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Videotaping of surgical procedures and outcomes following extraperitoneal laparoscopic radical prostatectomy for clinically localised prostate cancer

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Key words: Prostate cancer, extraperitoneal laparoscopic prostatectomy, functional, oncological, record-linkage methodology

Running title: Videotaping in radical prostatectomy procedure

Synopsis: Videotaping of surgical procedure such as minimally invasive (laparoscopic) radical prostatectomy is likely to become essential record keeping in the future. The present study explored the relationship between independent quality appraisal of videotaped procedure (extraperitoneal laparoscopic radical prostatectomy) with patients reported outcomes (functional and early oncological). The quality of surgical procedures were assessed independently using a validated scoring system which predicted early resumption of continence, however failed to correlate with re-admissions, surgical margin status, or other complications.

Abstract

Background: Video-recording of emerging minimally invasive surgical procedures is likely to become an integral component of patient record-keeping in the future for prostate cancer treatment. No prior work has shown the impact of videotaping of laparoscopic prostatectomy on patient outcomes. Our aim was to determine correlation between independent peer review of videotaping quality scores of extraperitoneal laparoscopic prostatectomy (ELRP) with complications, re-admissions, functional and early oncological outcomes.

Study design, setting, and participants: We conducted a single-institution prospective cohort study comparing videotaping quality scores with the outcomes of ELRP in men with localised prostate cancer. Videotaping of surgical procedures were scored by two experienced laparoscopic surgeons using a validated scoring method. Validated record-linkage methodology and self-reported questionnaires were used to assess surgical complications, re-admissions, functional and oncological outcomes based on a common identifier called as community health index (CHI) number. Pearson correlation coefficients were calculated between the different covariates with statistical significance considered at $p < 0.05$. Multivariate analyses assessed oncological outcomes (positive surgical margins/biochemical recurrence), post-operative complications and re-admission into hospital following initial hospital discharge with quality of surgical procedure.

Results: 200 men were recruited into the study. 51 (25.5%) participants had post-operative complications. Record-linkage methodology identified 18 (9%) participants had re-admissions within 90 days of the procedure. 13 (6.5%) of these men required percutaneous drainage with hospital stay following re-admissions ranged between 3-12 days. 10 (5.0%) participants had intra/perioperative complications. 23 (11.5%) men reported to primary care physicians for various indications. Higher quality surgical technique videotaped scores (assessed by independent peer review) had a significant correlation with early continence recovery at 3 months post procedure, ($p = 0.013$), but lost statistical significance with overall continence at 1 year. No statistical correlation was observed between videotaped scores and oncological outcomes (positive surgical margins/biochemical recurrence), post-operative complications and readmission into hospital.

Conclusions: Quality of surgical procedure assessed by independent third party videotaping score predicted early resumption of continence following extraperitoneal laparoscopic radical

prostatectomy, however it did not predict complications, oncological or functional outcome as assessed using patient reported outcomes at 12 months.

Introduction

Traditional methods of surgical record-keeping, including hand-written or physician-generated electronic records, are often not informative to evaluate the quality of surgical procedures. With improvements in video-recording technology and data storage capacity, video records of surgical procedures should be incorporated into patients' health records, similar to imaging data such as MRI or CT scans [1]. Moreover, it is likely that video-recording would improve the quality of surgical care. Several studies have shown that video-recording changes the behaviour of healthcare professionals [2] or has a positive impact on treatment outcome [3, 4]. There are a number of medical procedures (cardiac catheterisations, arthroscopy, and upper gastrointestinal (GI) endoscopy) for which video documentation is an integral part of record keeping in routine practice, and it is timely that the record button is turned on for surgical procedures such as minimally invasive surgery in prostate cancer. There are no studies to date, addressing the impact of independent appraisal of video-recording with clinical outcomes or indeed, exploring the potential benefits of this approach with a particular focus on improving service quality, patient experience, functional and oncological outcomes.

In a well-conducted study, Birkmeyer et al., [5] reported a variation in surgeons' technical skill based on peer-rated video-recording, and clearly demonstrated its association with postoperative outcomes (complication, re-admission and mortality rates). Video-recording technology has enormous potential for use in real-time feedback and surgical skills education. The Society of American Gastrointestinal and Endoscopic Surgeons, in partnership with the technology industry, has approved videotaping as a method of mentoring and reviewing surgical technical skills and performance [6].

