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ORIGINAL ARTICLE

Body mass index is an independent predictor of Clavien–Dindo grade 3 complications in patients undergoing robot assisted radical prostatectomy with extensive pelvic lymph node dissection

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Abstract

Robot assisted radical prostatectomy (RARP) with extensive pelvic lymph node dissection (ePLND) is an effective procedure for treating and staging prostate cancer; however, high grade complications represent a critical issue. To investigate clinical factors associated with the risk of Clavien–Dindo grade 3 complications in patients undergoing RARP with ePLND. The study included 211 consecutive patients who were operated in a period running from June 2013 to March 2017. Factors associated with grade 3 complications were evaluated by the logistic regression model. Receiver operating characteristic curves and area under the curve (AUC) were used to assess the risk model. Of the 211 patients included in the study, 55 (26.1%) had complications, which were classified Clavien grade one in 36 cases (17.1%), two in 7 (3.3%), 3a in 9 (4.3%) and 3b in 3 (1.4%). Higher median measurements of body mass index (BMI) were detected in grade 3 subjects (27.6 kg/m^2) when compared to grade 0–2 cases (25 kg/m^2) and the difference was significant ($P=0.015$). BMI increased the risk of high grade complications (odds ratio, OR 1.184; $P=0.047$) with a fair discrimination power (AUC 0.709). It generated a risk curve by the model, which stratified patients in low (BMI < 26 kg/m^2; probability risk less than 5%), intermediate (26 ≤ BMI (kg/m^2) ≤ 30; risk between 5 and 10%), and high (BMI > 30 kg/m^2; risk between 10 and 20%) risk classes for grade 3 complications. BMI is an independent predictor of grade 3 complications, which are increased by 18.4% for each unit rise. Patients may be stratified preoperatively by BMI into grade 3 risk categories, which include low (normal weight), intermediate (overweight), and high (obese) risk cases.

Keywords Prostate cancer · Robot-assisted radical prostatectomy · Lymph node dissection · Perioperative outcome · Postoperative complications · Body mass index

Introduction

In the natural history of prostate cancer (PCA), early lymph node invasion is an important event [1]. Although the risk of lymph node invasion may be predicted by nomograms, extensive pelvic lymph node dissection (ePLND) is the most effective method for assessing nodal metastases, which are not detectable on actual imaging modalities [2, 3].

In the last years, robot assisted radical prostatectomy (RARP) with ePLD has shown to be a valuable and safe approach for treating and staging PCA [4–6]. In operated patients, surgical complications should be sharply assessed and graded by the Clavien–Dindo score system [7, 8]. Although complications following RARP with ePLND are well known, clinical factors predicting high grade

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complications are actually missing. The aim of this study was to evaluate factors, if any, predicting the risk of high grade complications after RARP with ePLND.

Materials and methods

The study was retrospective and approved by internal Institutional Review Board. Each patient provided informed-signed consent.

Patients were assessed by the D'Amico clinical class risk categories [9] and staged according to the 2002 American Joint Committee on Cancer staging system for PCA. In each case, pelvic lymph node staging was assessed by computerized tomography (CT) and/or by multi-parametric magnetic resonance imaging (mpMRI) modalities. Enlarged pelvic nodes measuring more than 1 cm in diameter were considered suspicious for secondary involvement and staged as cN1 disease. The metastatic status was investigated by CT, bone scan and occasionally by 11-choline positron emission tomography CT (11C-PET CT).

In a period running from June 2013 to March 2017, we selected 211 consecutive cases who underwent RARP with ePLND. Patients who had had surgery for benign prostatic hyperplasia, radiation of the pelvis, and focal or androgen deprivation therapy for PCA were excluded from the study. A postoperative drain was placed in the pelvis and was removed on postoperative day (POD) one if the output was less than 150 mL/24 h. If postoperative outcome was uneventful, patients were discharged on POD 4 with the catheter removed on POD 12 without cystography. RARP was delivered by the Si da Vinci Robot System (Intuitive Surgical, Inc, Sunnyvale, CA, USA) and was performed through the transperitoneal approach with antegrade prostatic dissection [4, 10]. A transurethral 18 Fr Foley catheter was placed in all cases and the balloon was inflated with 7 cubic centimeters (cc) of physiologic solution. Extended PLND was performed according to a standard template, which included external iliac, obturator, internal iliac, Marcille's, common iliac and Cloquet's lymph nodes. Operating time was calculated as the interval between incision of the first laparoscopic port and suture of the last one. Procedures were performed by two experienced surgeons, coded as *x* and *y*. Prophylaxis of deep venous thrombosis with low molecular weight heparin was performed in all cases [4]. Early mobilization was activated starting from the day of surgery (POD 0). Deep venous thrombosis prophylaxis was prolonged till POD 28.

