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SHORT REPORT

Danish Urogynaecological Database

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Abstract: The Danish Urogynaecological Database is established in order to ensure high quality of treatment for patients undergoing urogynecological surgery. The database contains details of all women in Denmark undergoing incontinence surgery or pelvic organ prolapse surgery amounting to ~5,200 procedures per year. The variables are collected along the course of treatment of the patient from the referral to a postoperative control. Main variables are prior obstetrical and gynecological history, symptoms, symptom-related quality of life, objective urogynecological findings, type of operation, complications if relevant, implants used if relevant, 3–6-month postoperative recording of symptoms, if any. A set of clinical quality indicators is being maintained by the steering committee for the database and is published in an annual report which also contains extensive descriptive statistics. The database has a completeness of over 90% of all urogynecological surgeries performed in Denmark. Some of the main variables have been validated using medical records as gold standard. The positive predictive value was above 90%. The data are used as a quality monitoring tool by the hospitals and in a number of scientific studies of specific urogynecological topics, broader epidemiological topics, and the use of patient reported outcome measures.

Keywords: urogynecology, pelvic organ prolapse surgery, incontinence surgery, surgical quality monitoring

Introduction and aims of database

Urogynecology concerns pelvic floor dysfunction in women resulting in urinary incontinence (UI) and pelvic organ prolapse (POP). These conditions are never life threatening, but both can greatly impair quality of life and sexual function. The prevalence is high and increases with age. For UI, the prevalence is ~10% at 20 years of age increasing to 40% at 90.[1] For symptomatic POP, it increases from 30% among 30–39 years of age to 41% among 70–79 years.[2] First-line treatment in Denmark is hormone replacement, pelvic floor training, vaginal pessaries, and sometimes other medical therapies. More severe cases are treated with surgery and the lifetime risk of POP surgery has been estimated to be 6%–18% and about 5%–10% for UI surgery.[2] In order to monitor the clinical quality of urogynecological surgery in Denmark, the Danish Urogynaecological Database (DugaBase) was implemented.

There are several aims of DugaBase: i) to ensure a high and homogeneous quality of treatment throughout the nation; ii) to provide early warning if new urogynecological surgical procedures or devices may be associated with complications; iii) to provide data for research purposes and iv) to allow each gynecological department immediate

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online access to the department's own DugaBase data making it a valuable tool for monitoring the performance.

Study population

DugaBase was established in 2006 and fully implemented in 2007. All women undergoing UI or POP surgery are eligible to be included in the DugaBase (according to the "Nordic Classification of Surgical Procedures" for UI: KKDG00; KKDG01; KKDG10; KKDG30; KKDG31; KKDG40; KKDG50; KKDG96; KKDG97; KKDV20; KKDV22; KLEG00; KLEG10; KLEG10A; KLEG20; and KLEG96; and for POP: KLEF00; KLEF60; KLEF63; KLEF64; KLEF23; KLEF50; KLEF51; KLEF53; KLEF03; KLEF40; KLEF41; KLEF43; or KLCD10/KLDC10 in combination with ICD10 diagnose DN81.x) (An exact and updated list of included surgical codes is found in the latest annual report).[3] Data collection starts from referral to hospital and ends at the postoperative control. All information is manually and consecutively entered by the respective hospital departments and private hospital/clinics into a web-based national input module designed and stored exclusively for DugaBase. The number of procedures per year is around 4,100 POP-related surgeries. The number of UI-related surgeries has decreased from 1,545 in 2010 to 1,164 in 2014. By November 2015, the total number of procedures recorded in DugaBase was 41,000.

In Denmark (population ~5.5 million people), all citizens have free access to a tax supported health care system, and its uniform organization allowed us to use a population-based study design.[4] The availability of nationwide Danish registries makes it possible to retrieve data from The Danish National Patient Registry (NPR) about patients undergoing urogynecological surgical procedures, defined by the relevant surgical code. In general, the NPR is of high quality with positive predictive values of 94%–100% for surgical procedures[5–7] and is therefore used as gold standard for the completeness of DugaBase. (Database completeness is here defined as entities that as a minimum contain a personal ID number linked to a surgical code and a date matching the data in the NPR). In 2010, the completeness for UI was 89.2% and for POP 86.7% using the NPR as reference.[8] Since 2011, DugaBase contains more than 90% of all UI and POP procedures using the NPR as gold standard.[9] In order to achieve and maintain the high database completeness, the departments performing urogynecological surgery can continuously compare data on patient ID linked to surgical code from the NPR with the data entered into DugaBase. The completeness of the datasets (apart from the ID, surgical code, and date of surgery) varies, ranging from 39% for data on alcohol intake to 99% for data on symptoms.[9]

Main variables

The DugaBase data consist of six parts: Part one contains basic information on referral, such as referral diagnosis, date of referral, and referring party. Part two contains information from a validated patient questionnaire on symptoms and disease-specific quality of life[10,11] and information on parity, mode of prior deliveries, prior urogynecological surgery, current tobacco and alcohol consumption, and height and weight. Part three is a questionnaire which is completed by the gynecologist, based on a preoperative POP examination and, if relevant, urodynamic measurements as well as data on the patient's preoperative status according to the American Society of Anesthesiologists classification. Part four includes information about the surgical procedures, the surgeons' experience (self-reported total number of the same procedure), and company-specific products (mesh types/sling materials). The fifth and sixth parts record follow-up data entered respectively by the patient and the physician. The patient's part includes the same validated questionnaire as part two to allow assessment of improvement. The physician records possible complications and reoperations occurring after discharge from hospital as well as a final status. The follow-up part is usually completed within 3–6 months of surgery.

