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ORIGINAL RESEARCH

A protocol for Data Registry system for Reconstructive Urology procedures in Iran

Jalil Hosseini[1], Arshia Zamani hajiabadi[2], Rayka Sharifian[3], Samira Shariatpanahi[1], Somayeh Derakhshan[4], Seyed Mohamad Sadrameli[1], Keshvar Samadaee-Gelehkolaee[5]*

1. Men's Health and Reproductive Health Research Center, Shahid Beheshti University of Medical Sciences, Tehran, Iran
2. Department of Surgery, Shiraz University of Medical Sciences, Shiraz, Iran
3. Fellowship of reconstructive urology, Emam Reza Hospital, Amol, Iran
4. Department of Epidemiology, School of Public Health and Safety, Shahid Beheshti University of Medical Sciences, Tehran, Iran
5. Sexual and Reproductive Health Research Center, Department of Reproductive Health and Midwifery, Faculty of Nursing and Midwifery, Mazandaran University of Medical Sciences, Sari, Iran

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Abstract: Data registry systems are vital tools for systematically collecting, storing, and analyzing disease-specific data within defined patient populations. This protocol presents a national registry system designed to prospectively collect data on patients undergoing reconstructive urology surgeries in Iran.

A web-based registry involving multiple centers across Iran with official collaboration agreements will collect demographic, clinical, surgical, and follow-up data. Patients meeting inclusion criteria are enrolled following informed consent. Data confidentiality and integrity are maintained using a secure software hosted at the Men's Health and Reproductive Health Research Center in Tehran. Standardized clinical questionnaires International Index for Erectile Function(IIEF) , International Prostate Symptom Score(IPSS) , Patients Reported Outcome Measure for Urethral Stricture Surgery (USS_PROM) , International Consultation of Incontinence Questionnaire- lower urinary tract symptoms Quality of Life(ICIQ-LUTSqol) and checklists capture patient outcomes prospectively up to 27 months post-surgery.

The registry will provide epidemiological insights, monitor treatment outcomes, complications, and clinical improvements, extraction of guidelines, and policy brief, and support collaborative research nationally and internationally. This registration system was designed to achieve evidence-based data with the coherence of patient data for policy-making and therapeutic interventions.

Keywords: Iran; Registries; Urology

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1. Introduction

Reconstructive urology is a branch of urology including various techniques for reconstructing and correcting congenital or acquired defects of the urinary-genital tract (1). The urethral repair technique was first introduced in 1851, in which urinary function was established by changing the route of urine exit with the help of ureterosigmoidostomy (2). Over the years, a wide range of reconstructive techniques, including laparoscopic and robotic approaches, as well as tissue engineering, have been introduced to facilitate urinary tract repair and improve surgical outcomes. However, the goals pursued by these techniques extend beyond the mere restoration of urinary function; additional factors such as patient quality of life, sexual function, surgical feasibility, and the invasiveness of the procedure also warrant thorough investigation. The interplay of these diverse considerations underscores the critical need for a standardized and comprehensive data-recording protocol to enable meaningful evaluation and comparison of therapeutic strategies (1, 2).

One of the cases of using restorative urology techniques is lower urethral strictures, which are caused by a wide range of causes, including congenital causes, radiation, iatrogenic injuries, urinary tract stones, or urethral trauma (3). Recent studies have shown that the prevalence of urethral stenosis in the United States is about 627-229 per 100,000 men. Also, European studies indicate an average age of 44 years for sufferers, although urethra stenosis may be seen at any age. Urethroplasty is the gold standard method to repair urethral strictures. Recent studies indicate that the success rate of this technique is more than 98%. This method includes complex techniques and anastomoses to reach the urethra

* **Corresponding Author:** Keshvar Samadaee-Gelehkolaee; Sexual and Reproductive Health Research Center, Department of Reproductive Health and Midwifery, Faculty of Nursing and Midwifery, Mazandaran University of Medical Sciences, Sari, Iran. Email: K-samadaee@alumnus.tums.ac.ir, Moshaversamadai@yahoo.com, ORCID: 0000-0002-9692-187X.

and repair the stenosis. In this method, various techniques are used for repair, including incision and primary anastomosis, flaps, and tissue grafts (4, 5). The tissue samples that have been used so far in this technique are diverse and include skin, bladder, colon, and buccal mucosa (6).