In a craft speciality, such as minimally invasive surgery, the technical skill of the operating surgeon may be as important, if not arguably more important than perioperative care in determining the outcome of the procedure for the patient. There are several intraoperative events in minimally invasive laparoscopic surgery for prostate cancer, such as bleeding, tissue handling, precise dissection in anatomical planes, devascularisation and reconstruction of anastomosis, that are dependent on the surgical skill of the operator. There are empirical reports that clearly indicate a correlation between the level of surgical skill and the duration of surgical procedures. The latter is

important, as data has clearly linked prolonged operating times to increased risks of infection and venous thromboembolism [7, 8].

The present study aimed to assess the association of independent quality appraisal of video-recordings for patients undergoing minimally invasive surgery for localised prostate cancer with patient-reported clinical, functional and oncological outcomes over time. Specifically, our objectives were:

1. To correlate the quality of surgical procedure (using validated quality appraisal methodology and independent review) with complication rates (both perioperative and community-based), re-admission rate, clinical, oncological and functional outcomes of ELRP over time.
2. To assess the technical skills of operating urological surgeons by independent surgical review using a validated scoring system of videotaped surgical peri-operative procedure.

Patients and Materials

Study cohort and outcome assessment

This study had Institutional approval (Caldiott/CSAppGN021211). Between January 2010 and December 2014, 212 consecutive men underwent ELRP for clinically localised prostate cancer at one of the main cancer centres in Scotland, United Kingdom (UK). As described previously, Tayside Urological Cancer registry includes detailed information on demographic variables, comorbid conditions, the perioperative process of care, complications at 90 days, longer-term oncological and functional outcomes, including urinary incontinence, quality of life and erectile dysfunction [9]. All procedures were performed by one surgeon (GN). Patients who had received neoadjuvant hormone therapy (2 patients) or surgery following failed radical radiotherapy (10 patients) were excluded from the analyses. All patients were followed-up at 6 weeks and 3, 6, 9 and 12 months post ELRP. The surgical procedure has been previously described [10]. Pelvic lymphadenectomy was performed on all patients with a PSA >10 ug/L and a Gleason ≥ 7 . All pathological ELRP specimens were reviewed by a senior uropathologist (SL) and discussed in multidisciplinary team meetings.

Video-recording and peer review rating

All procedures were recorded using a Storz video-recording system (<https://www.karlstorz.com/ae/en/telepresence.htm>). Videos were stored and edited to remove all but the critical steps of the ELRP procedure and deconstructed into 8 step-wise components: apical dissection, dorsal venous complex control, intrapelvic urethral length, bladder dissection, including bladder neck preservation status, posterior dissection, including status of neurovascular bundles, posterior repair of tissues, quality of anastomosis, and suspension of bladder neck (anastomosis). A standardised pro forma checklist was implemented to edit video-recordings to capture the 8 step-wise components, the length of video-recordings ranged from 3-5 minutes. We evaluated the quality of the video-recordings by using a standardised scoring system called the Video Recorded Extraperitoneal Laparoscopic Radical Prostatectomy Score (VELP-Score) [11] for men with postoperative morbidity and re-admission [12].

The 8 step-wise components of surgical procedure were rated on a quality score that ranged from 1 to 3. A quality score of 1 was defined as poor surgical quality in operator ability, with a score of 3 classified as good surgical quality in operator ability, for each of the 8 components (see **Appendix 1**).

The quality appraisal of surgical skill for each of the components were summarised into three categories: score 10 and lower as poor quality; 11 to 18 as intermediate quality, and 19 or more as good quality surgical skill, previously defined [11, 12].

The video-recordings (2-3 minute length of each step) were distributed for peer review by experienced surgeons (with teaching and training experience in laparoscopic surgery atleast of 5 years) using the VELP-Scoring system. The independent peer review surgeons were unaware of the patient outcomes and were not involved in any of the surgical procedures.

Outcomes

The primary outcome was to assess correlation between quality of surgery (videotaped procedures by independent peer review) with postoperative complication immediately after surgery or within 90 days of the procedures, re-admission to hospital, and functional and oncological outcomes. Surgical complications included: bleeding, infection, urinary anastomotic leakage and anastomotic stricture. Medical complications included pulmonary and cardiac complications, such as, thromboembolism. We also examined 120-day rates of death, unplanned re-operation, re-admission and emergency department visits. The latter is independently recorded by quality performance indicators of our health organisation as a part of national data collection process (http://www.healthcareimprovementscotland.org/our_work/cancer_care_improvement/cancer_qpis.aspx)

Community-based complications assessment using record-linkage methodology

The TUCAN (Tayside Urological Cancers Network Database) collects routine data from the population of urological cancers in Tayside, Scotland. National Health Service (NHS) Tayside serves a predominantly Caucasian rural and urban population of more than 405,721 based on mid-year 2011 population estimates published by the General Register Office for Scotland. The population is registered with a healthcare board through a unique number known as the Community Health Index number (CHI number). This healthcare region is served by 75 general practices and a single tertiary urological cancer service. All newly diagnosed cancers are reviewed by a local multidisciplinary team, and the meeting records are stored in a database called the 'Tayside Urological Cancer Network Database' [13]. Study data was collected using a validated record-linkage methodology and a unique single number (CHI), as described by our group(see **Figure 1**) [14] .

