TECLA - an innovative technical approach for prostate cancer registries

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AbstractObjective: To present a code-driven, electronic database for patients TrEated with robotic-assisted radiCaL prostAtectomy (TECLA), developed at Innlandet Hospital (IH), Trust, Norway, for research, local quality control and to deliver data to the National Cancer Registry of Norway (CRN). Clinical data are directly extracted from the structured documentation in the electronic medical record (EMR).

Materials and Methods:

The urological department at IH treats about 200 patients with robotic-assisted radical prostatectomy (RARP) annually. All consenting patients registered with the procedure code for RARP are included in TECLA. Clinical data are obtained automatically from the EMR, by structured forms. Patient-reported outcome and experience measures (PROMs and PREMs) are filled in by the patients on an iPad or a smartphone.

Results: The basic construct of TECLA is presented. From August 2017 to June 2018, 200 men were treated with RARP, of which 182 (91%) provided consent for inclusion in the register. Of these, 97% completed the PROM survey before treatment and 91% at 3 months follow-up. PREMs were completed by 78%. All clinical variables for the hospital stay and for the 6-week follow-up were more than 95% complete.

Conclusion: This entirely electronic surgical quality register is easy to use, both for patients and clinicians, and has a high capture rate. The data collection is linked to the clinicians' workflow, without double data entry, so entering data does not add any extra work. The register design can be used by other hospitals for various surgical procedures.

Introduction: Prostate cancer is a leading cause of morbidity and mortality worldwide [1], and is the most common cancer among Norwegian men with about 5000 new cases each year [2]. For patients with localized or locally advanced disease and a life-expectancy of more than 10 years, radical prostatectomy is an established treatment [3]. In Norway, the standard procedure for surgical treatment is robotic-assisted radical prostatectomy (RARP). Relative survival 5 years after prostatectomy is about 98% [2]. Although the main aim is oncological control, minimizing treatment side-effects, particularly functional deficits (such as urinary leakage and sexual dysfunction), is essential to maintain quality of life (QoL). To assess the quality of radical prostatectomy, precise registration of procedure-related variables and clinical outcomes, including PROMs, is needed [4]. Furthermore, evaluating the quality of treatment and care from the patients' perspective through patient reported experience measures (PREMs) is recommended [5, 6].

There are several prostate cancer registries throughout the Western world, both population-based and procedure specific institutional registries [7]. The usefulness of clinical registries is often limited by missing data and poor capture rate [8]. Ideally, more than 90 % of the patients should be included [9]. Another problem is that few existing registries, especially those that are population-based, include PROMs and PREMs [7], and if PROMs and PREMs are included, the response rate is often poor [8]. Automatic capture of clinical data from the electronic medical record (EMR) and web-based PROMs and PREMs might enhance adherence and data completeness [8, 10, 11]. Some multi-institutional registries, such as the AQUA registry, extract data from the EMR [4]. This is, however, not routinely done because of the many different technological solutions and EMRs, which make the process expensive.

The Cancer Registry in Norway (CRN) is generally regarded as comprehensive and reliable [7]. It is based on the histopathology reports and clinicians are mandated by law to report data to the registry. The CRN captures histopathology data for 99 % of the newly diagnosed prostate cancers, but clinical data was reported missing for 32% of men diagnosed in 2016 [2]. One reason for this might be that it is time-consuming for the clinicians to complete the online form used for reporting. Automatic extraction of data from the electronic medical record (EMR) is not possible. Moreover, functional outcomes were until recently not included and clinical follow-up data are still not collected.

As the incompleteness of clinical data hampers the utility of CRN for quality control, we decided to develop a local electronic procedure-specific registry that is fully integrated with the EMR: TrEated with radiCaL prostAtectomy (TECLA). This article describes how TECLA is constructed, and reports adherence, data quality and completeness during the first ten months of use in its present form. Furthermore, potential improvements and future directions of clinical databases are discussed.

Materials and methods:

Setting

The urological department at Innlandet Hospital Trust serves a population of 400 000 people. Robotic-assisted radical prostatectomy (RARP) was introduced in March 2014. The annual number of RARPs has since then been approximately 200, divided between three urologists.

Development of TECLA

Our local radical prostatectomy database, TECLA, has been developed by the Information Technology Section at Innlandet Hospital Trust in close collaboration with the urological department. The process started in 2013 and since then TECLA has been revised several times. The latest version, which is fully integrated with the EMR, was introduced in August 2017.

Patients

Since the introduction of robotic surgery in 2014, all consenting patients who underwent RARP and were able to complete patient-reported questionnaires (fluent in Norwegian, orally and writing) were prospectively included in TECLA. The present analysis includes patients from August 2017, when the latest version of TECLA was launched.

