with a fragmentation and retrieval strategy to patients treated with a dusting strategy. Multiple stones were treated in approximately half of cases in the renal pelvis and 15% of cases with ureteral stones. The distribution of the number of stones when multiple calculi were treated was the same in the two treatment groups.

A comparison between the surgical procedures in patients treated with fragmentation and retrieval *vs* a dusting strategy is presented in table 2. More than half the number of procedures were performed by two endourologists (ØU and PG). In addition, these two surgeons also assisted the residents in the majority of their URSs. Another six urologists performed the remaining procedures. Intraoperative complications are presented in table 3. A postendoscopic stricture on follow-up CT after 3 months was registered in 28 patients (2.9%).

Urologists' predictions of stone free status

Overall, urologists predicted that 776 (85.8%) of their patients would be stone free at the end of the procedure irrespective of treatment strategy or stone location. Irrespective of stone location, significantly more patients were predicted to become stone free after treatment with fragmentation and retrieval *vs* dusting, 524 cases (91.0%) and 252 cases (76.8%) for the two treatment strategies respectively, $p < 0.0001$. For renal stones, urologists predicted their patients to be stone free in 201 cases (89.3%) when a fragmentation and retrieval strategy was used compared to 218 cases (77.9%) when the stones were dusted and left for spontaneous passage, $p = 0.001$. In the ureter, the vast majority of patients were treated with fragmentation and retrieval. Only 30 patients (10.3%) were treated with dusting. For patients with ureteral stones, urologists predicted that 267 patients (91.4%) would be stone free irrespective of treatment strategy.

Stone free status with no residuals vs practical stone free status

In total, 973 patients (95.5%) had a CT scan after 3 months. The SFR according to the strict definition of *no* residual fragments detected on CT, was 54.2% irrespective of treatment strategy or stone location. For stones located in the renal pelvis the SFR was 40.6%, for ureteral stones 83.3% and after combined treatment of stones located both in the renal pelvis and ureter 50.5%.

The *practical* SFR was higher. In total, 74.7% of patients ended up stone free using this definition when neither treatment strategy nor location of the stones was taken into consideration. The *practical* SFR after treatment of renal stones, ureteral stones and combined renal- and ureteral stones was 71.0%, 86.8% and 68.3% for the three groups, respectively.

By altering the definition of SFS from *no* residual fragments detected on CT to the definition of PSFS, 200 (38.0%) more patients were successfully treated and ended up «stone free». None of these needed further treatment at 3 months follow-up. In spite of this, 67 (33.5%) of these 200 patients did require a new procedure during the 5-year study period.

The SFR following fragmentation and retrieval compared to a dusting strategy are presented in table 4.

At CT follow-up 3 months postendoscopically in the 60 patients where no stone was found during URS, 35 (63.6%) were found to be stone free. In these patients, we can assume that the stones had passed in the time frame between the preoperative CT and the URS. In the remaining patients the calcifications first perceived as stones, were reassessed as Randall's plaques on the second CT. Only 2 patients (3.6%) where no stone was found on the first URS were scheduled for a second procedure.

Discussion

The present study illustrates that SFR after URS is influenced not only by the treatment strategy, but also by the definition of SFS.

We found an overall SFR of only 54.2% irrespective of treatment strategy or stone location when the strict definition of no residual fragments detected on CT was used. This number may seem disappointingly low compared to the SFR of 74 - 91% found in the literature [5-7]. However, the definitions of SFS used in these studies are significantly less strict and the results are therefore not comparable. On the other hand, the SFR in the present study is comparable to those seen in both randomized and retrospective studies with the strict definition of no residual fragments detected on CT [8, 9].

The variation in definitions of SFS used in the literature can be challenging. Large studies may have great impact because of their multicenter designs and the large number of procedures [5, 7]. However, there may be reason to doubt if the very high SFRs reported in these studies are truly correct, considering the inaccurate and diverse methods used for follow up. The results may therefore lead to a false impression of the SFR being higher than it actually is.

