



Retrospective analysis of a surgical innovation using the IDEAL framework: radical cystectomy with epidural anaesthesia

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Abstract

Objectives: To retrospectively analyse experience of radical cystectomy using spinal/epidural anaesthesia and to classify this method using the IDEAL criteria.

Methods: Data from patients who had undergone radical cystectomy using spinal/epidural anaesthesia were evaluated retrospectively, focusing on clinical data, intraoperative and perioperative parameters and postoperative complications. Current literature reporting on this technique was reviewed and, together with the present study, evaluated according to the IDEAL recommendations.

Results: Three male patients aged 66–79 years who had undergone radical cystectomy with epidural anaesthesia were identified. The operating time ranged from 159–261 min and only minor complications occurred. Between 2013 and 2015, three published studies reported experiences with radical cystectomy with epidural/spinal anaesthesia; one was prospective and two were retrospective in nature and they included a total of 55 patients. According to the IDEAL classification, the present study corresponds to stage I (idea) and overall the surgical technique can be ranked as stage 2a (development).

Conclusions: Radical cystectomy with epidural anaesthesia is feasible and applicable for those who are not fit for general anaesthesia. The present study confirmed the functional results of this technique, which can be classified as IDEAL stage 2a on the basis of published studies.

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Introduction

The introduction and description of new surgical methods, surgical innovations or variations in procedures do not yet follow clear standardized paradigms as is the case with the introduction process for new drugs. In contrast to the mandatory algorithm of the phase I to III clinical trial development process for the approval of a new drug, a surgical method or innovation currently needs neither to show evident study or functionality results nor superiority to a comparable method or product before being introduced into clinical practice. There is a need for the development of international standards for the reporting of surgical outcomes and contextual factors.

The current scientific literature provides a large number of publications about surgical procedures and their variations. It includes case reports, small and large case series and clinical, even randomized trials, meta-analyses and reviews concerning specific techniques. A new reporting approach, the IDEAL (Idea, Development, Exploration, Assessment, Long-term study) framework, was proposed in 2009 by McCulloch and colleagues.¹ This descriptive framework provides clear stages of surgical innovation that allow every procedure or technique to be assigned to a particular level of development and evidence, based on factors such as the number of treated patients, the type of report, the study design and the aim of the report. As the IDEAL framework is a new, preferably prospective strategy that has not yet been widely used in surgical science, the amount of data collected in order to classify a surgical method according to the IDEAL criteria is considerably limited to date. Although prospective data employing IDEAL criteria is limited, the large amount of

conventionally published data allows retrospective classification of a surgical method using this new concept. Several publications have reported innovative approaches in urology using the IDEAL framework.²⁻⁶ The present study retrospectively analysed the IDEAL status of radical cystectomy with epidural anaesthesia.

Radical cystectomy is the gold standard for the treatment of localized urothelial muscle-invasive bladder cancer.⁷ For patients with reduced performance status, relevant co-morbidities or advanced age, radical cystectomy using local or exclusive spinal and/or epidural anaesthesia has been described by several groups.⁸⁻¹⁰ These case series have reported on the feasibility of this method and have described the benefits relevant for patient outcomes. In the present study, experience with radical cystectomy using local or exclusive spinal/epidural anaesthesia at the University Hospital for Urology, Klinikum Oldenburg, Oldenburg, Germany, is reported and compared with existing published studies, and the method is classified according to the IDEAL criteria.

Patients and methods

Patients

Patients with an American Society of Anesthesiologists (ASA) physical status classification of II–III who had undergone open radical cystectomy with extended lymphadenectomy and urinary diversion under spinal/epidural anaesthesia in the period from November 2013 to May 2015 in the University Hospital for Urology, Klinikum Oldenburg, Oldenburg, Germany, were included in the retrospective analysis. These patients were either deemed unfit for general anaesthesia due to the presence of

severe comorbidities or did not consent to general anaesthesia. The innovative character of this anaesthesiological approach for ablative tumour surgery was explained in detail to the patients and all patients gave written informed consent.