Despite the recent advances in reconstructive techniques and their improvement (7, 8), complications such as failure of the surgical technique, recurrence of stricture, and erectile dysfunction are still seen (5). The prevalence and occurrence of these complications are different depending on the severity of the stricture, its location, and the technique used. Recent studies have shown that about 10-20% of people who undergo urethroplasty experience a recurrence of stenosis. These complications, especially erectile dysfunction after surgery, widely affect the quality of life and the level of patient satisfaction with surgery, even if it is successful.

The lack of accurate statistics on the need for reconstructive surgery, the prevalence of sexual problems, and the subsequent recurrence of the disease, as well as the existence of information gaps related to male sexual health and fertility in Iran, necessitate the need to launch this national registry. The protocol for establishing a national registry system for patients undergoing reconstructive urology treatment has been examined for the first time in Iran in this study. This system aims to standardize data collection, improve health services to enhance patients' quality of life, support research, and inform policy-making related to reconstructive urology treatments.

1.1. Specific goals of the registry

Specific goals of the registry are as follows:

1. Development of a prospective collection of clinical, etiological, laboratory, treatment, and outcome data of patients undergoing reconstructive urology treatment
2. Adding integrity to data sets
3. Providing the possibility to estimate risk measures by improving the quality of data
4. Establishing a framework for small-scale interventions and addressing quality gaps in data
5. Improving the quality of clinical data and creating infrastructure for secondary studies in urology texts, such as questionnaire design or localization
6. Promotion of clinical and research training for assistantship and fellowship students of clinical specialties and basic sciences
7. Improving and upgrading the provision of medical services to patients in need of restorative urology treatment, and unifying the quality and validity of clinical data required to conduct research
8. Gaining valuable experience in designing and implementing a registration system for restorative urology patients at the national level which is usable for doctors and researchers in healthcare, providing a useful platform for interaction and communication between restorative urology specialists in the country
9. Expansion of international cooperation with other registration programs regarding genitourinary diseases
10. Identification and development of health-related policy

2. Registry project and participants

Patients from all over the country will be included in the study through doctors specializing in restorative urology. At the hospital level, information from patient admission forms in the urology department and HIS (Hospital information system) will be used. Based on this, urologists are requested to introduce patients who meet the inclusion criteria and are receiving restorative urology treatments to enter the registration system. After identifying the eligible people and explaining the objectives of the study, the informed consent form is completed for the patients and their information is entered into the software by the registration expert.

1.2. Ethics approvals

The registration system started after obtaining the code of ethics from the Ethics Committee of Shahid Beheshti University of Medical Sciences (code IR.SBMU.RETECH.REC.1399.688). When obtaining information and entering it into the software, informed consent is obtained from the patient. To preserve the names and characteristics of patients, each patient is assigned a 3-digit code, which is determined as follows: The patient identification number is assigned sequentially starting from 1 and is not limited to a fixed number of digits. This structure allows the registry to accommodate an unlimited number of patients without any predefined upper limit.

At the time of establishing the registry, seven attending physicians are participating; therefore, the identification codes 1–7 are currently assigned. However, this coding structure is expandable. If additional physicians join the registry through collaborating centers under formal agreements, new sequential identification codes will be assigned accordingly.

In this study, all men in any age group with injuries that occurred in the anterior part of the urethra (caused by trauma or perforation due to trauma, displacement of penile constriction bands, and injuries of unknown cause due to medical manipulation) or injuries that occurred in the posterior part of the urethra (caused by a pelvic fracture due to traffic accidents), who referred to the urology departments of teaching hospitals in Tehran, Shiraz, Tabriz, Ahvaz, Mashhad, Urmia, Mazandaran and Yazd and treated by a urologist or restorative urology fellowship were included to be registered in the system.

1.3. Inclusion and exclusion criteria for data collection

The inclusion criteria are all male patients in any age group with one or a combination of the following injuries referring to the urology clinics of teaching hospitals or private clinics in the cities of Tehran, Isfahan, Mashhad, Tabriz, Ahvaz, Shiraz, and Urmia who have been treated by a specialist doctor

or restorative urology fellowship:
- Injuries related to restorative urology include urethral stricture, urethral cut following pelvic fracture, hypospadias especially in recurrent cases, external plaque
- Curvature of the penis
- Patients with Erectile Dysfunction who are candidates for prosthesis implantation surgery
- Patients with urinary incontinence who are candidates for surgery
- Exstrophy and Epispadias
Exclusion from the study was considered after loss of operated patients during follow-up (due to emigration, lack of access, or death).

