Welcome to the Stone Age: minimally invasive treatments for urolithiasis

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Part 2

Treatments evaluated

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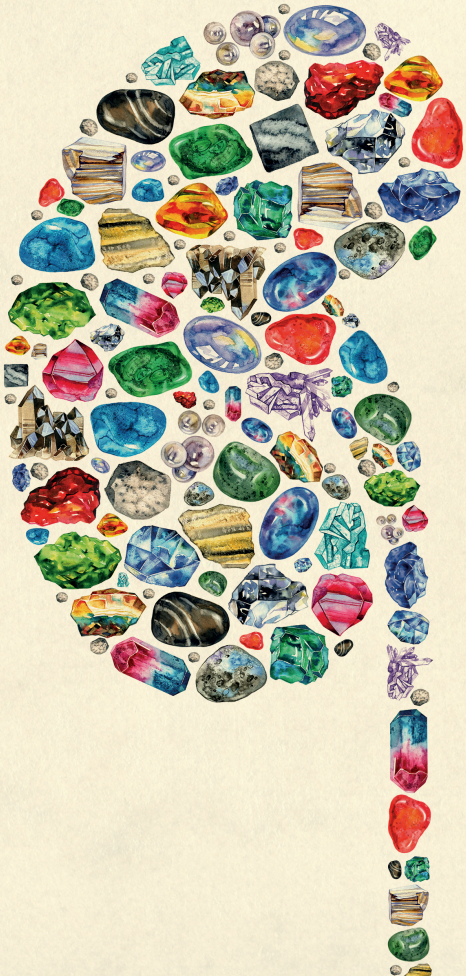

URS and PCNL: A quality control study

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ABSTRACT

Background

The use of minimally invasive surgery is increasing. Evaluating the quality of care brings new insights in the optimization of operating techniques.

Methods

We included all procedures performed in two hospitals during 2010 and 2011. A total of 264 patients were included in the ureterorenoscopy (URS) group and 77 patients in the percutaneous nephrolitholapaxy (PCNL) group. Data were gathered by retrospectively reviewing medical records.

Results

Mean stone diameter in the URS group was 9 mm. Patients suffered from a single stone in 79% of the cases. Calculi in the distal ureter, defined as the part of the ureter below the lower border of the sacroiliac joint, were most likely to be removed. A stone-free status was reached in 69% of the cases using URS. Mean stone diameter in the PCNL group was 23 mm. PCNL was successful in 70% of the cases in Haga Hospital versus 53% in Medisch Centrum Haaglanden. Incidence of complications was comparable between the hospitals ($p = 0.5$). Outcome and quality of both PCNL and URS was not influenced by sex, age or body mass index.

Conclusion

The clinical results were comparable with results in the literature. Further improvement can be made by optimization of technical aspects and centralization of treatment by urologists experienced in minimally invasive techniques.

INTRODUCTION

Incidence of stone formation in the urinary tract is increasing. It forms a major global medical problem in different healthcare systems [1]. Urolithiasis may cause severe pain, damage of renal function or even life-threatening septicemia. Extracorporeal shock wave lithotripsy (ESWL), ureterorenoscopy (URS) and percutaneous nephrolitholapaxy (PCNL) are the main treatment modalities for patients suffering from urolithiasis. Minimally invasive therapy for stones in the urinary tract has expanded over the last years, due to better imaging and technical modalities. In clinical practice, semi-rigid or flexible URS is usually applied for stones in the urinary tract when ESWL fails or is contraindicated. Semi-rigid URS is mainly used for distal ureteral stones. Flexible URS is preserved for the more proximal ureteral stones and renal calculi or migrated ureteral stones during semi-rigid procedure. PCNL is the treatment of choice for larger renal calculi [2, 3].

