SciMed Central

JSM Surgical Oncology and Research

Research Article

Comparison of Stress Response during Robotic-Assisted Versus Open Radical Cystectomy in Bladder Cancer: A Prospective Observational Study

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Submitted: 19 August 2016

Accepted: 21 September 2016

Published: 22 September 2016

ISSN: 2578-3688

Keywords

- Robot assisted radical cystectomy
- Open radical cystectomy
- Bladder cancer
- Cortisol
- Stress response

Abstract

Background: It not evaluated to what extent robot-assisted radical cystectomy (RARC) vs. open radical cystectomy (ORC) is associated with a stress response. This study evaluates the extent that RARC versus ORC is associated with a stress response, and hypothesized that plasma cortisol and catecholamine responses are smaller during RARC than during ORC.

Methods: Plasma for determination of cortisol and catecholamines was obtained before surgery, after resection of the bladder, and at the end of surgery for 20 RARC and 20 ORC procedures. A prospective, one university/tertiary centre observational study.

Results: Preoperative characteristics were not significantly different between RARC and ORC groups. During both RARC and ORC plasma cortisol was reduced with the lowest values after RARC (56 vs. 92 nmol/l, P=0.004). Plasma adrenaline also decreased, while plasma glucose increased during surgery without significant difference between groups. The duration of surgery and consequently the use of remifentanil was high in the RARC group (P=0.0001 and P=0.001) and the decrease in plasma cortisol was related to dose of remifentanil (r = -0.718, P=0.0001) besides to duration of surgery (r = -0.715, P=0.0001).

Conclusion: Both plasma adrenaline and cortisol decreased during surgery and the decrease in plasma cortisol was pronounced during RARC related to the duration of the procedure. Thus under cover of propofol-remifentanil anesthesia cystectomy is not associated with a significant stress response.

ABBREVIATIONS

CO: Cardiac Output; GDT: Goal Directed Fluid Therapy; HPA: Hypothalamic-Pituitary-Adrenocortical; HR: Heart Rate; MAP: Mean Arterial Pressure; ORC: Open Radical Cystectomy; RARC: Robot-Assisted Radical Cystectomy; SV: Stroke Volume

INTRODUCTION

Treatment of Invasive bladder cancer involves robot assisted radical cystectomy (RARC) and open radical cystectomy (ORC). A systematic review concludes that RARC is associated with few perioperative complications, a low blood loss and therefore low need for transfusion and results in a short length of in-hospital stay [1]. Nevertheless, uncertainty remains in regard to balance between risks and benefits of RARC [2-6]. One concern related to surgery is the associated "stress response". The endocrine response to surgery includes secretion of catabolic hormones but the pathophysiological role of the stress response remains debated [7]. Laparoscopic surgery reduces injury and considering that the stress response to surgery reflects tissue injury, it follows that the stress response to minimal invasive surgery is low when compared to open surgery. For example, laparoscopic cholecystectomy is associated with a reduced endocrine response compared to open cholecystectomy [8] and resection of esophageal cancer by minimal invasive surgery could lead to reduced postoperative morbidity when compared to conventional resection [9]. Also plasma cortisol and adrenaline are low after endoscopic versus open abdominal aortic aneurysm repair [10]. In contrast, both open and laparoscopic rectal cancer surgery is reported associated with a surgical stress response and challenged immune competence [11]. Two neuro endocrine systems are activated by "stress": the hypothalamic-pituitary-adrenocortical (HPA) axis and the sympathetic nervous system with adrenaline released from the adrenal medulla. Plasma cortisol reflects activation of the HPA axis and is produced during chronic stress too. According to its circadian rhythm, plasma cortisol levels are low at midnight, build up overnight to peak in the morning and then declines throughout the day and is suppressed by the administration of dexametasone [12] that we administer in preparation for surgery. Cortisol secretion may increase 4-fold from baseline during surgery, depending on the surgical trauma [7]. No data are, however, available regarding the stress response to RARC compared to ORC. This study hypothesized that the plasma cortisol and catecholamine responses to RARC are reduced compared to the responses developed during ORC.

MATERIALS AND METHODS

Study design/Patient Identification

The study was approved by the local ethics committee (H-1-2012-135), Twenty ORC patients were included between February 2013 and July 2014 [13,14] as part of a randomized controlled study registered in Eudra CT (2012-005040-20). Furthermore, we investigated a second group of 20 patients undergoing RARC who were prospectively included during the same period. The Declaration of Helsinki criteria were followed and the study was monitored by the Agency for Good Clinical Practice at the University of Copenhagen [15]. At least 24 h before scheduled surgery written informed consent was obtained from the participants. We excluded patients from this investigator-initiated, prospective trial if consent was withdrawn. Data were gathered by the investigators and remained confidential throughout the trials. The authors were involved in every step of manuscript generation and vouched for the completeness and accuracy of the data. No third party influenced the study design, data analysis, or reporting.

