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Development of a prospective data registry system for retrograde intrarenal surgery in renal stones: Turkish Academy of Urology Prospective Study Group (ACUP study)

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ABSTRACT

Objective: We aimed to report the development of a prospective data registry by generating a retrograde intrarenal surgery (RIRS)-specific electronic case report form (eCRF), which can be used by multiple centers in Turkey.

Material and methods: The Stone Disease Study Group of Turkish Urology Academy developed a template for the necessary data to be collected, which was then implemented within a dedicated server. Urologists from different universities, research and training centers, and private hospitals were invited to participate in this data registry. Each urologist was provided with a unique username and password after they agreed to participate in the study.

Results: In March 2015, the development of the eCRF was completed, and the server was opened for data input in April 2015. We started a prospective clinical data registry for all patients undergoing RIRS for renal stone(s) in 15 participating hospitals. Until the end of June 2016, 1112 RIRSs on 1264 patients have been included in the dataset.

Conclusion: The easy-to-use eCRF specifically developed for RIRS was first of its kind in Turkey. This prospective data registry harvests important data that will be used to identify real-world demographic, clinical and operative data of patients with renal stone who undergo RIRS in various urology departments throughout Turkey. The results of this dataset will be presented in various papers.

Keywords: Minimally invasive surgery; registry; retrograde intrarenal surgery; stone management; urinary stone disease.

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Introduction

Urinary stone disease is a major health problem, which affects 5%-10% of the world population with a prevalence of 10.1%-12% in men and 6%-8% in women in the USA.[1] The direct medical cost for stone disease, which has been reported to be 10 billion USD in 2012 for the USA, is expected to increase by 1.24 billion USD by 2030.[2,3] The treatment for stone disease is planned according to the age and weight of the patient, localization, and size and type of the stone.

In recent years, apart from the not-so-common laparoscopic and open surgeries, minimally invasive treatment modalities, such as shock wave lithotripsy (SWL), percutaneous nephrolithotomy (PCNL), semi-rigid ureterorenoscopy (URS), and retrograde intrarenal surgery (RIRS), constitute the commonly used treatment options for kidney stones. Moreover, RIRS is more frequently used due to the improvements both in digital and mechanical properties of flexible ureteroscopies (fURS) and in auxiliary devices. With the accumulated evidence, it is now being used even for stones sized larger than 2 cm.

Electronic patient record systems ensure the capture of patient data in a safer and detailed and reliable manner, which indirectly increases the quality of patient management. Various patient record/follow-up systems have been de-

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veloped for urology in addition to other specialties. Surveillance, Epidemiology, End-Results (SEER) Program, Cancer of the Prostate Strategic Urologic Research Endeavor (CaPSURE™), and American Urological Association Quality (AQUA) Registry are some examples. A few electronic patient record systems have been developed specifically for urinary stone disease. A study published in 2008 demonstrated that the registry for ureteral stents used in the United Kingdom at that time was not efficient enough, and some of the stented patients were not followed up appropriately.[4] The Registry for Stones of the Kidney and Ureter (ReSKU™) has been developed by collaborating academic and non-academic endourologists in the USA, Canada, Japan, and China and has been implemented in the hospitals' electronic patient file systems.[5] The researchers pointed out that stone disease patients would be better followed up and recorded with this registry system, and the scientific studies performed with this database would be of higher quality. With the initiations of the registry for hereditary stone disease in Germany, it is expected not only to increase the quality of the management of the patients, but also to determine some of the not yet known genetic properties of this disease.[6]

With the primary objective of collecting data for prospective studies, we decided to develop a national, prospective registry specific to stone disease patients undergoing RIRS in various hospitals in Turkey. In this report, we present the development and implementation of this multicentric registry.

Material and methods

A template for the data to be collected was developed by Stone Disease Study Group of Turkish Urology Academy (SG, MCK, MS). An electronic case report form (eCRF) was prepared in Turkish. While defining the parameters to be included in the eCRF, we emphasized on not requesting additional or sophisticated diagnostic tests that are not routinely used in clinical practice. This eCRF was then sent to the Steering Committee of Turkish Urology Academy for review. According to their recommendations, the necessary modifications were done in a consensus. The eCRF included a total of 65 questions, which were divided into three subsections as preoperative, intraoperative, and postoperative evaluations. These subsections are given in Table 1, 2, and 3, respectively.

The Turkish Urology Academy announced the launch of the Academy of Urology Prospective Study Group (ACUP) study to all its members via the website and e-mail. An additional invitation was also sent via e-mail to the departments that were known to have conducted the procedure frequently (>40 RIRS/year) and reported their experience in literature. After receiving the replies, willing and qualified centers were sent a second e-mail including a link to create their account. Individuals or groups who provided case entry and regular follow-up were included in the study.

An ethics committee approval was received from the Ethics Committee of İstanbul Medipol University (date: 04/16/2015, number: 217). Patients were informed that the data of the RIRS operation that they would undergo will be maintained in a secured electronic database, in addition to the routine hospital records, and will eventually be used for scientific studies. Patients provided written inform consent prior to the operation.