All patients underwent a standardized preoperative assessment including laboratory tests and staging with at least abdominal and thoracic computed tomography scans and ultrasound of the upper and lower urinary tract.

Data relating to their hospital admissions were collected from patients' records. Follow-up data covering a period of at least 1 year were obtained from outpatient records from the University Hospital for Urology or other office-based urologists.

Surgery

Bowel preparation was performed 1 day before surgery. Radical cystectomy with pelvic lymph node dissection was performed by a single surgeon as open surgery using a median lower abdominal laparotomy. In male patients, the prostate and seminal vesicles were also removed. In order to keep the peritoneal cavity closed for as long as possible, an ascending approach for bladder preparation was used, and modified when technically necessary. Lymph node dissection was performed in the regions of the internal and external iliac vessels and the obturator fossa bilaterally.

Data relating to transfusion requirements, operation time, intra- or perioperative minor and major complications, the potential need for extended monitoring or a prolonged stay in the intensive care unit were recorded. Complications were classified following the Clavien–Dindo recommendations.¹¹

Anaesthesia

Prior to surgery, all patients were discussed in a multidisciplinary team meeting

including urologists, surgeons and anaesthetists to determine intraoperative treatment strategies. Anaesthesia was started with the application of standard anaesthetic monitoring (invasive or non-invasive blood pressure, electrocardiography and oxygen saturation) and insertion of two at least 18G peripheral cannulas into the hands or forearms. Injections were performed under aseptic conditions and after application of 2–5 ml lidocaine 1% to the skin.

Epidural anaesthesia was applied between vertebrae T11 and L2. In a midline approach using a 17G Tuohy needle, the epidural space was identified using loss of resistance to normal saline. An epidural catheter was inserted and a test dose of 2.5 ml of bupivacaine 0.5% with adrenaline 1:100 000 applied to exclude intravascular placement. A bolus dose of 10 ml ropivacaine 0.75% was then given, followed by a continuous infusion of ropivacaine 0.2% at a rate of 6–10 ml/h for 1–2 h. Successful placement of the neuraxial block was verified using pinprick and cold stimuli to the skin. A dermatomal level of anaesthesia up to T4 was deemed sufficient for surgery.

After surgery, patients were discharged to the intensive care unit for postoperative care. Patients without epidural catheters *in situ* received a patient-controlled analgesia pump (PCA) allowing a bolus administration of 3–4.5 mg of piritramide every 10 min when necessary. In addition, all patients received metamizole (up to 4 g/day) and oxycodone/naloxone (up to 40 mg/day) as part of their postoperative analgesic regimen. Epidural catheters and PCAs were usually removed after 5 days and the analgesic regimen of metamizole and oxycodone continued until discharge.

Grading according to IDEAL

The present study was classified according to the IDEAL criteria. In addition, a PubMed search for publications reporting on radical

cystectomy with spinal/epidural anaesthesia was performed, and the identified studies were also analysed in accordance with the IDEAL framework.

Results

A total of three patients who had undergone open radical cystectomy with extended lymphadenectomy and urinary diversion under spinal/epidural anaesthesia were eligible for inclusion in the study. Indications for surgery were muscle-invasive bladder cancer, recurrent high grade superficial tumours, and increasing frequency of non-endoscopically manageable bleeding. Radical cystectomy was performed with curative intent in all patients.

Patient characteristics and technical outcome

The characteristics of the three patients are summarized in Table 1. They were all male, with a mean age of 73 years (range 66–79 years). Two patients (both ASA III) had pulmonary disease (one had a history of chronic obstructive pulmonary disease and the other had pulmonary tuberculosis) and were therefore not recommended to undergo surgery under general anaesthesia and artificial respiration. One patient (ASA II) specifically requested epidural anaesthesia. None of the patients had received chemo- or radiotherapy prior to surgery. One patient had a previous medical history of radical prostatectomy for prostate cancer requiring intraoperative adhesiolysis. In addition, this patient presented with a congenital right-sided singular kidney. In this patient, an additional inguinal hernia was corrected with alloplastic mesh during the cystectomy procedure.