Interventions

The participants received Gabapentin 600 mg, dexamethasone 8 mg, and paracetamol 1 g about 2 h prior to surgery and consumed food up to 6 h and clear fluid until 2 h before surgery. Goal directed fluid therapy (GDT) was secured by determination of stroke volume (SV) from recording of arterial pressure fluctuations obtained through a radial arterial catheter in the non-dominant arm connected to a modified Nexfin monitor (Bmeye B.V, Amsterdam, The Netherlands) [16]. A thoracic epidural catheter was inserted (Th. 9-12) for postoperative pain treatment and its placement was secured with the response to injection of 3 ml lidocaine 2% with epinephrine and epidural anesthesia was established when the operation was completed. For induction of anesthesia, remifentani (0.5 μg kg^{-1}min^{-1}) was initiated and when the patient reported sedation, propofol (2.0 mg/kg) was administered. Propofol (5-10 mg · kg^{-1} h^{1}) and remifentanil (1.8 range 1.1-2.9 mg/h) maintained anesthesia.

Patients in the ORC group were supine throughout surgery while RARC patients were in a 30° Trendelenburg position during resection of the bladder and lymph node dissection using a da Vinci System (5.0 robotic, Intuitive Surgical Inc., Sunnyvale, CA, USA). For RARC the bladder reconstruction was established via a lower laparotomy with the patient supine. Two surgeons performed all ORC procedures while two others performed the RARC.

Data Collection

Heart rate (HR), mean arterial pressure (MAP), SV, cardiac output (CO), and central venous oxygenation (SvO_2) were determined after induction of anesthesia but before surgery (T_1), after resection of the bladder (T_2), and at the end of anesthesia (T_3) before epidural anesthesia was activated. If systolic pressure fell below 80 mmHg, then 5 to 10 mg of ephedrine was administered.

Blood samples were drawn at T_1, T_2 and T_3 while the patients were supine. We analyzed blood for adrenaline, noradrenaline, cortisol, and creatinine. The samples for hormone analyses were centrifuged for 10 min at 3.000 rpm at -5° C and stored at -80°C until analyzed. Simultaneously, blood was drawn from the central venous catheter for blood gas variables and also glucose and lactate (ABL 825, Radiometer, Copenhagen, Denmark). Plasma cortisol was analyzed by competitive immunoassay (Bayer Diagnostics, Mijdrecht, The Netherlands) and for plasma catecholamines a radioimmunoassay was used (Labor Diagnostika, Nordhorn, Germany).

Statistical Analysis

A sample size of 20 patients in each group was estimated for 80% power and α=0.05. A significant difference in catecholamine and cortisol levels between RARC and ORC groups was defined as the primary end-point.

We used two-sided or unadjusted chi-square tests, t-test and Fisher's exact test for continuous and dichotomous variables, respectively. Results are presented as mean (SD) or median with 95% confidence interval (CI) as appropriate. Test for differences were by the non-parametric Spearman's test, $\chi 2$ test for categorical data and analysis of variance or Mann-Whitney *U*-test and Wilcoxon signed ranks test for continuous data where appropriate. A two-sided P value < 0.05 was considered to indicate statistical significance. Statistical analyses were performed using SPSS V.20.0 (SPSS Inc., Chicago, Illinois, USA).

RESULTS

The patients were directed prospectively to RARC or ORC depending on BMI, previous morbidity and abdominal surgery (Table 1).There were no significant intergroup differences in patient demographics.

Endocrine and autonomic stress response

Table (2) shows changes in plasma cortisol, adrenaline, and noradrenaline besides in glucose and lactate for the two groups of patients. In the RARC group plasma cortisol became low compared with the ORC group (70 vs 139 nmol/l at T_2 and

56 vs 92 nmol/l at T_3; *P*=0.004). From T_1 to T_3 the reduction in plasma cortisol was to 20% (18-23) vs 32% (27-36) in the RARC vs the ORC group (*P*<0.001; (Figure 1)). Yet, the decline in plasma cortisol was largest during ORC: 0.82 (±0.29) vs 0.59 (±0.23) nmol/l/min; *P*<0.009.