Results

The eCRF was completed in March 2015 and was placed on a secured server, which was supplied by the Turkish Association of Urology, in April 2015 (http://acup.uroturk.org.tr/). Fifteen centers agreed and qualified to participate in this registry. These urology departments were from government and private university hospitals, government research and training hospitals, and private hospitals. The centers were sent a third e-mail stating that data can be entered from the beginning of May 2015. Data entry was closed at the end of June 2016. During this period, 1264 cases were registered in the database, and 1112 met the inclusion criteria.

Discussion

Registries provide population-based data, which are retrieved during daily clinical practice, and therefore are better indicators of how the patients are managed routinely. With a reliable registry, real-world data can additionally help the researchers to define the effectiveness and safety of a specific intervention, particularly with an appropriate follow-up. Moreover, most of the clinical research in urolithiasis depends on the data retrospectively collected. Except ReSKU™, most of the prospective registries used for urolithiasis, such as the Ureteric Stent Card Register, Hereditary Kidney Stone Disease Registry, Clinical Research Office of the Endourological Society (CROES) percutaneous nephrolithotomy and ureteroscopy global registries, Brushite Kidney Stone Registry, Rare Kidney Stone Consortium (RKSC) Registry, Percutaneous Nephrolithotomy Registry, Health-Related Quality of Life in Rare Kidney Stone Registry, and Vietnam Era Twin Registry, are either limited to specific procedures or have a limited follow-up.[4-10]

As a prospective registry retrieves all required data regarding patient characteristics and preoperative evaluation, intervention outcomes, and follow-up, it can be used to improve the management of patients and the quality of life of the patients in the long term. Patients with urolithiasis have two specific situations, namely residual stone and stone recurrence, which affect the outcome of the intervention and the follow-up. Therefore, a registry

Table 1. Data collected in the preoperative evaluation (Questions 1-29)

Patient's age
Patient's sex
- Female
- Male

Weight (kg)
Height (m)
ASA score
- 1 to 4

Charlson comorbidity index
- 1 to 16

Complaint at presentation
- Pain
- Hematuria
- Urinary tract infection
- Hypertension
- Other

History of prior treatment for the present complaint
- No
- Yes (→ *Brief description*)

Use of anticoagulant-antiplatelet medication
- No
- Yes

History of urinary stone disease
- No
- Yes, but no intervention
- Yes, SWL performed
- Yes, RIRS performed
- Yes, PCNL performed
- Yes, laparoscopic surgery performed
- Yes, open surgery performed

Familial history of urinary stone disease
- No
- Yes

Presence of any comorbidity
- No
- Diabetes mellitus
- Hypertension
- Coronary arterial disease
- Heart failure
- Chronic obstructive pulmonary disease
- Hyperparathyroidism
- Osteoporosis
- Other

Additional urinary system disease/anomaly
- No
- Yes

Presence of preoperative hydroureteronephrosis
- No
- Yes

Score for Resorlu-Unsal Stone Score
- 1 to 4

Preoperative urine culture
- No
- Yes

Perioperatively given antibiotic
- No
- Yes

Placement of preoperative double-J stent (passive dilatation)
- No
- Yes

Date of surgery
Preoperative creatinine level
Preoperative leucocyte level
Preoperative hemoglobin level
Preoperative C-reactive protein (CRP) level

Preoperative radiological imaging technique
- KUB
- CT
- US
- IVU
- Other

Maximal value of Hounsfield Unit (HU)

Laterality
- Right
- Left
- Bilateral

Localization of stone
- Renal pelvis
- Lower calyx
- Middle calyx
- Upper calyx
- Ureter
- Staghorn
- More than one localization

Number of stones
Dimension of stone (mm) (sum of the largest dimensions in case of more than one stone)

Parameters in *italics* need to be written manually. Answers for all other parameters are clicked from the options listed below the parameters.

specifically designed to retrieve the outcome and follow-up data longitudinally will be more beneficial to urolithiasis patients. ReSKU™ was developed with this intention to not only have preoperative and operative data, but also the long-term follow-up data of patients with any kind of stone type or who had any type of intervention. Due to implementation into an electronic patient file system, it did not require a labor-intensive data collection, and made it a sustainable registry.[5]

We developed a prospective registry for the urolithiasis patients who would undergo RIRS. After meeting the inclusion criteria, 15 centers across Turkey participated in data collection for this registry. We specifically selected the collected data items to ensure that the centers would not perform any additional tests apart from their clinical routine, and therefore no increase in their workload or the cost of treatment could be possible. With this setting, we aimed to the lower barriers of participation and make the registry sustainable. Since this was the first initiative in Turkey, we first aimed to have data retrieval for 2 years and to observe if this prospective registry could be sustained during this period without implementation into hospitals' electronic patient file systems. This registry would serve as a pilot study to evalu-

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Table 2. Data collected in the intraoperative evaluation (Questions 30-51)

Anesthesia type
- Spinal
- General

Position of the patient
- Lithotomy position
- Frog-leg position
- Other

Postponement to second session after insertion of DJ stent due to ureteral stricture or injury
- No
- Yes