Surgical specimens were assessed by the dedicated pathologist. All specimens were processed according to the Stanford protocol [11]. Tumors were classified according to the Gleason grading group system [12, 13]. Nodal packets were grouped into left and right nodes, tagged and submitted in separate packages. The removed lymph nodes were assessed for histopathological analysis after hematoxylin and eosin staining. Immuno-histochemical staining was performed when appropriate. In each case, the number of removed and metastatic nodes were assessed. Specimens were then staged according to the 2002 American Joint Committee on Cancer staging system for PCA.

Each patient was evaluated for age (years), body max index (BMI; kg/m^2), baseline total prostate specific antigen (PSA; ng/mL), proportion of biopsy positive cores, prostate volume (mL), tumour and nodal clinical stage, Gleason score in biopsy cores and surgical specimen. Perioperative surgical risk was evaluated by the American Society of Anesthesiologists (ASA) score [14]. Complications were monitored within a period of four months and classified by the Clavien–Dindo score system [7, 8]. The event of hospital readmission was also considered.

Statistical methods

Patients were classified in two groups according to the Clavien–Dindo score system (grade 3a–3b versus grade 0–2 complications). Data on continuous variables are reported as medians with their respective inter-quartile ranges and differences among groups analysed by Mann–Whittney *U* test. Data on categorical variables are presented as percentages, and differences among groups analysed with Pearson's Chi-squared test or Fisher exact test as appropriate. Associations between factors and risk of Clavien–Dindo grade 3 complications were evaluated by the logistic regression model. A receiver operating characteristic (ROC) curve was used to determine the efficacy of factors predicting the risk of Clavien–Dindo grade 3 complications. The software used to run the analysis was IBM-SPSS version 20. All tests were two-sided with $P < 0.05$ considered to indicate statistical significance.

Results

Of the 211 patients, 24 (11.4%) were low, 116 (55%) intermediate, and 71 (36.6%) high risk cases. In the surgical specimen, high grade cancer (Gleason score > 7) was detected in 27 (33.1%) cases. Extraprostatic extension of cancer was observed in 68 (32.2%) patients of whom 29 (13.7%) had extracapsular extension and 39 (18.5%) seminal vesicle invasion. A total of 67 (31.7%) subjects had surgical margins invaded by cancer. Of the 211 operated cases, 28 (13.3%) had lymph node invasion. Surgical complications, which were detected in 55 (26.1%) cases, were coded as low-intermediate (grade 1–2) in 43 patients (20.4%) and high grade (3a–3b) in 12 subjects (5.7%).

As shown in Table 1, of the 211 investigated subjects, 26 (12.3%) were ASA score one, 170 (80.6%) ASA score two, and 15 (7.1%) ASA score three. The overall median (and inter-quartile range) baseline age, BMI, prostate volume, proportion of positive cores, number of dissected lymph nodes, operating time, blood lost, and length of hospital stay are reported. A total of 11 (5.2%) cases had clinical extraprostatic extension of the tumour. Suspected clinical lymph node invasion (enlarged nodes) was observed in 19 (9%) patients. A total of 44 (20.9%) patients had high grade cancer at biopsy (Gleason score > 7). Overall, a median of 26 (IQR 21–33) lymph nodes were removed from all patients. Of all clinical (age, BMI, PSA, prostate volume, biopsy tumour grade, tumour and nodal clinical staging, ASA score, surgeon, length of hospital stay) and peri-operative factors (number of nodes removed, operating time, blood lost), only

Table 1 Clinical features associated with surgical complications by the Clavien–Dindo score system