In the UROICE-study, SFS was defined as no residual fragments evaluated by endoscopic and radiologic control at the end of the procedure [5]. In the present study, the urologists predicted that 85.8% of patients would be stone free at the end of the procedure. irrespective of the treatment strategy or the stone location. The actual SFR was 54.2% determined by CT after three months. Even when using the less precise definition of PSFS, which was 74.7%, the urologists' predictions were too optimistic. The results clearly illustrate the inaccuracy of using endoscopic evaluation to determine if the patient is stone free. The surgeon is biased in relation to the procedure and has a desire to achieve the best possible result. As a consequence, there is a risk of overestimating the SFS and minimize or ignore complications.

In the present study the operating urologists expected significantly more patients to be stone free after fragmentation and extraction compared to after a dusting strategy. The predictions of SFS were less precise following dusting compared to following fragmentation and retrieval. This may, at least partly, be explained by more procedures in the dusting group being complicated by disturbing bleeding, probably due to more extensive use of laser. Endoscopic assessment of SFR is obviously difficult when there is disturbing bleeding, and fragments that are too large for spontaneous passage are likely to be overlooked.

The retrospective design in the present study does not allow for a bombastic conclusion of which treatment strategy that is superior. The dusting strategy was almost exclusively used for renal stones, and the stones were significantly larger in this group compared to the fragmentation and retrieval group. Nevertheless, the SFR was higher and the intraoperative complications rates lower, when the stones were fragmented and extracted compared to when dusted and left for spontaneous passage. No randomized trials comparing the two treatment strategies for renal stones exist. However, in a randomized trial comparing dusting and basketing strategies for ureteral stones, Schatloff et al. could not demonstrate a significant difference in the SFRs [10]. A review conducted by Matlaga and coworkers concludes that no strategy is clearly superior to the other, although the immediate SFR seems to be higher when a fragmentation and retrieval strategy is applied [11].

The need for standardization when reporting SFR seems obvious. By altering the definition of SFS from *no* residual fragments to practical stone free, the SFR in the present study was more than doubled after dusting a renal stone (31.9% *vs* 64.1%). By changing the definition of «stone free», 200 (38.0%) more patients ended up being successfully treated. However, using a less strict definition of SFR comes at a certain cost. Nearly one third of these extra 200 patients ultimately needed a second URS during the 5-year study period. This figure reflects the retreatment rate of residual fragments and is in accordance with previous publications [3].

The definition of SFR should be based on objective criteria. The most sensitive imaging modality for this purpose is CT. Low-dose non-contrast CT has superior sensitivity (97%) and specificity (95%) compared to ultrasound (11-93% and 82-100%, respectively) and plain kidney-ureter-bladder (KUB) radiography (45-58% and 69-77%, respectively) [12]. A major concern using CT for follow-up has been radiation exposure. This is especially important considering the need for recurrent investigations in stone patients. A standard-dose CT abdomen has a radiation exposure of up to 12.6 mSv. This is 13 times more than a regular KUB (0.5-1.0 mSv) [13, 14]. The significant radiation exposure from a standard-dose CT has therefore been a main argument against its use in follow-up. Low-dose non-contrast CT has a radiation exposure of 0.97 - 1.9 mSv which is only slightly more than a KUB [14]. Low-dose non-contrast CT therefore seems to be the most appropriate radiologic modality in the follow-up after URS.

In our opinion, it is proper to report the zero-fragment rate on CT, as this leaves no room for subjective assessment of small residuals. This definition is also supported by others [2]. In addition, including so-called small insignificant fragments in the definition of stone free may result in stone growth and symptomatic events, even when the residuals are < 2 mm [15]. Other and less strict definitions of SFS may well be used, but only when reported as an addition to the zero-fragment rate, and hence leaves the decision of the clinical relevance to the reader.

The presence of small calcium compound aggregates attached to the renal papilla, known as Randall's plaques, may interfere with the strict definition of SFS [16]. Endoscopically, Randall's plaques appear as small calcifications attached to the renal papilla. They are often covered by the mucosa and can thus be distinguished from a free-floating calculus in the collecting system. On CT, Randall's plaques appear as < 2 mm calcifications and is defined when > 50% of the plaque is surrounded by renal parenchyma [16]. The strict zero-fragment definition on CT can therefore still be applicable despite the presence of Randall's plaques.