Use of UAS
- No
- Yes

USA length (cm)
- 13
- 28
- 35
- 45
- 55
- Other

USA thickness (Fr)
- 9.5-11.5
- 10.7-12.7
- 12-14
- 14-16
- Other

Level of USA placement
- Renal pelvis
- Proximal ureter
- Mid ureter
- Distal ureter

Use of safety wire
- No
- Yes

Use of semi-rigid URS
- No
- Yes

Fluoroscopy time (sec)

Stone opacity (under fluoroscopy)
- Opaque
- Semi-opaque
- Non-opaque

Stone disintegration technique
- Painting
- Drilling
- Pop-corn
- Combined

Repositioning with basket catheter
- No
- Yes

Presence of residual fragment
- No
- Yes

Estimated dimension of the residual fragment (mm) (sum of largest dimensions in case of more than one stone)

Intraoperative DJ stent insertion
- No
- Yes

Anesthesia time (min)

Surgery time (min)

PULS grade
- 0 to 5

Number of laser shooting

Thickness of laser probe (µm)
- 200
- 272
- 365
- 550
- Other

Laser settings (maximum)
- Power
- Frequency
- ΣE (total energy)

Parameters in *italics* need to be written manually. Answers for all other parameters are clicked from the options listed below the parameters.

ate the feasibility of prospective data collection among various hospitals across Turkey, and the necessity of implementation of the registry into electronic patient file system, as it requires great amount of information technology and financial support. Although a 2-year data collection was initially aimed, the registry had to be closed due to the feedback from the centers about the difficulties in data entry (mainly because of not being implemented in electronic patient file systems). Given the high workload of some of the centers (especially university hospitals), managing the clinical routine and data entry simultaneously was challenging. Nevertheless, the data of 1112 RIRS patients were collected in 14 months from 15 centers across Turkey.

This registry has some important points that need to be mentioned. Firstly, it is the first prospective multi-center registry in Turkey designed not only for the benefit of urolithiasis patients, but also in the field of urology. Urologists from different centers were eager to participate; however, for uniformity in the experience of the centers, we included those with a caseload of >40/year. The registry had a user-friendly style with clicking boxes used for the vast majority of the parameters and very few parameters to be entered manually (written in italics in Tables 1, 2, and 3). This registry showed us that prospective data collection could be performed in Turkey even though it is not implemented in electronic patient file systems. After data quality control, 86% of the collected data was available for final analyses. After the closure of the registry, we received positive feedback from the centers pointing out that it helped them to define the parameters to be included mandatorily in their patient files.

This registry was not devoid of limitations. First, a group of centers was invited, and some of them were selected. While we wanted to ensure that RIRS was a routinely performed procedure in the centers with an inclusion criterion of >40 cases/year, it undoubtedly

Table 3. Data collected in the postoperative evaluation (Questions 52-65)

Postoperative antibiotic
- No
- Yes

Complications observed (according to the modified Clavien-Dindo classification)
- No
- Yes

Hospitalization time (hour)
Postoperative 1st day creatinine level
Postoperative 1st day leucocyte level
Postoperative 1st day hemoglobin level
Postoperative 1st day CRP level

Postoperative complete stone-free
- No
- Yes

Postoperative stone-free evaluation time (day)

Postoperative radiological imaging technique
- KUB
- CT
- US
- IVU
- Other

Dimension of residual fragment on postoperative evaluation (mm)

Localization of residual fragment on postoperative evaluation
- Renal pelvis
- Lower calyx
- Middle calyx
- Upper calyx
- Ureter
- More than one localization

Management of the residual fragment
- Follow-up
- Intervention

Additional information about the patient (i.e., stone analysis, stone type, metabolic evaluation of the patient)

Parameters in *italics* need to be written manually. Answers for all other parameters are clicked from the options listed below the parameters.

created a selection bias. Second, the registry was not implemented into the electronic patient file systems of the hospitals. This procedure needed extra labor, time, money, and information technology support. Also, various different electronic patient file systems are being used across Turkey, which makes it difficult to adapt this registry to every single system. Third, due to the deficiency that the registry was not implemented into the hospitals' systems, it was terminated before the scheduled time. Fourth, long-term follow-up data of the patients were not collected. Fifth, the easiness of the eCRF and the perfection of the registry have not been evaluated by surveying the ideas of the participating urologists. Lastly, it was developed only for RIRS patients.

In conclusion, this easy-to-use registry was initiated successfully and it allowed us to collect data about RIRS patients even though it was not implemented in electronic patient file systems. As it was first of its kind in Turkey, we hope that this registry sets a precedent to additional registries (preferably those implemented into hospitals' systems) not only in urolithiasis but also in other urological diseases.

Ethics Committee Approval: Ethics committee approval was received for this study from the ethics committee of Medipol University (Date: 16/04/2015, Number: 217).

Informed Consent: Written informed consent was obtained from patients who participated in this study.

Peer-review: Externally peer-reviewed.

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