	Overall (n = 211)	Clavien–Dindo score system		P value
		Grade (0–2) (n = 199; 94.3%)	Grade 3 (3a–3b) (n = 12; 5.7%)	
Age (years)				0.920
Median	65	65	65.5	
Interquartile range	61–70	61–70	58.5–71	
Body mass index (BMI; kg/m^2)				0.015
Median	25.3	25	27.6	
Interquartile range	23.5–28	23.4–28	26.3–28.7	
Prostate specific antigen (ng/mL)				
Median	7	7.1	6.1	0.953
Interquartile range	4.9–9.9	4.9–9.9	5.3–15.2	
Biopsy positive cores (proportion)				0.998
Median	0.42	0.43	0.42	
Interquartile range	0.25–0.60	0.25–0.60	0.24–0.59	
Prostate volume (mL)				0.158
Median	40	40	30	
Interquartile range	30–50	30–51	25–41	
Removed lymph nodes (number)				0.325
Median	26	26	28.5	
Interquartile range	21–33	21–33	21–38.5	
Operating time (OT; min)				0.222
Median	225	225	250	
Interquartile range	200–255	200–250	204–265	
Blood loss (BL; mL)				0.618
Median	250	250	3000	
Interquartile range	150–400	150–400	200–475	
Length of hospital stay (LOHS; days)				0.713
Median	4	4	4	
Interquartile range	4–5	4–5	4–5	
ASA score; number (%)				0.324
ASA 1–2	196	184 (92.5)	12 (100)	
ASA 3	15	15 (7.5)	0 (0)	
Clinical stage (cT); number (%)				0.962
cT (1)	142	134 (67.3)	8 (66.7)	
cT (2–3)	69	65 (32.7)	4 (33.3)	
Clinical nodal stage (cN); number (%)				0.933
cN0	192	181 (91)	11 (91.7)	
cN1	19	18 (9)	1 (8.3)	
Surgeons (SURG); number (%)				
SURG 1	154	146 (73.4)	8 (66.7)	0.621
SURG 2	57	53 (26.6)	4 (33.3)	

BMI associated with high grade complications. Patients who had Clavien–Dindo grade 3a–3b score showed higher BMI median values (27.6 kg/m^2) when compared to cases who scored grade 0–2 (BMI 25 kg/m^2) and the difference was significant ($P=0.015$). Pathological features (pathologic stage, tumour grade, surgical margin status, lymph node invasion) did not associate with high grade complications.

Table 2 shows the list of complications. Of the 211 patients included in the study, 55 (26.1%) had complications, which were classified Clavien grade one in 36 cases (17.1%), two in 7 (3.3%), 3a in 9 (4.3%) and 3b in 3 (1.4%). A total of 11 (5.2%) subjects were re-admitted within a period of 120 days after discharge from the hospital. Symptomatic lymphocele was observed in 5 (2.4%) subjects of whom 2 underwent percutaneous and 3 surgical drainage. A total of 6 (2.8%) patients had anastomotic urinary leakage, which was treated by indwelling Foley catheter. One (0.5%) case had ureteral injury, which was treated conservatively. Symptomatic pelvic hematoma was observed in 4 (1.9%) patients who were treated conservatively. A total of 6 (2.8%) patients needed blood transfusion. So far, of the 55 patients who had complications, 11/211 (5.7%) were grade 3. Of the 11 subjects with Clavien grade 3 complications, 6/211 (2.8%) were related to extended pelvic lymph node dissection and 6/211 (2.8%) to radical prostatectomy.

The logistic regression model showed that BMI increased the risk of high grade complications (odds ratio, OR 1.184; $P=0.047$), as showed in Table 3 (continuous model). The receiver operating characteristic (ROC) curve indicated that BMI had also a good discrimination power (area under the

Table 2 List of complications in patients ($n=211$) who underwent robot assisted radical prostatectomy with extended pelvic lymph node dissection