Moreover, plasma adrenaline (*P*<0.01) was reduced during surgery within the groups, while plasma glucose (*P*<0.01), noradrenaline (*P*<0.05), and lactate (*P*<0.01) increased. There was no significant difference in the changes between groups in regard to plasma glucose (+20 vs +26%) and adrenaline (-30 vs -40%). Five patients were treated for diabetes, four in the ORC group and one in the RARC group. For those five patients plasma glucose increased only slightly (by 1-10%) during surgery, while the increase in the non-diabetic patients was by 20%, (*P*<0.001).

The plasma noradrenaline was different before surgery (T_1) in the two groups, but there was no significant difference in the changes in plasma noradrenaline during surgery in the RARC (+19%) compared to the ORC group (+20%; *P*=0.85). Only lactate was larger in the RARC group compared with the ORC group by the end of anesthesia (*P*<0.016) and still quite low (about 2.4 mmol/l).

Hemodynamics

During surgery MAP increased by approximately 10% in both groups (from 60 to 70 mmHg; P<0.01) without difference between groups and also there was no intergroup difference in HR. CO and SV increased by 37 % and 22% respectively during surgery in the RARC group and were higher in this group during and at the end of surgery compared to the ORC group (*P*=0.001). The S_vO_2 increased by 4% in the RARC group during anesthesia, whereas S_vO_2 decreased 4% in the ORC group (*P*<0.01).

Perioperative events

The ORC group received 6180 µg (± 1519) remifentanil and the RARC group 11159 µg (± 2343); *P*= 0.0001, reflecting that the rate of infusion was similar (0.380 vs 0.368 µg/kg/min; (Table 1)). At the end of surgery creatinine was elevated to 112 (± 27) mikromol/L in the RARC group compared with 88 (±18) mikromol/L in the ORC group (*P*=0.004), but creatinine normalised spontaneously by two days after surgery.

Plasma cortisol associated with perioperative variables

Applying Spearman´s correlation analysis to the continuously recorded preoperative characteristics of the cohort, changes in plasma cortisol (T_1 to T_3) were associated to age (*r* = -0.372; *P* = 0.018) and duration of surgery (*r* = -0.715; *P*=0.0001), to CO (*r* = -0.372; *P* = 0.018), and to remifentanil dose (total µg) (r = -0.718; *P*=0.0001; Figure 2).

DISCUSSION

This prospective study demonstrates a decrease in both plasma adrenaline and cortisol during cystectomy when covered by propofol-remifentanil anesthesia. Thus surgery did not disturb the spontaneous decline in plasma cortisol during the day but the decline was related to the surgical procedure, RARC vs ORC equating the dose of analgesia because the RARC procedure took longer than ORC.

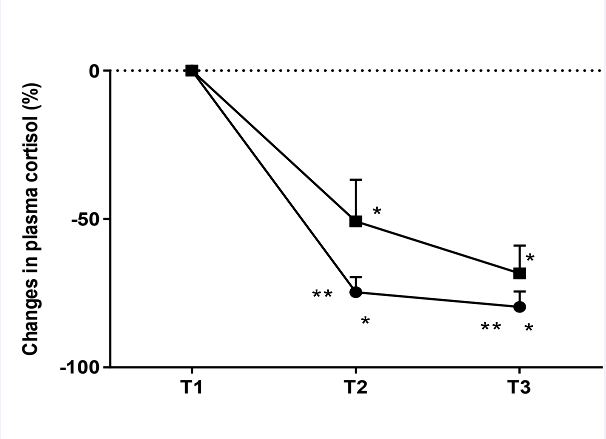

Figure 1 Plasma cortisol before surgery (T1), after cystectomy (T2), and at the end of anesthesia (T3). *P < 0.05 compared within the group, and ** P < 0.05 compared ORC (black square) with RARC group (black circle).

Table 1: Patient Characteristics and Perioperative Data.

Variable	RARC (n=20)	ORC (n=20)	*P*-value
Age, yrs.	64.8 (8.5)	68.6 (6.5)	0.12
Male sex	18 (90)	14 (70)	0.24
BMI, kg/m2	25.8 (3.3)	25.1 (7.1)	0.70
ASA classification ,I and II/III	17/3	15/5	0.69
Cardiopulmonary disease	11(55)	12(60)	1.00
Hypertension	9 (45)	7 (35)	0.37
Chronic heart failure	1 (5)	1 (5)	0.76
Diabetes	1 (5)	4 (20)	0.17
duration of anesthesia, min	381 (37)	240 (47)	0.001
Duration of surgery, min	325 (37)	184 (45)	0.001
Total dose of remifentanil, µg	11159 (2343)	6180 (1519)	0.0001
Infusion of remifentanil, µg$\cdot$kg^{-1}min^{-1}	0.380 (0.071)	0.368 (0.049)	0.518