1.4. Collecting data sources

The data collection sources of the current registration system include the following types:
1) Hospital form: including clinical information such as type of primary diagnosis, clinical description of the patient, and type and technique of reconstructive surgery used.
2) Follow-up visits from the third week to 27 months (3, 6, 12, 18, 27) after surgery including clinical information such as ejaculation dysfunction, erectile dysfunction, recurrence, obstructive disorders, excitatory disorders, type of intervention, and the result of imaging.
3) Other information including socio-economic characteristics, death status, need for re-surgery or other treatment measures, infections/diseases, and urinary function will be collected by checklist.

1.5. Data collection method and tools

All patients receive the necessary treatments and care according to the doctor's diagnosis. To record information in this system, a web-based software has been designed, which has 7 portals for 7 cities (Mazandaran, Shiraz, Tabriz, Ahvaz, Mashhad, Urumieh, and Yazd) and the main portal (server), which is located in Tehran at the Men's Health and Reproductive Health Research Center located in Shohadaye Tajrish Hospital. After confirming the inclusion criteria of each patient in one of the 7 mentioned cities, the goals of the registration system are explained to the patient by the attending physician and an informed consent form is obtained from the physician. The attending physician then collects patient information, including clinical history from the interview, standardized questionnaire scores (IPSS, IIEF, ICIQ, USS-PROM), and data from follow-up visits. According to the study protocol, in each city, a nursing expert (or a graduate familiar with the urology department) will be responsible for transferring the information of the questionnaire and forms to the registration software. This information is sent monthly to the main portal in Tehran and is inspected and reviewed by the registration expert based in Tehran and the executive officer of the registration. Also, to ensure the quality assurance of the project implementation methodology, a pilot study will be conducted on a proportion of the data of patients who underwent restorative urology treatment during the previous 24 months.
The data collection tool, to achieve objectives 5, 6, and 7, consists of a hospital admission form, a researcher-made checklist, and the standard questionnaires listed below (Figure 2).
- IIEF (International Index of Erectile Dysfunction) questionnaire to investigate sexual disorders (9),
- IPSS (International prostate symptom score) to measure obstructive symptoms (10),
- USS_PROM (Urethral stricture surgery patient-reported outcome measure) to measure treatment outcomes and health-related quality of life (11),
- ICIQ-LUTSqol (International Consultation on Incontinence Questionnaire-Lower Urinary Tract Symptoms Quality of Life) to check the outcome and satisfaction level of surgery (12).
The checklist made by the researcher includes the following: Demographic characteristics, clinical history (including the history of injury or trauma, history of surgery, prostatectomy, urethroplasty, circumcision), history of sexual disorders and sexual health (including erectile dysfunction, ejaculation, libido, orgasm), history of taking drugs, family history of urogenital disorders, preoperative characteristics of anterior duct stenosis or obstruction (including the cause of stenosis, length of the stenosis, location of the stenosis, number of stenoses, etiology, the functional importance of stenosis, severity of urinary retention, condition of the bladder neck, etc.), preoperative characteristics in posterior ductal stenosis (length of the stenosis, location of the stenosis, number of stenosis, etiology of stenosis, etc.). The results of ultrasound, and blood and urine tests will also be documented. The required information includes things such as total blood cell counts, creatinine and urea in urine, ultrasound of the bladder, results of cystourethrogram, results of urethrography, surgical procedures, type of surgical technique, and specifications. The patient's clinical information will be recorded after the operation.

2. Registry time frame

Registration of the patients' information was conducted after the approval of the project, but the deadline for the completion of this system has not been determined. Routine follow-up of the patients according to the clinical guidelines of restorative urology treatments has been determined up to 27 months (3, 6, 12, 18, 27) after surgery. However, since one of the main goals of the registration system is to investigate the trend of long-term complications among patients, the schedule for the follow-up of patients in this proposal has been set until the end of the second year after surgery. In other words, the probability of serious complications after the end of the second year following reconstructive urology surgery is very small and absence of complications by then can be considered as an indication of surgery success.
Considering the registry-based (not cross-sectional or clini-

cal trial) design, a census sampling method will be employed from the accessible population. However, to ensure adequate statistical power for future exploratory analyses (such as multivariate regression models), a minimum sample size has been estimated. Minimum sample size estimation: Based on annual statistics from reconstructive urology patients at Shohadaye Tajrish Hospital in Tehran (the sole tertiary referral center in Tehran), approximately 150 patients receive specialized treatments per year. Accounting for additional patient referrals from six other cities—though at a lower estimated rate—a minimum enrollment of 1000 patients over the first 24 months is anticipated. It is necessary to explain that sampling will continue after reaching this value, and in fact, this number provides the minimum sample size required for the analyses.