The mean operating time in this small cohort was 195 min (range 159–261 min); the type of urinary diversion performed was the main determinant of operating time. Two

patients received a transureteroureterocutaneousostomy, while one patient received an ileum neobladder, resulting in a prolonged operating time but not a prolonged hospital stay (Table 1). No major complications were observed intraoperatively or postoperatively. All patients stayed in the intensive care unit for 1 day postoperatively. The mean intraoperative blood loss was 1000 ml (range 700–1300 ml); no blood transfusions were required intra- or postoperatively. The mean hospital stay was 19 days (range 14–22 days).

Only minor postoperative complications occurred, namely temporary bowel paralysis ($n=1$), urinary infection ($n=2$) and peripheral nerve damage ($n=1$) (Table 2). None of the complications reached a Clavien–Dindo score higher than 2a. Those complications were not related to the specific technique used but are known postoperative events after cystectomy in general; for example, urinary infection can occur because of ureter stenting, temporary bowel paralysis can occur after neobladder construction, and peripheral nerve damage can occur after pelvic lymph node resection. All of these complications were resolved with conservative treatment.

IDEAL evaluation

Table 3 shows the five main stages of development according to the IDEAL criteria, with the respective specifications and requirements.¹² Table 3 also shows the classifications given to the present study and reports of the same procedure identified by a PubMed search.

The present report of three patients treated with radical cystectomy under epidural anaesthesia was classified as stage 1 (idea) using the IDEAL recommendations. The method was shown to achieve the therapeutic goal of treating multi-morbid patients with highly aggressive cancer by performing a radical complex tumour ablation under epidural anaesthesia and gives additional proof

Table 1. Characteristics of patients undergoing open radical cystectomy with extended lymphadenectomy and urinary diversion under spinal/epidural anaesthesia.

Sex	Age, years	ASA score	BMI, kg/m ²	Tumour type and stage ^a	Operating time, min	Blood loss, ml	Transfusion	Type of urinary diversion	Length of ICU stay, days	Length of hospital stay, days
Male	73	II	35	Diverticulum tumour: pT1 G3 pN0 R0	165	1300	None	TUUC	1	22
Male	79	III	22	TCCU: pT2a (is) pN0 L0 V0 G3 R0 Incidental PCa: pT2a pN0 L0 V0 Pn0 R0 G3, Gleason 3 + 3 = 6	159	700	None	TUUC	1	14
Male	66	III	27	TCCU: pT2a (in situ) pN0 L1 V0 G3 R0	261	1000	None	IN	1	20

ASA score, American Society of Anesthesiologists physical status classification; BMI, body mass index; IN, ileum neobladder; PCa, prostate cancer; TCCU, transitional cell carcinoma of the urinary tract; TUUC, transureteroureterocystectomy.

^apT, invasiveness of tumour assessed pathologically; G, tumour grade; pN, involvement of lymph nodes assessed pathologically; R, completeness of tumour resection; L, lymphatic vessel invasion; V, venous invasion; Gleason, primary and secondary Gleason grades.

Table 2. Postoperative complications following radical cystectomy with extended lymphadenectomy and urinary diversion under spinal/epidural anaesthesia.

Complication	n	Clavien–Dindo classification ¹¹
Temporary bowel paralysis	1	2a
Urinary infection	2	2a
Peripheral nerve damage	1	1

of this specific concept. The number of individuals required for stage 1 (from a single individual to a few) is achieved and adequate. The suggested method for stage 1 of case reports is also met.