Variables registered in TECLA

TECLA includes electronic documentation about opt-in consent, administrative data, clinical data, PROMs and PREMs (Table 1). Clinical data are registered prospectively. PROMs are registered before surgery (baseline), and 3 and 12 months after surgery. PREMs are registered just before discharge after surgery and 12 months after that. The Expanded Prostate Index Composite for Clinical Practice (EPIC-CP) is used for PROM assessment and an adapted version of Quality from the Patients Perspective (QPP) for PREM assessment [12], [13]. Surgical complications are registered using the Notable Outcome and Trackable EventS (NOTES), developed by the MUSIC collaboration in the state of Michigan [14]. NOTES contains various variables for surgical complications and quality: estimated blood loss (EBL) of more than 400 ml, rectal injury (yes/no), drain for more than two days (yes/no), readmission (yes/no), 30-day mortality, replacement of catheter (yes/no), catheter for more than 14 days (yes/no), and length of stay more than two days (yes/no).

Results

The construct of the database

Data entry into the register is closely linked to the clinicians' workflow. Clinical data are entered into the EMR using structured, XLM formatted forms instead of text. This allows automatic data extraction from the EMR to TECLA, hence double registrations are avoided.. The structured forms are made up of boxes with drop down menus, and work simultaneously as documentation in the EMR and as registration forms (Fig 1). The forms remain in the EMR, containing the most essential clinical information related to the RARP procedure. Additional information that is required is added to the EMR as text according to routines. There are three forms: Form 1 encompassing administrative and clinical data at the time of surgery, Form 2 for the final histopathology report and Form 3 for follow up data.

Data are registered in seven different steps (Fig. 2), starting at the preoperative outpatient visit.

In the initial step, an electronic consent form, approved by the Regional Ethics Committee and by the Data Protection Official at our institution, is presented to the patients. EPIC-CP is completed by the patient using a tablet, by which the patient also completes the electronic documentation of informed consent. The EPIC-CP responses and the consent are then automatically transferred to a secure server.

The second step is at the time of the operation. TECLA is driven by the procedure code for RARP, so when the surgeon registers this code in the EMR, the patient is included into TECLA, provided that consent to participation also exists. At the time of the operation, the first structured form (Form 1), (Table 1) for clinical data is also completed by the surgeon.

In the third step, the patients complete an electronic version of the PREM survey (QPP), using an iPad before discharge. The data are automatically imported into TECLA.

The last four steps combine the remaining structured forms (Form 2 and 3) and electronic surveys. The histopathology report is transferred to Form 2 by a secretary (step 4 of Fig. 2 and Table 1). This procedure is necessary as the Department of Pathology does not use EMR. Clinical follow-up data at 6 weeks, 3 months and 12 months post-surgery are obtained using the structured Form 3, completed by a registered nurse (step 5 of Fig. 2 and Table 1). EPIC-CP is completed by the patients at the 3 months' and 12 months' follow-up visits, and QPP at 12 months. Non-responders and patients who prefer follow-up by their general practitioner, will receive a reminder by email.

TECLA is designed to deliver data to the Cancer Registry in Norway. This pathway is approved, but not established. All data are stored locally.

Registrations completed August 2017 to June 2018

Between 1st August 2017 and 8th June 2018, 200 patients underwent RARP. Three patients were not included into the database as they were not Norwegian speaking, and 15 did not provide informed consent, leaving 182 (91%) of the eligible patients for follow up in TECLA. By September 2018, all of these patients had a minimum follow-up time of three months. EPIC-CP was completed by 176 patients (96.7%) at baseline and 165 (90.7%) patients after 3 months. The QPP administered before discharge was completed by 142 (78 %). For all patients, the structured forms 1 (at the time of surgery), 2 (pathology report), and 3 (follow-up form) were completed and transferred to TECLA. Table 2 demonstrates the completeness of data. Descriptive statistics of the population are presented in Table 3.

Discussion

In its current form, TECLA is completely integrated in the EMR and data entry is linked to the patients' peri- and postoperative journey. Clinical data are obtained as a natural part of the clinician's workflow and registration with structured forms in the EMR avoid parallel data entry. PROMs and PREMs are electronically registered and automatically transferred to the database. During the first 10 months of functioning, the vast majority of eligible patients were included and the overall compliance was good, indicating that TECLA is easy to use both for clinicians and patients.

In comparison to other and larger registries, the completeness of the data in the present version of TECLA is good, and fully complies with the requirements that a clinical registry with good quality should include more than 90 % of the eligible population [9]. TECLA was planned not only for quality control but also for research, we chose opt-in consent for inclusion. Experience from Australia suggests that opt-out consent is associated with higher participation [9]. As the main reason for non-inclusion into TECLA was lack of informed consent, a change to opt-out consent might improve the capture rate.