The timing of the postoperative evaluation is also important, especially if the stone is treated with a dusting strategy and left for spontaneous passage. Early follow-up may result in lower SFR. In addition, post endoscopic ureteral strictures may develop several months following URS [17]. A post endoscopic ureteral stricture was registered in 2.9% of the patients in the present study. Possible causes and risk factors for stricture formation in this material have been presented in a recently published study [18]. Follow-up with a CT 3 months after the URS seems appropriate, and is in accordance with other reports [8, 9, 19]. This does not exclude earlier evaluation when there is suspicion of the patient requiring a second procedure. Nevertheless, early evaluation should in such instances be performed in addition to the 3 months CT.

This study has important limitations. The retrospective design may have contributed to rough registration of data such as the surgeons' predictions of the patients being stone free. However, in most cases this was specified in the report and when there was doubt, the predictions could be interpreted from the follow-up strategy chosen in each case. The comparison between the two treatment strategies, dusting *vs* fragmentation and extraction, was also influenced by the retrospective design as the two groups were not entirely equal. This can only be achieved in randomized trials. Multiple stones were treated in approximately half of cases in the renal pelvis and 15% of cases with ureteral stones. Due to the definition of stone size in this study, the total stone burden in these cases was underestimated. Because the distribution of the number of stones was equal in both groups, we believe that this definition did not unduly influence the results. Nevertheless, conclusions regarding the results of the treatment strategies should be drawn with caution.

Stone analysis was not included in this study. This could be considered a limitation as different stone compositions may influence the SFRs. However, stone density as a proxy for stone composition, has not been shown to influence the SFRs in URS [20].

A strength of the study is the high number of patients available to follow-up with CT, leaving us able to determine the SFR in accordance to the strictest possible definition.

Conclusion

Urologists are too optimistic when predicting their patients' SFS following URS. This may delay the timing of a second procedure. Predictions of SFS following a dusting strategy seems to be more inaccurate than after a fragmentation and retrieval strategy.

The present study illustrates the need for a standardization when reporting SFS. In our opinion, it is proper to define SFS as *no* residual fragments detected on CT 3 months after the URS procedure.

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Disclosure Statement

Øyvind Ulvik is a consultant for Olympus, who was not involved in the design, collection, analyses, interpretation or reporting of the data. The two other authors have nothing to disclose.

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Table 1 Basic characteristics

Characteristics		*Total*	*Fragmentation and retrieval*	*Dusting*	*p-value*
Side of treatment					
Right		**432 (42.4%)**	237 (41.1%)	142 (43.3%)	*0.575*
Left		**587 (57.6%)**	339 (58.9%)	186 (56.7%)	
Stone status - renal pelvis					
Size, mean mm (95%CI)		**8.7 (8.3 - 9.0)**	7.7 (7.2 - 8.1)	10.3 (9.7 - 10.9)	*< 0.0001*
No. of stones	*1*	**340 (51.4%)**	138 (46.5%)	154 (54.4%)	*0.131*
	2	**112 (16.9%)**	49 (16.5%)	50 (17.7%)	
	3	**60 (9.1%)**	33 (11.1%)	23 (8.1%)	
	> 3	**149 (22.6%)**	77 (25.9%)	56 (19.8%)	
Location*	*Renal pelvis*	**212 (32.1%)**	86 (29.0%)	112 (39.6%)	*0.009*
	Upper calyx	**129 (19.5%)**	64 (21.5%)	49 (17.3%)	*0.209*
	Middle calyx	**144 (21.8%)**	62 (20.9%)	58 (20.5%)	*0.919*
	Lower calyx	**415 (62.8%)**	204 (68.7%)	162 (57.2%)	*0.005*
Stone status - ureter					
Size, mean mm (95%CI)		**7.4 (7.1 - 7.7)**	7.2 (6.9 - 7.5)	8.8 (7.9 - 9.7)	*0.001*
No. of stones	*1*	**409 (86.1%)**	310 (85.4)	62 (87.3%)	*1.000*
	2	**37 (7.8%)**	28 (7.7%)	5 (7.1%)	
	3	**6 (1.3%)**	5 (1.4%)	1 (1.4%)	
	> 3	**23 (4.8%)**	20 (5.5%)	3 (4.2%)	
Location*	*Proximal*	**154 (32.4%)**	92 (25.3%)	48 (67.6%)	*< 0.0001*
	Middle	**62 (13.1%)**	45 (12.4%)	9 (12.7%)	*1.000*
	Distal	**272 (57.1%)**	236 (65.0%)	16 (22.5%)	*< 0.0001*
Obstruction prior to URS		**347 (34.1%)**	233 (40.5%)	86 (26.2%)	*< 0.0001*
Prestented with JJ		**149 (14.6%)**	92 (16.0%)	49 (14,9%)	*0.704*