The PubMed search for publications reporting on the same procedure identified three further studies.^{8–10} Two of these studies reported on series including more than 10 individuals.^{8,9} Of these, Friedrich-Freksa et al.⁸ reported on a prospective series, whereas Tzortzis et al.⁹ described their experiences retrospectively. However, both reports fulfil the criteria for stage 2a (development) in terms of the number of patients. They provide more data regarding the safety and efficacy of an established concept (at least at their institution) and discuss the best indications and probable variations of the approach based on their higher number of treated individuals and the respective learning curves. However, although the methods used correspond to stage 2a (development), these reports were not classified according to IDEAL in the original publication. An additional publication by Karl et al.¹⁰ reporting on nine patients may also be classified as stage 2a on the basis of the form of reporting. However, again this report was not labelled according to the IDEAL criteria.

Discussion

Radical cystectomy is the standard and most effective treatment option for high-risk or

Table 3. Stages of the IDEAL classification with classification of published reports on radical cystectomy with spinal/epidural anaesthesia (modified from McCulloch et al.²)

	Stage 1 Idea	Stage 2a Development	Stage 2b Exploration	Stage 3 Assessment	Stage 4 Long-term study
Purpose	Proof of concept	Development	Learning	Assessment	Surveillance
Number and types of patients	Highly selected	Few; selected	Many; may expand to mixed; broadening indication	Many; expanded indications	All eligible
Number and types of surgeons	Very few; innovators	Few; innovators and some early adopters	Many; innovators, early adopters	Many; early majority	All eligible
Output	Description	Description	Measurement; comparison	Comparison; complete information for non-RCT participants	Description; audit; regional variation; quality assurance; risk adjustment
Intervention	Evolving; procedure inception	Evolving; procedure development	Evolving; procedure refinement; community learning	Stable	Stable
Method	Case reports	Prospective development studies	Research database; explanatory or feasibility RCT (efficacy trial); disease based	RCT with/without additions; alternative designs	Registry; routine database; rare-case reports
Outcomes	Proof of concept; technical achievement; disasters	Mainly safety; technical and procedural success	Safety; clinical outcomes; short-term outcomes; patient-centred and feasibility outcomes	Clinical outcomes; middle-term and long-term outcomes; patient-centred outcomes; cost-effectiveness	Rare events; long-term outcomes; quality assurance
Ethical approval	Sometimes	Yes	Yes	Yes	No
Radical cystectomy with epidural anaesthesia	Present study (n = 3)	Karl et al. ¹⁰ (n = 9) Tsortzis et al. ⁹ (n = 18) Friedrich-Freska et al. ⁸ (n = 28)	Currently no report available	Currently no report available	Currently no report available

RCT, randomized controlled trial.

muscle-invasive bladder cancer. In addition to being the oncological treatment of choice, it also represents an option to manage cancer-related complications such as recurrent bleeding and hydronephrosis, positively influencing the quality of life of patients.¹³

The present study confirmed the feasibility of radical cystectomy performed under epidural anaesthesia on the basis of three patients with high-risk bladder cancer. This surgical approach seems to be a viable alternative without an increased rate of major complications for elderly patients and/or those with multiple comorbidities who are not fit for general anaesthesia.¹⁴ Those findings are supported by other previously published reports.⁸⁻¹⁰ In the future, the incidence of urological malignancies in Germany has been predicted to rise.¹⁵ In addition, the need for anaesthesiological alternatives to general anaesthesia for tumour ablative surgical procedures such as radical cystectomy is likely to increase, particularly in an ageing patient population with comorbidities.

Most of the patients who have undergone this type of surgical approach reported in the literature so far were male. This may be due to the higher prevalence of muscle-invasive bladder cancer in men.¹⁶ However, there may also be a bias towards surgery in men when introducing new techniques for radical cystectomy due to the higher peri-operative risk and technically more challenging procedures in women.¹⁷ When summarizing all available publications regarding the technique of radical cystectomy with epidural anaesthesia, it is clear that the method is still at the development stage (2a) according to the IDEAL criteria.