3. Security, maintenance, validity, and release of data

All information is obtained after obtaining informed consent from the patient by the attending physician or his assistant and in accordance with the ethical considerations of the Declaration of Helsinki. To enter and save the patients' information, a software has been prepared with the cooperation of the Information Technology Department of Shahid Beheshti University of Medical Sciences. After entering the information into the software and using the access filters, the patient's information is only available to their treating doctor in the same city and is not available to other collaborating doctors of the plan in other cities. All the information along with the identification codes (Identifier) are only available to the main person responsible for registration and a support person (who is an epidemiologist and is responsible for summarizing and analyzing the information). The ownership and dissemination of data is solely under the authority of the Men's Health and Reproductive Health Research Center and is done under the supervision of the center's director. To minimize missing data, the following measures will be implemented: Designing a web-based software with validation for mandatory fields during data entry. Providing standard training for data entry personnel at each center. Periodic review of submitted data by the central registration expert and immediate follow-up on incomplete cases with the relevant center. Analysis and Reporting: The rate and pattern of missing data for each important variable will be reported systematically (e.g., in a separate table). Compensation Methods in Analysis: The choice of method will be based on the nature of the missingness.

To minimize loss to Follow-up, the following measures will be implemented: Recording multiple contact details (patient's phone, next of kin's phone, address) and updating them periodically. Comprehensive education of the patient regarding the importance of long-term follow-up. Coordination with SMS platforms to send visit reminders.

The number and primary reasons for loss to follow-up at each stage of the study will be meticulously recorded and presented in the final report. To assess potential bias due to loss to follow-up, baseline characteristics (age, initial diagnosis, type of surgery) will be compared between patients who remained until the end of the follow-up period and those who were lost, using appropriate statistical tests (Sensitivity analysis). Data validity will be ensured through multiple approaches, including the implementation of standardized protocols and operational guidelines, a dedicated and continuous training program, a data quality audit and control system (including audits at the center and server levels, random data reviews, and the appointment of an expert committee), and accommodation of technical diversity while ensuring precise and accurate recording.

4. Conclusions

The registry of reconstructive urology patients in Tehran is the first national registry of reconstructive urology data in Iran. The registry provides an opportunity to summarize epidemiologic data on geographic, socioeconomic, and ethnic factors that may contribute to prevention of relapse and improve patients' quality of life. This facilitates research and provides a single access point of data for treatment to physicians, patients, and their families. By providing a better understanding of patient status and outcomes of such subspecialty surgeries, registries support better patient care, management decisions, research, and health economics.

5. Declarations

5.1. Acknowledgments

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5.2. Authors contributions

Jalil Hosseini: Conceptualization, Project Administration, Supervision
Rayka Sharifian: Investigation, Methodology
Keshvar Samadaee Gelehkolaee: Formal analysis, Writing – Original Draft Preparation, Writing – Review & Editing
Samira Shariatpanahi and Seyed Mohamad Sadrameli: Data Curation, Software
Somayeh Derakhshan: formal analysis, Writing – Original Draft Preparation
Arshia Zamani Hajiabadi: Writing – Original Draft Preparation, Writing – Review & Editing
All authors read and approved the final version of manuscript

5.3. Conflict of interests

All authors have disclosed no conflicts of interest.

5.4. Funding

This study has not been funded.

5.5. Approval of the research protocol

The present study was performed in line with the principles of the Declaration of Helsinki. This manuscript is taken from the diseases registry, titled" Establishment of a National Registry System for patients undergone Reconstructive Urology procedures" and code number IR.SBMU.RETECH.REC.1399.688 from the ethics committee that was supported by the deputy of research and technology at Shahid Beheshti University of Medical Sciences (http://dregistry.sbmu.ac.ir).

5.6. Funding section

This project was supported by the deputy of research and technology at Shahid Beheshti University of Medical Sciences.

5.7. Availability of data and materials

The datasets used and/or analyzed during the current stare study are available from the corresponding author upon reasonable request.

5.8. Informed Consent

Informed consent was received from all participants. The patients were assured that their information would be used confidentially and only for conducting research. Participation in the survey was voluntary as participants could decline to participate at any time during the study. All methods were performed in accordance with the relevant guidelines and regulations in practice.

5.9. Using artificial intelligence chatbots

The authors acknowledge that they used DeepSeek AI (the latest version available as of February 17, 2026, likely the V4 preview) to edit the English text.

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