The outcome of these procedures varies in the literature, partially depending on the definition of stone-free status, which differs between publications. Social awareness, governmental authorities, insurance companies and patient organizations increasingly demand objective quality-controlled data in different fields of medicine, including care in urolithiasis [4]. Due to these requirements, medical specialists are increasingly starting to work in subspecialties. An effort is made to provide state of the art care by centralization and concentration of particular medical conditions. The treatment of calculi is one of these subspecialties in urology.

The goal of this study was to provide a clear view of the quality, obtained by URS and PCNL, in 2 hospitals in a major city in the Netherlands. We compared our results with the literature in order to detect possible points of improvement. We discussed technological aspects that could improve the quality and safety of these procedures.

MATERIAL AND METHODS

The URS and PCNL procedures, performed in Haga Teaching Hospital (Haga) and Medisch Centrum Haaglanden (MCH) during 2010 and 2011 were included in this study. A total of 264 patients were included in the URS database. Of this group, 196 patients were treated in Haga and 68 in MCH. PCNL was performed in 77 patients during the study period, of which 47 were operated in Haga and 30 in MCH. A database was created in Windows Office Excel 2010 with variables of quality. Patient data were gathered by

retrospective viewing of the medical records. The software of IBM SPSS Statistics 20.0 was used to perform statistical analyses. These analyses were individually done for each hospital and were also combined. All outcomes were compared with the literature.

Pearson's chi-squared test was used to assess categorical variables. When analyzing smaller amounts of patients, Fisher's exact test was used. The Mann-Whitney U test was used to compare non-normal distributed variables between 2 groups. Univariate and multivariate logistic regression analysis was performed to show associations between independent categorical variables. When continuous variables were compared with more than 2 groups, the ANOVA test was used with a Bonferroni correction for multiple testing. A P-value of $p < 0.05$ was assumed to be statistically significant. The local ethical committee was informed.

RESULTS

URS

The average age of the 264 patients (male = 179, female = 85) included in the URS group was 55 ± 16 years. Their average body mass index (BMI) was 27 ± 4.7 kg/m2. Most patients (79%) suffered from only a single stone. The mean stone diameter (measured by kidney, ureter and bladder) was approximately 9 mm (8.9 ± 4.2 mm). Indication for semi-rigid or flexible URS was based on EAU guidelines. A safety wire was introduced in all semi-rigid procedures. An access sheet was used for introduction of the flexible ureteroscope. A Holmium laser was applied for defragmentation in the majority of cases. Small fragments were removed using a grasper. Patients were not pre-interventionally stented. The procedure was successful in 69% of all patients, as intra-operatively estimated by the surgeon. Stones in the distal ureter were most likely to be removed. In Haga a flexible URS for ureteral calculi was significantly more often used (39%) than in MCH (6%, $p < 0.01$). Mean operating time (55 minutes) was significantly longer in Haga, than it was in MCH (35 minutes, $p < 0.01$) (table 1).

Complications were more likely to occur when the number of stones to be removed was more than 1 ($p = 0.04$). The number of stones varied between 1 and 3, but in 1 case, 4 stones were treated. The number of complications were comparable between the hospitals ($p = 0.5$). The type of complication and its grade, using the Clavien grading system, varied. For example, abrasions or perforation of the ureter/renal pelvis occurred more often in MCH, whereas in Haga more postoperative infections were observed (table 2).

TABLE 1. URS type, operating time, stone removal and postoperative complaints

	MCH (n=68)	Haga (n=196)	Total (n=264)
URS type			
Semirigid	87% (59)	52% (102)	61% (161)
Flexible	6% (4)	39% (76)	31% (80)
Both	7% (5)	9% (18)	8% (23)
Mean operating time (range)	35 (7-123)	55 (11-152)	50 (7-152)
Stones removed			
yes	63% (43)	71% (138)	69% (181)
no	34% (23)	19% (38)	23% (61)
yes, but residual fragments	3% (2)	10% (20)	8% (22)
Free of complaints*			
yes	62% (42)	72% (141)	69% (183)
no	38% (26)	25% (49)	28,5% (75)
missing	0% (0)	3% (6)	2,5% (6)