Including the present study, there are currently four reports of this technique, with the number of treated patients ranging from three to 28, giving a total of 58 patients. The IDEAL classification was applied here for the first time and the current stage of experience for radical cystectomy under

epidural anaesthesia became apparent. On the basis of the currently available literature, the method is still at the development stage (2a). The remaining IDEAL stages (exploration, assessment and long-term study) have not yet been met by the currently available evidence, neither in terms of the number of treated patients nor the study design. It is unlikely that this method will move beyond stage 2a because the requirements for both the numbers and the study design for the subsequent stages are unlikely to be met with such a narrow patient indication (Table 3).

Other authors have stated that further randomized studies are needed to show the superiority of this method over comparable techniques.⁸⁻¹⁰ However, it is unlikely that such studies will be conducted in the near future. For example, the next step according to the IDEAL criteria would be stage 2b (exploration), which requires prospective collaborative observational studies or feasibility randomized controlled trials including hundreds of patients (Table 1), but developing and conducting such a trial seems unrealistic for this method. As this technique is reserved for a very specific indication and patient subgroup, evidence of safety and efficacy, as required for stage 2a, may be accepted as sufficient and the highest quality level achievable.

Among the currently available studies of radical cystectomy with regional/epidural anaesthesia, only one was prospective in nature. Friedrich-Freska and colleagues⁸ reported on a group of 28 patients with muscle-invasive bladder cancer undergoing this technique who were prospectively observed from 2011 to 2012. According to the IDEAL criteria, this approach represents the closest analogy to the suggested form of reporting at the development stage, which recommends prospective rather than retrospective studies.¹² However, the optimal form of reporting for this stage is not yet met since key elements such as a prior,

officially registered protocol, clearly defined objective outcome criteria and sequential reporting of cases showing when changes in indication or technique are made¹⁸ were not present. At the time that the study of Friedrich-Freska et al.⁸ was planned and conducted, the IDEAL recommendations were not as widely known as today, which increases the value of the group's report as they already meet several of the basic IDEAL criteria. This also explains why their study was not labelled according to the IDEAL criteria. The IDEAL recommendations are still in the process of being developed, implemented and accepted for the reporting of surgical innovations. As the majority of surgical techniques and innovations have been reported on without labelling according to the IDEAL criteria, retrospective analysis of available literature may help to rank and evaluate particular techniques and their reporting quality. In addition it may also help to clearly define the current stage of development of surgical techniques. This is likely to encourage surgeons to use this pattern for reporting future innovations and will help to establish the new standard.

The development of international standards for the reporting of surgical outcomes and contextual factors, including a common terminology and taxonomy, is necessary, and a number of groups have contributed to this, such as the study by Dindo et al.¹¹ on the classification of surgical complications, and the COMET initiative's development of core outcome measures.¹⁹ It is likely that key outcomes (such as grading of functional performance and the scope and severity of complications) as well as contextual factors (such as grading of patient risk factors, the severity of comorbid pathology or general health, the scale of surgical insult, the environment for surgery and the urgency status of the performed procedure) will need consensus among specialist communities and specialities as well as journals in order

to standardize reporting.¹² The development of the IDEAL criteria is in its infancy, but the field of urology has provided several pioneer publications in this field. In particular, new robot-guided techniques have been reported in prospective fashion and are increasingly published as IDEAL adapted reports of surgical innovations.^{5,6,20} Although a new method or innovation should preferably be classified in a prospective fashion, it is not possible to evaluate the status of all the surgical techniques currently reported in the literature in this way. Therefore, retrospective analysis of the available data as used in the present study may be an appropriate way to analyse the current IDEAL status of published techniques.

In conclusion, the current study confirmed the feasibility and functional results of existing studies for radical cystectomy performed with epidural anaesthesia. For the first time this method was ranked retrospectively according to the IDEAL criteria, with the highest level for previously published reports of this method reaching stage 2a (development), whereas the current report was classified as stage 1 (idea).

Declaration of conflicting interest

The authors declare that there is no conflict of interest.

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