The small proportion of missing data shows that compliance is excellent among patients, surgeons, and registered nurses, and patient adherence demonstrates that PROMs and PREMs can be successfully obtained when questionnaires are presented electronically as a natural part of the patients' journey. The structured forms, integrated into the patients` EMR, are basic components for registration of clinical data into TECLA. Being a part of the EMR, these forms provide a simple, but clear overview over the essential clinical data related to the patients` disease, RARP procedure and follow-up, and stand alone as documentation in the EMR. With further improvement, they may also be the basis for information to the referring

physician. More importantly, the structured forms enable easy transferal of data without adding work-load for the surgeons, and contribute the observed completeness of data. Structured documentation with boxes and drop-down menus enhance capture rate and reduces the risk of human error. Another factor that may contribute to success is that a local database can provide immediate feedback to the responsible clinicians on their performance, and thereby highly motivate their adherence. Automatic extraction from the EMR do not require extra staff, hence it is efficient and cost-effective. Local solutions, like TECLA could, therefore, can act as a cornerstone in larger networks of registries. Provided that systematic surveillance of the database is also organized (e.g. by a local nurse), missing clinical data can easily be retrospectively entered into the structured forms to further improve completeness. For TECLA this is easily done through the structured EMR forms as the most recent version of each form is automatically transferred to the TECLA database.

To adequately assess health care quality and promote person-centered care, a clinical database must include PROMs and PREMs [15]. However, only about one-third of established clinical databases include PROMs. [9]. TECLA includes both PROMs and PREMs. For PROMS, we have chosen to use the EPIC-CP. Other options for PROMs include quality of life questionnaires, such as The Functional Assessment of Cancer Therapy Prostate Instrument (FACT-P) [16] and EuroQual-5D (EQ-5D) [17]. EPIC is, however, well-validated and frequently used to assess outcomes of prostate cancer surgery. Several versions of varying comprehensiveness exist [12]. EPIC-CP is the shortest, but it gives the information needed to evaluate the central outcomes after prostatectomy. Thus, to minimize the burden for the patients, and thereby potentially enhance compliance, we chose EPIC-CP and found it to be appropriate for our purpose. For PREMs, our assessments are based on the QPP short form [13]. This questionnaire has formerly been used and validated in a variety of other settings [18], and has the advantage to assess both the patients' perceived reality and their

evaluation of the subjective importance of care aspects. Information from the QPP will therefore allow us to implement quality improving measures targeting the aspects that the patients regard as most important. For the present context, RARP specific questions were added, which will be validated and potentially revised with the aim of making this RARP specific version of the QPP recommendable for general use. For the assessments of surgical complications, we chose NOTES rather than the more commonly used Clavian-Dindo classification because it includes objective data that can be easily measured. TECLA thus fulfills the standard criteria for evaluation of the quality of care for prostate cancer patients, and facilitates comparisons of our results with results from other institutions.

We believe that digitalization and automatic extraction of clinical data from the EMR to quality registries are essential for a successful quality control of health care services. A well-functioning local registry like TECLA is an excellent basis for local quality control. This includes being a measure to improve the performance of individual surgeons. Each surgeon will for instance have immediate and continuous access to their proportion of positive surgical margins and the location of such margins. In our unit, this information is actively used in the training of less experienced surgeons, and for consecutive evaluation of their improvement. TECLA is also an important basis for research. Inclusion of baseline PROM data and introduction of QPP enable publications of real life data from a non-selected cohort and quality of care from the patients` point of view. However, the value of a local, single institution registry is limited if its data cannot be delivered to other registries. TECLA is designed bearing this in mind. Data may easily be exported to the Cancer Registry in Norway (CRN), and enhance the capture rate of this registry. Deliverance of clinical data is approved, but not yet established, and the patients consent form has to be revised before a link to the CRN commence. Principally the structured forms are modified text-documents, and can be adopted by other hospitals with different EMRs, also abroad. The main advantage is the

usability of TECLA, and only minor efforts are required to adapt the system to other patient groups and procedures. As a code-driven system, the use is limited for non-surgical patients without a medical procedure code.

In conclusion, TECLA is a locally developed database for quality control of radical prostatectomy that automatically imports data from the EMR, as well as from electronic PROM and PREM surveys, and can export data to the national registry. TECLA's basic construction can easily be transferred to other surgical procedures and health care settings, and minimize the burden for clinicians to deliver data to clinical registries. The TECLA platform is free to use by other hospitals, and we are happy to support the initial set up in centers that wish to use TECLA.

Disclosure statement

No potential conflict of interest was reported by any of the authors

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