**at follow up 4 weeks post-operative, no relapse in 1 year*

TABLE 2. URS complications

	MCH (n=68)	Haga (n=196)	Total (n=264)
Complication			
yes	28% (19)	22% (46)	23% (65)
no	72% (49)	76% (146)	75% (195)
missing		2% (4)	2% (4)
Clavien grade			
0	72% (49)	76% (146)	75% (195)
1	19% (13)	7% (14)	10% (27)
2	6% (4)	13% (25)	11% (29)
3a	-	0,5% (1)	0,5% (1)
3b	3% (2)	3% (5)	3% (7)
4	-	-	-
5		0,5% (1)	0,5% (1)

The mean hospitalization time for URS was 3 days. Additional treatment of residual fragments or newly formed calculi was considered to be needed in about 1 of every 3 patients during follow-up. In most cases ESWL or URS was used for retreatment. Stone free status after retreatment has not been evaluated. Sex, age and BMI did not have any influence on quality and outcome of URS.

PCNL

The mean age was 54 ± 15.4 years in the PCNL group. The proportion of male and female patients was 46 and 31 respectively. The average BMI was 27 ± 4.8 kg/m2. The average stone diameter was 23 ± 16.3 mm. Stones were located in the renal pelvis and its different calyces. The pyelocaliceal system was accessed by a thin needle, using ultrasound and X-ray control. A guide wire was introduced and preceded into the ureter. After this step, the tract was dilated using a balloon dilator. A 30F Amplatz sheath was subsequently placed in situ, through which the scope was inserted. The procedure was significantly more successful in reaching a stone-free status in Haga (70%) compared to MCH (53%) (p = 0.02). Operating time was longer when the stone diameter was larger than 20 mm (p = 0.03) (table 3).

TABLE 3. PCNL stones removed, postoperative complaints and operating time

	MCH (n=30)	Haga (n=47)	Total (n=77)
Stones removed			
yes	53% (16)	70% (33)	64% (49)
no	27% (8)	4 % (2)	13% (10)
yes, but residual fragments	20% (6)	26% (12)	23% (18)
Free of complaints			
yes	73% (22)	67% (31)	70% (53)
No	27% (8)	33% (15)	30% (23)
Mean operating time (range)	83 (34-143)	77 (31-173)	79 (31-173)

Again, there was a difference in type of complication and its Clavien grading (table 4) between the hospitals. Postoperative bleeding occurred in MCH in 10% of patients versus in 2% in Haga. Blood transfusions were more often necessary in MCH (table 4), but this was not significant. Unlike MCH, Haga preferred to use a nephrostomy tube postoperatively in most cases. The hospitalization time was longer in Haga (5 days), compared to MCH (4 days, p = 0.28). Sex, age and BMI did not have any influence on quality and outcome of PCNL.

TABLE 4. PCNL complications

	MCH (n=30)	Haga (n=47)	Total (n=77)
Complications (n)	30% (9)	33% (15)	32% (24)
Clavien grade			
1	3% (1)	13% (6)	9% (7)
2	17% (5)	9% (4)	12% (9)
3a	7% (2)	-	3% (2)
3b	3% (1)	11% (5)	8% (6)
4	-	-	-
5	-	-	-
Transfusion received (n)	13%(4)	4%(2)	8%(6)
Type of complication			
Fever / infection	10,0% (3)	9% (4)	9% (7)
Postoperative bleeding	10% (3)	2% (1)	5% (4)
Parenchymal laceration	-	13% (6)	8% (6)
Readmittance because of pain	3,3% (1)	2% (1)	3% (2)
Hydronephrosis	3,3% (1)	-	1% (1)
Parenchymal laceration + infection	-	2% (1)	1% (1)
Parenchymal laceration + hydronephrosis	3,3% (1)	-	1% (1)
Re-intervention < 4 weken	-	5% (2)	3% (2)

DISCUSSION

Average URS operating time in both clinics was comparable to the mean value reported in the literature (18– 93 minutes) [5, 6]. Flexible URS, in contrast to semi-rigid, was more often performed in Haga. This fact, as well as the larger number of residents performing surgery in this hospital, may be a cause of a longer operating time in Haga [6].