Values are mean (SD) or numbers (%). *P*-value by univariate analysis
BMI, body mass index; ASA class, American Society of Anesthesiologists
Values are mean (SD) or numbers (%). *P*-value by univariate analysis
BMI: Body Mass Index; ASA class, American Society of Anesthesiologists

For the time that surgery is carried out, plasma cortisol is reduced by about 50 nmol/L (from 9 am until 14 pm) [17] and in this trial the decrease was by fully 200 nmol/L (to about 25% of the initial value) after an about 40% reduction at the time of bladder resection. The baseline values of plasma cortisol and the decline during surgery corresponds to the long duration of RARC compared to ORC, equalizing the high dose of analgesia used while the preoperative immunosuppressive therapy by dexamethasone did not seem to affect the initial value (about 280 nmol/l). In support administration of opioid rather than inhalation-anesthesia blocks the plasma cortisol and glucose responses to surgery [18-20] as does local analgesia [21], thoracic epidural [22,23] and spinal anesthesia [24]. The impact of tissue injury on the stress response remains debated. In a randomized trial

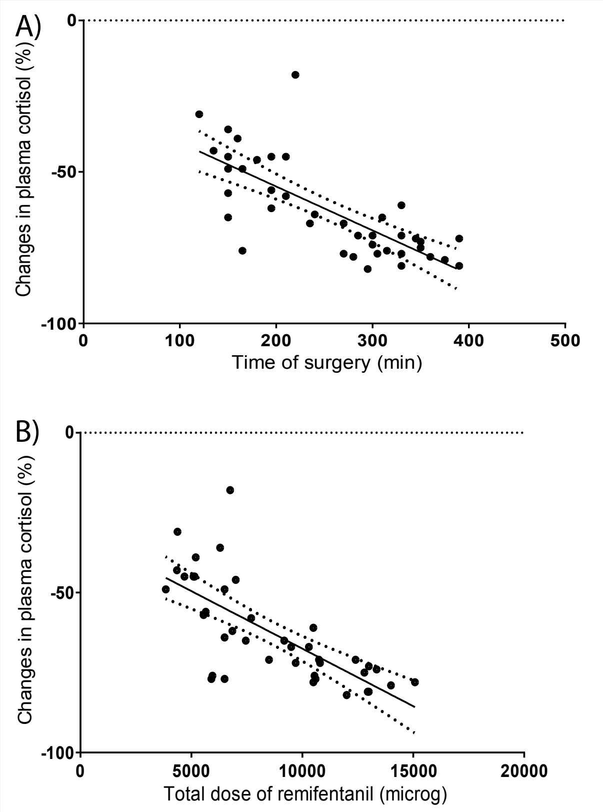

Figure 2 Plasma cortisol during anesthesia in relation to (A) time of surgery (r2 = 0.555, P=0.0001) and (B) administration of remifentanil (r2 =0.516, P=0.0001). Correlation lines precented with 95%-CI.

the surgical stress response to laparoscopic vs conventional total mesorectal excision revealed no significant differences in plasma cortisol between groups [11]. Also an animal study compared the stress response to bilateral adnexectomy using single-port access with conventional laparoscopy and found plasma cortisol levels identical [25]. Likewise in a systematic review, the plasma cortisol was not associated with the surgical injury [26]. In the present trial plasma cortisol decreased in both groups, and about 30% faster in the ORC than in the RARC group. A review comparing open versus endovascular repair of an abdominal aortic aneurysm finds that the plasma cortisol levels are higher in the open repair group [10]. Even though the urinary diversion in the present trial was carried out via laparotomy below umbilicus in the RARC group, the resection of the urine bladder was performed laparoscopic whereby the extent of tissue injury is expected to be small.

Plasma glucose reflects mobilization of energy and indicates activation of the sympathoadrenomedullary system. Plasma cortisol promotes gluconeogenesis and plasma glucose was expected to increase during stressful conditions. Intraoperative hyperglycemia is an independent risk factor for complications and in-hospital outcome (odds ratio 7.2) [27]. In the present study, plasma glucose increased during surgery in both groups with no intergroup difference, but the increase was minimal (by about 20% to about 9 mmol/l), as in a trial for orthopedic surgery using remifentanil for anesthesia [19]. There are potential selection biases in non-randomized studies, currently there was a trend towards more diabetics in the ORC group and they tended to be older than RARC patients, and age affects the stress response to surgery [28] as confirmed here. Sympathetic

Table 2: Comparison of hormone variables during anaesthesia between the study groups.