	Clavien–Dindo, grade				Total (%)
	1	2	3a	3b	
Urinary retention	1	0	0	0	1 (0.5)
Anastomotic leakage	0	0	6	0	6 (2.8)
Suspected urinary leakage	1	0	0	0	1 (0.5)
Ureteral injury	0	0	1	0	1 (0.5)
Lymphocele	0	0	2	3	5 (2.4)
Lymphorrhea	4	0	0	0	4 (1.9)
Pelvic hematoma	1	3	0	0	4 (1.9)
Anemia	0	2	0	0	2 (0.9)
Lymphedema	4	1	0	0	5 (2.4)
Vomit	0	1	0	0	1 (0.5)
Diarrhoea	1	0	0	0	1 (0.5)
Ileus	1	0	0	0	1 (0.5)
Fever	15	0	0	0	15 (7.1)
Subcutaneous emphysema	1	0	0	0	1 (0.5)
Rib injury	1	0	0	0	1 (0.5)
Superficial phlebothrombosis	1	0	0	0	1 (0.5)
Pneumonia	1	0	0	0	1 (0.5)
Abdominal pain	3	0	0	0	3 (1.4)
Scrotal swelling	1	0	0	0	1 (0.5)
Total (%)	36 (17.1)	7 (3.3)	9 (4.3)	3 (1.4)	55 (26.1)

Table 3 Association of body mass index (BMI) with the risk of grade 3 Clavien–Dindo complications

	Coefficient	Standard error	Odds ratio	95% confidence interval	*P* value
Continuous model					
BMI	0.169	0.085	1.184	1.003–1.399	0.047*
Constant	−7.296	2.350	0.001		0.002
Dichotomy model					
BMI < 26	Ref.				
BMI ≥ 26	2.589	1.054	13.322	1.688–105.161	0.014**
Constant	−4.691	1.005	0.009		< 0.0001

*Area under the curve (AUC) = 0.709 (95% confidence interval: 0.615–0.804)

**Area under the curve (AUC) = 0.732 (95% confidence interval: 0.615–0.849)

curve, AUC 0.709) in the model (Fig. 1). It was identified a cut point of BMI 26 kg/m^2 with sensitivity of 0.912 (true positive rate) and 1 − specificity of 0.452 (false positive rate). In the dichotomous model (Table 3), BMI ≥ 26 kg/m^2 versus BMI < 26 kg/m^2 (reference category) significantly increased the risk of grade 3 complications (OR 13.322; $P = 0.014$) with a fair discrimination power (AUC 0.732; Fig. 1). A risk curve was computed by applying the regression coefficients of the continuous model to BMI measurements in overall cases ($n = 211$). The probability of BMI predicting high grade complications is illustrated in Fig. 2, which shows the risk curve originated by the model. As illustrated, the risk of high grade complications rises from 5 to 10% at BMI between 26 and 29.9 kg/m^2 (overweight patients) and from 10 to 20% at BMI between 30 and 35 kg/m^2 (obese patients).

Discussion

Although it has been shown that RARP associated with ePLND can be performed routinely and safely in all risk cases, high grade complications represent a critical issue [4–6, 15]. Literature reviews show that Clavien–Dindo grade 3 complications rates range from 0.5 to 7% [6]; however, only few studies reported complications by EAU recommended criteria [8]. In contemporary series, grade 3 complications range from 2 to 4.9% [16–18]. In our study, overall grade 3 complications were detected in 7 cases (5.7%), which were similar to those reported by recent series.

Clinical studies have shown that BMI associates with aggressive prostate cancer and increases the risk of metastases, recurrence as well as cancer specific mortality [19–22]. Patients may be classified into three groups by BMI according to the World Health Organization (WHO) definition [23]. Group I (normal) include cases who have a BMI less than 25 kg/m^2, group II (overweight) patients with a BMI between 25 and 29.9 25 kg/m^2, and group III (obese) subjects who have a BMI greater than or equal to 30 kg/m^2. Clinical studies evaluating perioperative outcomes and predictors for complications after RARP did not show any association because of important biases related to the methodology; moreover, BMI associated with only with longer operative time, but did not show any association with high grade complications [6]. Although it has been suggested that increased BMI has a negative impact in PCA robotic surgery [4], high quality studies dealing with this topic are actually missing [24]. Recently, a controlled non-inferiority trial assessing pelvic drain placement versus no pelvic drain placement after RARP, has also investigated predictors of complications [25]. The trial showed that only clinical Gleason grade was an independent predictor of complications, while other preoperative variables, which also included BMI, did not show any association [25]. To the