Complication rates of URS were largely the same in both hospitals. Minor lesions of the ureter or renal pelvis were most frequent, with percentages in the literature ranging from 0 to 15.4% [7]. In Haga minor lesions of the urinary tract occurred in 2% and in MCH in 16% of the patients. The more frequent use of semi-rigid URS in MCH may cause this higher percentage. However, the literature does not support this conclusion.

For PCNL there was an important difference between MCH and Haga. Access to the pyelocaliceal system and the stone site in MCH was established in the operating theatre, using ultrasound for guidance during puncture. In Haga this procedure was pre-planned, based on CT reconstruction images and access was preoperatively established under ultrasound and fluoroscopy. In MCH, a stone-free status, based on abdominal X-ray (kidney, ureter and bladder) was achieved in 53% of the cases and in 70% of

the cases in Haga. Preoperative stone load per patient appeared to be similar in both hospitals. Successful PCNL is reported in the literature as ranging from 74 to 92% [8]. The definition of clinically insignificant residual fragments and stone-free status is often reported differently in publications and may cause confusion in the interpretation of these results [9, 10]. Average hospital stay in both hospitals was comparable with the literature [11].

Our results support the evidence that both PCNL and URS are treatment options of choice, for aged and/or overweight patients, male or female. Outcome is not influenced by any of these characteristics [12, 13]. Endurance of quality and further improvement of URS and PCNL is demanded by both care providers (government, doctors and social authorities) and consumers (patients). We investigated the quality of stone care in 2 hospitals. Our results support that URS, as a treatment for smaller calculi in the urinary tract, can be safely used in both hospitals. It is clear that a single simple stone in the distal ureter can be treated by all urologists practicing endourology. However, flexible URS and PCNL are also used as a treatment modality for larger and more complex stones in the upper urinary tract. These more complex treatments need a precautionary plan. Knowledge of renal anatomy is of utmost importance in order to find and eliminate calculi. When preplanning URS or PCNL, these anatomical data need to be applied and personalized for the renal anatomy of individual patients in order to provide optimal surgical information for the urologist. In our PCNL group, 90% were evaluated using CT abdomen in order to establish optimal anatomical data pre-operatively.

Rigid PCNL is limited in its maneuvers in the curved pyelocaliceal system and a flexible URS is often unstable in the ureter. Optimization of technical aspects and instruments can provide better outcome of minimally invasive procedures. For example, a (short) flexible renoscope can be used for PCNL to facilitate sight and operative maneuvers in order to work around narrower angles.

Another example is a thinner flexible URS, is able to pass any narrow points in the ureter.

When it comes to large, hard stones or those situated in an unattainable position, we believe that centralization and sub-specialization will improve quality of minimally invasive procedures. The two hospitals discussed in our quality analysis have decided to refer and to treat more difficult cases in Haga.

CONCLUSION

The success rate of URS in both clinics and PCNL in Haga concur with those reported in the literature. Complication rates, operating and hospitalization time correspond with the literature for both procedures and clinics. Outcome and quality of PCNL and URS is not influenced by sex, age or BMI. Further improvement in minimally invasive surgery for renal and ureteric calculi is feasible and can be made by optimization of technical aspects and knowledge of renal anatomy. Also, sub-specialization and centralization in the treatment and care of urolithiasis is mandatory. A study group has been initiated with a main focus on stone pathology, technical aspects of minimally invasive surgery, and improvement of care in urolithiasis.

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