The variables included: need for antibiotics, self-referral to general practitioners (primary care physicians), re-admissions, peer-review of case notes and video-documented procedures from the following databases:

1. *Hospital-based daily electronic patient care plans*: these sources maintained data on all the urology admissions and in-patient records in a large region of Scotland for the past 10 years.
2. *TUCAN MDT records*: these records contained information on all the patients who had prostate specimen histopathology as well as recommendations of treatment options based on their pathological staging (including the need for salvage treatment). This is part of the requirement for quality performance indicators in Scotland, and is monitored independently by the Quality Improvement Team.
3. *Hospital electronic databases*: ICE (Integrated Clinical Environment); Insite (In House Surgical Information System Web and Technology; TOPAS (Patient Administration System); electronic documentation (Clinical Portal); video-recording system (Karl Storz; Qlikview), including microbiology database.
4. *The Scottish morbidity record (SMR1)*: These records hold a list of all hospital discharges in NHS Tayside and reasons for admissions and any transfer of care.

Functional and oncological outcome using Patient Reported Outcome Measures (PROMs)

Men were given the self-administered International Consultation Incontinence Questionnaire (ICIQ-UI) [15] at 3, 6, 9 and 12 months post-surgery by a nurse in the clinic. Continence was defined as using no pad or a safety pad [16] in a 24-hour period. Potency was assessed by asking patients if they experienced an erection and whether it was satisfactory for intercourse. The questionnaires were collected and analysed independently of the operating surgeon.

Statistical Analysis

Data were double entered into the Statistical Package for Social Sciences (SPSS, version 21). Pearson product moment correlation coefficients, paired sample t-tests, Chi-square and the Kruskal–Wallis H test were used. Continence rates were obtained using the principles of Kaplan–Meier analysis, the Log-Rank test, Breslow test and the Tarone–Ware were used. Inter-rater reliability analysis of the two independent surgeon's ratings using the VELD scoring system revealed substantial agreement (kappa = 0.62; $p < 0.001$). Similarly, record-linkage methodology using both deterministic and probabilistic methods showed a 100% match for various databases. We used multivariate logistic

regression for risk adjustment in assessing correlations between surgical skill (VELP-Score) and patients reported outcomes. Statistical significance was defined as $p < 0.05$.

Results

Surgical skills rating and complications

The mean age of the cohort was 65.7 (± 5.4) years, with a median follow-up of 26 months (range 6–60 months), see **Table 1**. There were 100 patients rated as good (mean 21.1 ± 2.9), 93 rated as intermediate quality (16.8 ± 3.2) and 7 patients rated as poor quality (9 ± 1) using the VELP-Score classification. The mean operating time was 240 minutes (range 120 to 300). No man in this series required a blood transfusion, and there were no conversions to open surgery. There was one mortality during follow-up within 120 days. The man died from multiple pulmonary embolisms. In total, there were 51 complications during and over the course of follow-up after ELRP, see **Table 1**. One-hundred-and-forty-nine men (74.5 %) did not experience any post-surgical complications. Using the Clavien–Dindo Classification of Surgical Complications [17], complications were classified as Clavien grade I for 2 patients (minor bleeding, high Co^2 retention), grade II for 3 patients (sepsis, and post-op ileus), grade III for 23 patients (post-op bowel fistula, lower limb ischemia, bladder neck strictures, surgical clip migration to the anastomosis, bladder injury), grade IV for one patient (pulmonary embolism) and grade V (one patient died secondary due to multiple pulmonary embolisms). Three patients developed bladder neck strictures and required laser bladder neck incision. Two of these patients had clips migrated into anastomosis (**Figure 2 supplement**). The median hospital stay was 2 days (1–35 days), and the average duration of indwelling urinary catheter was 14 days (8–35 days). Only 4 men in this cohort had cystograms.

Record-linkage methodology showed that 19 (9.5%) patients had re-admissions within 90 days of the procedure for various indications including: urinary infection, haematuria, urinary leakage and pelvic collections. Of these men, 13 (6.5%) required percutaneous drainage and hospital stay following re-admission ranging from 3 and 12 days (median 4 days). Video clips (were independently peer reviewed using the VELP-Scoring classification. During the study period, 23 (11.5%) men reported to primary care physicians for various indications ranging from minor upper respiratory tract infection to suspected pulmonary embolism. The majority of these were catheter-related problems or urinary symptoms including incontinence (sometimes peri-catheter discharge).