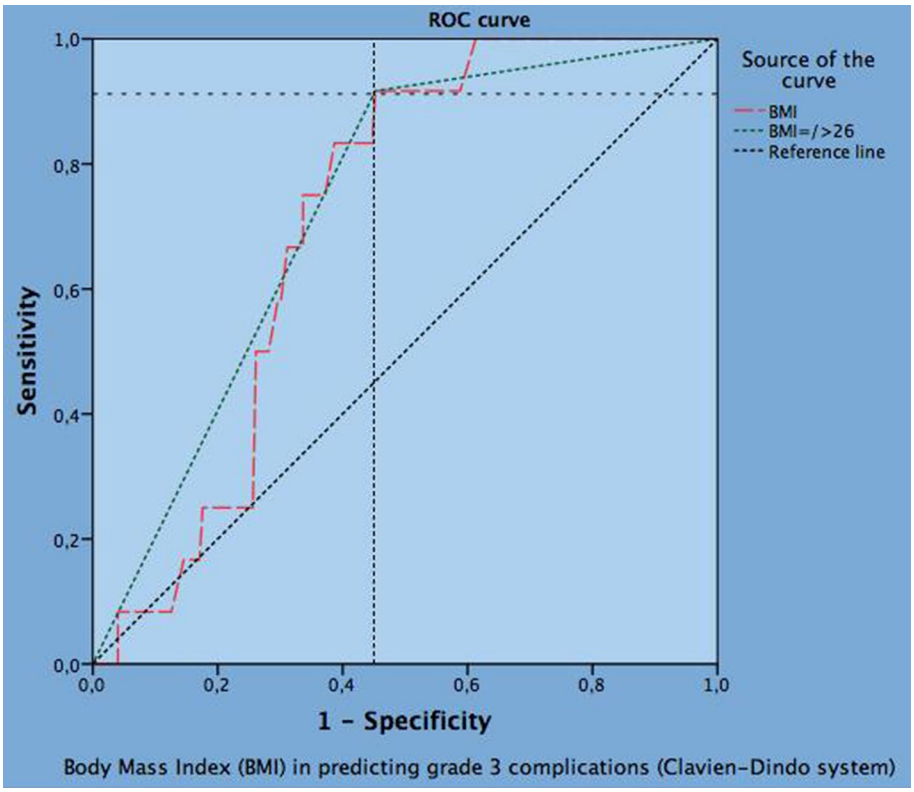

Fig. 1 The efficacy of BMI predicting the risk of Clavien–Dindo grade 3 complications