A full list of variables (in Danish) is available at the database website.[12]

The variables form the background for a set of 16 clinical quality indicators (see Table 1). The clinical quality indicators are defined and revised by the steering committee. The indicators are chosen in order to monitor key points in clinical quality, such as patient satisfaction and reoperation rates, which by the steering committee are considered as logical endpoints. One of the 15 indicators represents waiting time from referral to first visit, as this indicator is regulated by law. Data on process are not being used as indicators at the present time, but this is under consideration.

Each department's performance with regard to these quality indicators is calculated and presented in an annual report with the comments and recommendations of the steering committee and eventual comments from the gynecological departments involved. Moreover, the annual report contains additional information on various aspects, such as database completeness, annual trends in quality indicator results, and descriptive statistics.

Table 1 10.3 Clinical indicators

Indicator number and domain	Indicator	Type	Standard (%)
1. Waiting time 30 days	Time from receipt of referral at the hospital to the first visit to the hospital	Process	Minimum 90
3. UI: subjective patient assessment of success	Subjective patient assessment of success after surgery for UI	Result	Minimum 70
6. POP: objective score on POP after surgery[a]	Objective measure of success of surgery for POP, assessed by grade of prolapse. The goal is ≤ stage 1	Result	Minimum 90
7. POP: subjective patient assessment of success	Patient satisfaction after surgery for POP	Result	Minimum 80
9. UI: further need for treatment[b]	Need of further treatment after surgery for UI	Result	Maximum 10
10. POP: further need for treatment[b]	Need of further treatment after surgery for POP	Result	Maximum 10
11. UI: reoperation 2 years after sling surgery	Reoperation 2 years after sling surgery following UI recurrence	Result	Maximum 5
12. UI: reoperation 5 years after sling surgery	Reoperation 5 years after sling surgery following UI recurrence	Result	Maximum 5
13. Reoperation 2 years after surgery for POP in anterior compartment	Reoperation 2 years after operation for prolapse in the anterior compartment	Result	Maximum 5
14. Reoperation 5 years after surgery for POP in anterior compartment	Reoperation 5 years after operation for prolapse in the anterior compartment	Result	Maximum 10
15. Reoperation 2 years after surgery for POP in middle compartment	Reoperation 2 years after operation for prolapse in the middle compartment	Result	Maximum 5
16. Reoperation 5 years after surgery for POP in middle compartment	Reoperation 5 years after operation for prolapse in the middle compartment	Result	Maximum 10
17. Reoperation 2 years after surgery for POP in posterior compartment	Reoperation 2 years after operation for prolapse in the posterior compartment	Result	Maximum 5
18. Reoperation 5 years after surgery for POP in posterior compartment	Reoperation 5 years after operation for prolapse in the posterior compartment	Result	Maximum 10
19.[c] Subjective patient assessment after surgery for UI using the PGI-I scale	Subjective patient assessment after surgery for UI using the PGI-I scale	Result	Minimum 90
20.[c] Subjective patient assessment after surgery for POP using the PGI-I scale	Subjective patient assessment after surgery for POP using the PGI-I scale	Result	Minimum 90

Notes: [a]Indicator stopped in 2013; [b]indicator stopped in 2015; [c]indicator introduced in 2013. The clinical indicators used for annually reporting from the DugaBase (2015).
Abbreviations: DugaBase, Danish Urogynaecological Database; UI, urinary incontinence; POP, pelvic organ prolapse; PGI-I, Patient Global Impression of Improvement.

Further follow-up

Apart from the follow-up included in each course, no other follow-up is planned. As the collection of data is ongoing, any recurrent surgery will be recorded in the database. This is monitored by quality indicators of recurrent surgery within 2 and 5 years after primary surgery (see Table 1, indicators 11–18).

Examples of research

DugaBase has provided data for several published articles and a PhD thesis[13] and a number of publications and theses are in progress.

A validation study showed that the overall percent agreement between DugaBase data and data compiled from the medical records was at least 90% for a number of key variables.[8]

The use of patient reported outcome measures has been found to be a valid tool for monitoring success of treatment for this group of patients.[14] A study has shown how the use of anti-incontinence medicine preoperatively is a strong predictor for continued use of the same kind of medicine after incontinence surgery.[15]

The mentioned publications have reported both on matters of national interest (differences in registration between public and private hospitals within Denmark)[16] and of international interest as the DugaBase has been part of an international study comparing POP and IU surgery in the OECD contries.[17]

Administrative issues and funding

DugaBase is a national clinical database approved by the Danish Health and Medicines Authority to monitor the health professional services in this disease area (record no. 7-201-03-11/1/KIKR). For all public and private departments and clinics, it is mandatory by Danish law to

report data to an approved national clinical database. Further individual patient consent or Ethics Review Board approval is not required according to Danish law when the data are used to monitor, secure, and improve the quality of the surgical procedures.

DugaBase is funded by the Danish Regions (the Danish public authority running the secondary health care). It works within the framework of the Danish Clinical Registries (RKKP) by Danish Regions. The database has a steering committee consisting of clinical urogynecologists from all regions and representatives with epidemiologic and data management expertise.

The institution responsible for the epidemiological and biostatistical support, including preparation of annual reports, is the Center for Clinical Epidemiology, Odense University Hospital. The annual reports and further information about the database (in Danish) can be accessed by the database website.[12]

Conclusion

DugaBase is an established well-validated database recording variables from around 90% of all POP and UI surgeries in Denmark. The variables are recorded along the course of contact to the hospital from which the patient is referred to a 3–6 month postoperative control. The variables consist both of physician and patient reported data. An annual report is produced focusing on a number of clinical quality indicators concerning surgical complications, patient reported outcome measures, and recurrence of surgery.

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