Oncological outcomes

The pathological tumour stage according to the TNM classification is listed in **Table 1**. There were 13 staged pT2a, 3 were pT2b, 101 were pT2c, 52 were pT3a, 25 were pT3b, 5 were pT4 and 1 was positive for nodal involvement, pT2c, nN1. The majority of men (164; 82.0%) had a Gleason score ≤ 7 while 36 (18%) had a score ≥ 8 . Across the series, 72 (36%) men had positive surgical margins (49 with pT3a or more), of whom 21 (10.5%) had biochemical relapse and required salvage treatment (either hormonal therapy or radiotherapy to the surgical bed). Overall, the biochemical recurrence-free survival rate was 96.8% at 12 months. VELP score did not correlate with positive surgical margins or biochemical recurrences.

Functional and quality of life outcomes

Age, cancer stage, Gleason score, salvage treatment, number of pads used at baseline and preoperative PSA levels did not significantly affect recovery of incontinence as assessed by self-reported ICIQ-UI (121) at 12 months. As expected, a significant difference was found in the number of pads used by men at time 1 (3 months [median 3, min 0, max 5; 3.4, SD 2.6] and time 2 (6 months [median 3, min 0, max 4; 1.9, SD 2.1], $t(116) = 7.92$, $p < .000$ (two-tailed)), and at time 3 (9 months [median 1, min 0, max 3; 1.3, SD 1.4]) and time 4 (12 months [median 0, min 0, max 3; 0.9, SD 1.2; $t(102) = 4.875$, $p < .000$ (two-tailed)). Using the definition of 0–1 pads for continence in a 24-hour period, 91.5% of men were continent at 12 months (see **Figure 3** in supplementary information).

Kaplan–Meier curves were used to represent the return to baseline continence over time. There was a statistically significant trend of continence recovery being influenced by the involvement of physiotherapy. A log rank test was used to determine whether there were differences in the continence distribution for those individuals who received physiotherapy input and those who did not ($\chi^2(1) = 25.673$, $p < .000$). The potency rate was assessed in all the men; out of 150 men with nerve preservation surgery, 62 (40.6%) had either spontaneous erections or erections aided with phosphodiesterase inhibitors.

A significant difference was found in terms of overall quality of life at time 1 (3 months [5.59, SD 3.21]) and time 2 (6 months [7.37, SD 2.77], $t(77) = 5.008$, $p < .000$ (two-tailed)). No significant difference was found between the quality of life score between time 3 (9 months [7.82, SD 2.12]) and time 4 (12 months 7.87, SD 2.34). Using Pearson Product-Moment Correlation coefficients, no significant associations were found according to quality of life scores or the number of containment pads used at follow-up between the following variables: age, duration of urinary catheter, preservation of nerves, length of hospital stay, cancer stage, baseline PSA or most recent PSA. A

significant relationship was found between quality of life and the number of containment pads used at each follow-up time point (3, 6, 9, and 12 months) (see **Table 2**). Similarly, a significant correlation was found between VELP score and continence status at 3 months (detailed below).

Correlation between surgical skill and outcomes

There was no correlation between post-hospital discharge complications and surgical skills ($p = 0.230$). Most complications in this category were related to infection and required a course of parental antibiotics administration. Similarly, there was no correlation between hospital re-admission and technical skill ($p = 0.481$). Positive surgical margins were also not correlated with surgical skills; however, on multivariate analysis, Gleason scores on biopsies and clinical stage were a significant predictor of margin status on histopathology ($p = 0.001$). There were differences in incontinence rates between the three groups at 1 year, although patients in the good quality VELP score group achieved continence (no pads or one pad for protection) significantly earlier than those in the intermediate and poor groups (**Figure 4**; mean 2.6 months vs. 10.4 months; $p = 0.002$). Men with higher VELP scores required a significantly lower number of pads at 3 months (correlation between VELP score and number of pads at 3 months: $r = .35$, $p = .013$; Figure 5). This difference was independent of stage, grade, previous endoscopic surgery on prostate, socio-economic status, size of prostate, and co-morbid conditions. There was no correlation between VELP score and recovery of erection or need for treatment of erectile dysfunction.