Variable	Overall (n=40)		RARC (n=20)		ORC (n=20)		*P* Value
Cortisol (nmol/l)							
T_1	278	(93)	276	(99)	280	(88)	0.799
T_2	105†	(59)	70†	(31)	139†	(60)	0.001
T_3	74†	(41)	56†	(24)	92†	(46)	0.004
Glucose (mmol/l)							
T_1	7.37	(1.69)	7.43	(2.11)	7.31	(1.20)	0.640
T_2	8.67†	(1.62)	8.95‡	(1.69)	8.38‡	(1.54)	0.271
T_3	8.85†	(1.75)	8.48‡	(1.61)	9.21‡	(1.84)	0.193
Lactate (mmol/l)							
T_1	1.20	(0.48)	1.18	(0.50)	1.22	(0.47)	0.818
T_2	1.75†	(0.73)	1.57‡	(0.56)	1.83‡	(0.83)	0.128
T_3	2.00†	(1.48)	2.59‡	(1.92)	1.44	(0.46)	0.016
Adrenaline (nmol/l)							
T_1	0.23	(0.11)	0.24	(0,13)	0.22	(0.09)	0.459
T_2	0.16‡	(0.13)	0.19‡	(0.18)	0.13‡	(0.05)	0.164

T_3	0.16‡	(0.09)	0.17‡	(0.10)	0.16+	(0.08)	0.726
Noradrenaline (nmol/l)							
T_1	2.62	(1.21)	3.26	(1.27)	2.00	(0.71)	0.001
T_2	3.15+	(1.56)	3.89+	(1.86)	2.40+	(0.58)	0.01
T_3	2.75	(1.39)	3.33	(1.56)	2.17	(0.92)	0.01

T_1 = before start of surgery; T_2 = after resection of the urinary bladder; T_3 = at the end of anaesthesia. Data are mean (SD), *P*-value determined by univariate analysis. *t- test*compared differences in hormones between the RARC and ORC group.
+ $P<0.05$ difference from anaesthesia induction within the group; ‡ $P<0.01$ difference from anaesthesia induction within the group; and † $P<0.001$ difference from anaesthesia induction within the group (Wilcoxon Signed Ranks test).

activation increases secretion of catecholamines from the adrenal gland while noradrenaline is released as a neurotransmitter with some spillover to the circulation. Increased sympathetic activity results in tachycardia and hypertension, however, the increased CO in the RARC group is more likely related to the intravascular fluid status [14]. In regard to sympathetic activation, Kriki et al., found plasma adrenaline and noradrenaline higher during open compared to laparoscopic cholecystectomy [8] and similarly Moris et al., in a review conclude that plasma adrenaline increases during open compared to endoscopic aneurysm repair [10]. The present data showed slightly reduced plasma adrenaline in both groups without intergroup differences during surgery and plasma noradrenaline increased by about 20%. During major laparoscopic surgery high dose remifentanil lowers plasma catecholamines [29] and during laparoscopic colectomy remifentanil attenuates the increase in plasma cortisol and adrenaline decreased [20].

This study is strengthened since the procedures were performed by only few surgeons, thereby reducing the risk of confounding. Yet, the study is limited because the participants were not randomly assigned to the surgical procedure and the risk of biases, i.e. due to lack of reporting tumor stage and type of urinary diversion are relevant. For more details regarding postoperative observed events, please see [14]

CONCLUSIONS

This prospective study demonstrates a decrease in both plasma adrenaline and cortisol during cystectomy when covered by propofol-remifentanil anesthesia. Surgery did not disturb the spontaneous decline in plasma cortisol during the day and because the robot-assisted procedure was long lasting, plasma cortisol became low. Thus, administration of remifentanil at about 1.8 mg/h seems to impair the stress response to major surgery. The study was not randomized to the surgical procedure – robotic assisted vs. open radical cystectomy – and a randomized controlled study and enrolment of more patients are needed to reveal a difference in outcome related to plasma cortisol or adrenaline.

ACKNOWLEDGEMENTS

This work was supported by grants from The Maersk Fond, The Augustinus Fond, and Aase and Ejnar Danielsen's Fond, Denmark.

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Cite this article

Rasmussen KC, Højskov M, Ruhnau B, Thind P, Sennels HP, et al. (2016) Comparison of Stress Response during Robotic-Assisted Versus Open Radical Cystectomy in Bladder Cancer: A Prospective Observational Study. JSM Surg Oncol Res 1(1): 1005.