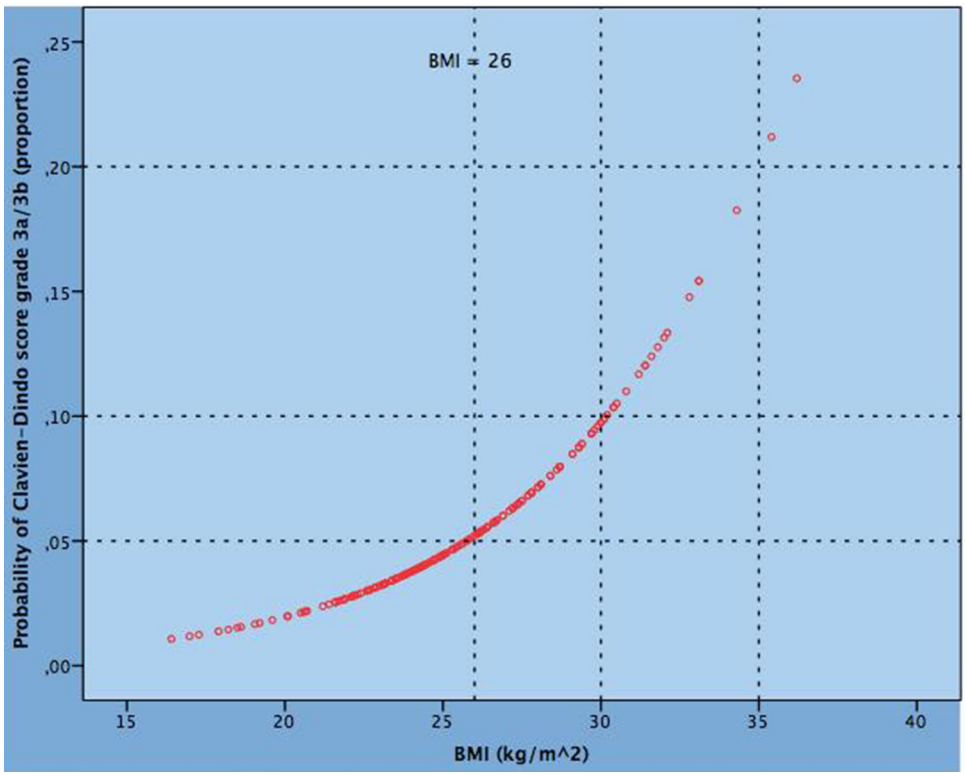

Fig. 2 Risk of Clavien–Dindo grade 3 complications according to different BMI

best of our knowledge, this is the first study showing a positive association between increasing BMI values and risk of high grade surgical complications in patients undergoing RARP with ePLND. Median BMI was significantly higher in patients who had grade 3 complications (27.8 kg/m^2) than cases who did not (25 kg/m^2). The logistic regression model showed that the risk of grade 3 complications increased by 18.4% for each unit increase of BMI (Table 3), which showed a fair discrimination power that allowed the identification of a cut point of BMI 26 kg/m^2 (AUC 0.732) with high sensitivity (rate of true positives 0.912) and acceptable false positive rate (1 − specificity 0.452). The curve, which was generated by the model, illustrates the association between increasing BMI values and risk of grade 3 complications (Fig. 2). In normal weight subjects, the risk of grade 3 complications is low (less than 5%), but it increases (10%) in overweight cases and explodes (20%) in obese patients. The risk curve illustrated in Fig. 2 is very useful and applies to clinical practice when we council patients before RARP with ePLND. Indeed, overweight patients should be informed that they have an increased risk of high grade complications, which is between 5 and 10% and doubled when compared to normal weight cases. Moreover, obese patients who decide to undergo robotic surgery, should be aware of the high risk of grade 3 complications (10–20%), which are double and fourfold when compared to overweight and normal weight cases respectively. Importantly, diet measures focused on loosing weight before surgery will decide the risk of high grade complications. In addition, the surgeon who realize that a patient falls in the overweight or obese area of the model has to consider the risk and be prepared to perform a challenging surgery as well as to face high grade complications.

Robotic surgery becomes challenging in overweight and obese PCA patients who show increased rates of surgical complications, which are mainly related to higher intraoperative blood lost and duration of surgery [4, 6, 24]. Main reasons that explain these findings include excessive fat tissue and a relatively narrowed pelvis, which represent a difficult task even for experienced surgeons [4, 24]. Robotic surgery in overweight and obese patients needs also further investigation focused on pathophysiology to improve outcomes and reduce the risk of adverse events. In this prospective, our model may be useful for assessing and stratifying patients into risk areas before surgery (Fig. 2).

The retrospective and single centre are features that limit our study, which, however, shows the effectiveness of stratifying patients into risk categories by BMI. Confirmatory studies are awaited.

Conclusions

In PCA patients undergoing RARP with ePLND, BMI is an independent predictor of the risk of Clavien–Dindo grade 3 complications, which are increased by 18.4% for each unit rise of BMI. Patients may be stratified preoperatively by BMI into grade 3 risk categories, which include low (normal

weight patients with risk less than 5%), intermediate (overweight cases with risk between 5 and 10%), and high risk cases (obese subjects with risk between 10 and 20%). The positive association between BMI and risk of high grade surgical complications needs further research.

Compliance with ethical standards

Conflict of interest Antonio B. Porcaro, Marco Sebben, Alessandro Tafuri, Nicolò de Luyk, Paolo Corsi, Tania Processali, Marco Pirozzi, Riccardo Rizzetto, Nelia Amigoni, Daniele Mattevi, Maria A. Cerruto, Matteo Brunelli, Giovanni Novella, Vincenzo De Marco, Filippo Migliorini and Walter Artibani in this study declare that they have no conflict of interest.

Ethical approval All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1975, as revised in 2000. Informed consent was obtained from all patients for being included in the study.

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