Discussion

The present study is one of the first studies to prospectively evaluate patient outcomes following ELRP using a procedure-specific peer-review of videotaping, standardised instrument (ICIQ-UI) and validated record-linkage methodology to assess community-based complications within 90 days of the procedure. We acknowledge that using the ICIQ-UI evaluation is the gold standard for evaluating patient's health status [18], and controlling for variations in surgical ability and skill [19] was a strength of this study's methodology. The quality of data collection is fundamental to the reliability of the assessment of procedure-related complications. In this study, community surveillance after surgery (using record-linkage methodology and CHI number) found that around one in ten men had problems and reported to healthcare professionals in the community for complications that previously, had not been recorded by the standard follow-up procedures and existing record-linkage methodology studies using administrative data [20, 21]. More importantly, these complications were not related to the technical skill of the surgeon. In contrast to many population-based studies reporting surgical complications [20, 21], the region where the present study was conducted has a unique CHI number for each inhabitant, which facilitated healthcare information to be securely stored for analyses in one safe complaint database. The aggregation of information without such a unique identifier is difficult and possibly unreliable. The region serviced by the institution in the present study has a stable population of more than 400,000 individuals and a migration rate of less than 1%; hence, all patients were followed-up closely with no risk of loss of follow-up. Many issues related to surgery become apparent after discharge from hospital in the weeks following surgery and are treated in the community. Such community based complications have remained unknown, up until now.

Technical skills rated by peer surgeons did not predict complications following surgery or re-admissions, and most of these issues were related to the overall care process, including catheter-related infections in the community. Working more carefully with community-based nurses and holistic need assessment of individual patients with evidence-based care plans prescribed at the

time of discharge may help in lowering these problems. Although general practitioners could provide the requisite information and treatment, we found a high incidence of general practitioners treating post-radical prostatectomy catheter-related issues with antibiotics when there was little evidence of infection.

A number of studies [22-24] have reported on system and process approaches for measuring surgical morbidity, however no studies have reported on independent peer review of intra-operative recordings as a tool for learning and improvement. With advancements in minimally invasive surgery and video-recording systems, we show in the present study that this approach is feasible and has the potential to improve surgical education, particularly that of trainees/residents. Re-admission following laparoscopic radical prostatectomy in the present study is 9%, which is similar to that shown in previous studies [25]. Anastomotic leakage leading to urinoma remained an issue despite good quality anastomosis, as seen in Figure 3. Video review (including estimation of VELS score) found no technical concerns, but other factors need to be studied. One such factor could be differences in the healing processes of individuals and possibly a differential rate of achieving bursting strength during healing. A number of reported technical variations [26-28] have been cited to overcome this challenge, however, none of these has been correlated surgical technique with hospital re-admission or long-term outcomes.

Urinary incontinence remains a recognised complication of radical surgery for prostate cancer, and data from the present study correlates technical skills with the early resumption of continence. Only two patients falling within category of good ratings scale of technical skills required physiotherapy visits and physio-supervised pelvic floor training compared to forty in the poor or intermediate group. None of the men in the good technical skills group needed surgery for incontinence. Our observation is not in isolation. Quality of surgery and detailed preservation of the sphincter has been related to improved continence rate [29, 30].

The single-surgeon design, videotaping of procedures, peer review process, validated record-linkage methodology and third party assessment of outcomes is advantageous to the study methodology as all patients received the same postoperative care and counselling. This allowed for a more critical comparison of oncological and functional outcomes following ELRP over time. Furthermore, the data in our study was gathered prospectively by a third party and assessed without the involvement of surgeon to avoid recall and reporting bias. We acknowledge limitations to our prospective longitudinal observational study. We did not use validated questionnaires to assess erectile dysfunction and instead asked a single question. Despite these limitations, this is the first study to

report community-based surveillance of complications within 90 days following ELRP using record-linkage methodology, video-recording review of surgeons' technical skills and their correlation with the outcomes.

Conclusions

Quality of surgical procedure assessed by independent third party videotaping score predicted early resumption of continence following extraperitoneal laparoscopic radical prostatectomy. The VELP scoring of videotaped procedures did not correlate with the complication (community/population-based), stage, grade, previous surgery, socio-economic status, functional or oncological outcome at 12 months of surgery.

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Legends for figures

Figure 1: Schematic diagram showing use of linkage methodology to assess complications and other clinical events following laparoscopic radical prostatectomy

Figure 2: Showing clip migrated into bladder from bladder neck

Figure 3: Recovery of continence after laparoscopic radical prostatectomy as assessed by patients reported outcomes.

Figure 4: Correlation between VELP Score and recovery of continence after laparoscopic radical prostatectomy

Supplementary Figure: Video showing quality of anastomosis (vesico-urethral)