*Some patients had stones in multiple locations.

Table 2 Comparison of characteristics related to the URS procedure

Characteristics	*Fragmentation and retrieval*	*Dusting*	*p-value*
Location of the stone treated			
Renal pelvis	225 (39.0%)	280 (85.4%)	
Ureter	262 (45.5%)	30 (9.1%)	*< 0.0001*
Both renal pelvis and ureter	89 (15.5%)	18 (5.5%)	
Operator experience			
Resident	160 (27.8%)	72 (22.0%)	
Consultant	106 (18.4%)	83 (25.3%)	*0.024*
Endourologist	310 (53.8%)	173 (52.7%)	
Safety guide wire	11 (1.9%)	9 (2.7%)	*0.482*
Access sheath	21 (3.6%)	14 (4.3%)	*0.720*
Need for balloon dilatation	69 (12.0%)	58 (17.7%)	*0.022*
Post endoscopic drainage with JJ-stent	398 (69.1%)	281 (85.7%)	*< 0.0001*
Operating time - minutes (95%CI)	51.8 (49.7 - 53.9)	57.5 (54.9 - 60.1)	*0.001*

Table 3 Intraoperative complications

	Fragmentation and retrieval	*Dusting*	*p-value*
Total cases	32 (5.6%)	39 (11.9%)	*0.001*
Disturbing bleeding	21 (3.6%)	37 (11.3%)	*< 0.0001*
Perforation	13 (2.3%)	11 (3.4%)	*0.390*
Mucosal abrasion	10 (1.7%)	3 (0.9%)	*0.395*

Disturbing bleeding was registered as a complication when vision was impaired to an extent that hindered further endoscopy. Perforation was assessed endoscopically or as contrast leakage on retrograde pyelogram. Mucosal abrasion was defined as grade 2 or higher according to the classification of ureteral wall injuries presented by Traxer et al [16]. More than one complication occurred in some patients. There were no ureteral avulsions.

Table 4 Stone free rates after URS

	Fragmentation and retrieval	*Dusting*	*p-value*
Stone free (no residual fragments on CT) - total	372 (68.0%)	113 (35.5%)	*< 0.0001*
Stone location			
Renal pelvis	115 (53.2%)	86 (31.9%)	*< 0.0001*
Ureter	213 (85.6%)	20 (66.7%)	*0.011*
Both renal pelvis and ureter	44 (53.0%)	7 (38.9%)	*0.309*
Practical stone free - total	455 (83.1%)	206 (64.8%)	*< 0.0001*
Stone location			
Renal pelvis	176 (81.5%)	173 (64.1%)	*< 0.0001*
Ureter	221 (89.1%)	22 (73.3%)	*0.021*
Both renal pelvis and ureter	58 (69.9%)	11 (61.1%)	*0.577*
Stone free status predicted by surgeons - total	524 (91.0%)	252 (76.8%)	*< 0.0001*
Stone location			
Renal pelvis	201 (89.3%)	218 (77.9%)	*0.001*
Ureter	246 (93.9%)	21 (70.0%)	*0.0003*
Both renal pelvis and ureter	77 (86.5%)	13 (72.2%)	*0.158*