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ORIGINAL PAPER

Visceral adiposity is associated with worse urinary and sexual function recovery after radical prostatectomy: Results from a longitudinal cohort study

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Summary *Objective: A prospective longitudinal cohort study on the impact of anthropometric measures on the sexual function and continence recovery in patients treated with laparoscopic radical prostatectomy (LRP) is presented.*

Material and methods: Anthropometric measures, International Index of Erectile Function (IIEF-5) and International Prostatic Symptoms Score questionnaires, were collected before surgery and at the end of follow-up period. All patients were assigned into the following groups: A) non-obese; B) non-obese with central adiposity; C) obese without central adiposity; D) obese with central adiposity. Urinary and sexual functions were the outcome measures.

Results: At the end of follow-up, in 29 patients with visceral adiposity (VA) the median IIEF-5 was 14 (IQR 7-18) while in 49 non-VA patients (62.8%) was 22 (IQR 17-24) (p < 0.001). Twenty-three patients (79.3%) with VA reported complete continence, while 6 (20.7%) used ≥ 2 pads per day. Forty-eight patients (97.9%) without VA reported complete continence. VA was confirmed as a strong independent predictor for worse continence (HR 3.67; 2.75-4.51 CI95% p = 0.003) and sexual function recovery (HR: 4.51; 3.09-5.63 CI95% p < 0.001).

Conclusion: We truly believe obese with visceral adiposity patients with prostate cancer should receive detailed preoperative counseling before surgery, including higher risk of suboptimal functional outcomes.

KEY WORDS: *Prostate cancer; Adiposity; Metabolic syndrome; Body mass index; Quality of life.*

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INTRODUCTION

Several treatment options are available for the management of localized *prostate cancer* (PCa). To date, more than 40% of PCa patients have *radical prostatectomy* (RP) for their definitive treatment (1-2). Quality of life after surgery is strictly related to continence and potency sphere (3). As such, apart from cancer control, functional outcomes have been widely explored in an endeavor to timely predict which patients may experience worse sexual and continence recovery (4-5). In the last few years, obesity has emerged has a clinical factor potentially influencing perioperative features. Indeed, several studies have reported evidence for obesity being independently associated with higher complication rates (6), as well as worse oncologic (7) and functional outcomes after surgery (8). However, we are still far from drawing definitive conclusions. To date, current literature on this issue has been critically influenced by several features: 1) most studies have defined body habitus using *body mass index* (BMI), whilst data on district adiposity parameters such as *waist circumference* (WC), subcutaneous and abdominal fat were poorly investigated; 2) a significant body of evidence still derives from open RP series. As such, reported findings may be not completely contemporary, being RP increasingly performed nowadays by laparoscopic or robot-assisted approach. To address this unmet need, we designed this longitudinal cohort study with a long-term follow-up period to better understand the impact of abdominal *visceral adiposity* (VA), WC and BMI on the recovery of sexual function and continence in patients with PCa treated with *laparoscopic RP* (LRP).

MATERIALS AND METHODS

Patients, dataset and study schedule

All patients affected by localized intermediate-risk prostate cancer and treated with laparoscopy radical prostatectomy at our Centre between January and December 2012, have been enrolled in this longitudinal cohort study. Clinical (including BMI and WC), instrumental, surgical, and

No conflict of interest declared.

pathological features were recorded before enrolment. All surgical procedures were performed by a single highly trained laparoscopic surgeon (GM). In brief, all procedures have been performed by using an extraperitoneal 5-trocar approach (9). The vesico-urethral anastomosis was made via 2 running sutures with 2-0 Monocryl according to the technique described by *Van Velthoven* (10).
All patients underwent oncological follow-up evaluations, in line with International Guidelines, for prostate cancer and with our previous studies (9, 11). After six months, one year after surgery and at each year follow-up evaluation, additionally to the standard biochemical and instrumental evaluations, all patients underwent specific questionnaires about quality of life and sexual function. The Figure 1 shows the study schedule. The median follow-up period was 86 months (82-95). The study was conducted in line with the STROBE statement (*http://www.strobe-statement.org*) and in line with the Good Clinical Practice guidelines and the ethical principles laid down in the latest version of the Declaration of Helsinki.

Inclusion and exclusion criteria

We consider all patients affected by localized intermediate-risk prostate cancer, in line with the definition and criteria of *D'Amico* (12), and candidates for laparoscopy radical prostatectomy.
We excluded from the study patients who had a history of erectile disfunction, patients on PDE-5 or 5α-reductase inhibitors, patients with penile prosthesis implants. Patients affected by hypotestosteronemia and with other concomitant major diseases were excluded. Finally, all patients who require adjuvant hormonal therapy after surgery were also excluded.

Body mass index and anthropometric measures

At the enrolling time, the following anthropometric measures have been collected: height (cm), weight (kg), and waist circumference (cm) measurement. BMI was calculated as weight in kg divided by squared height in meters (kg/m^2). The waist circumference was measured using a standard measurement strip with the patients standing and breathing normally, at the midway between the lowest rib margin and iliac crest. In line with the *National Cholesterol Educational Program Adult Treatment Panel III* (NCEP: ATP III) (13), a cut-off of 102 cm for the waist circumference and of 30 kg/m^2 for the BMI has been considered. In line with *De Nunzio et al.* (14). patients were then categorized in 4 body habitus groups:

a) non-obese (BMI < 30 kg/m^2 and WC < 102 cm)
b) non-obese with central adiposity (BMI < 30 kg/m^2 and WC ≥ 102 cm)
c) obese without central adiposity (BMI > 30 kg/m^2 and < WC 102 cm)
d) obese with central adiposity (BMI ≥ 30 kg/m^2 and WC ≥ 102 cm)

Even if some authors stated that visceral adiposity index was shown to be a better surrogate index than these single anthropometric indices to use in clinical practice, we decided to not use it due to the complexity of its calculation (15, 16). In fact, visceral adiposity index is comprised of anthropometric measures like BMI, WC and clinical measures of serum triglycerides and high-density lipoprotein-cholesterol levels (15).

Data collection and urological evaluations at each follow-up visit

At the time of surgery, in addition to all anthropometric measures, the following parameters were recorded: the patient's and partner's age, the Charlson comorbidity index, preoperative prostate-specific antigen levels, Gleason score, clinical prostate cancer stage (through an abdominal *computed tomography* (CT) scan and skeletal scintigraphy), duration of hospital stay and surgical complications. All patients underwent a standard follow-up schedule (Figure 1) depending on individual tumors and characteristics, in line with *International Guidelines* and in line with our everyday clinical practice (1, 17). In brief, clinical evaluation with DRE, prostate-specific antigen level and instrumental evaluation. Moreover, after six months, one year after surgery and at each year follow-up evaluation all patients underwent the following questionnaires: *International Index of Erectile Function* (IIEF-5) (18) and *International Prostatic Symptoms Score* (IPSS) (19) questionnaires, in line with previous study (20). Continent patients were defined by use of 0 or 1 safety pad/day (11).

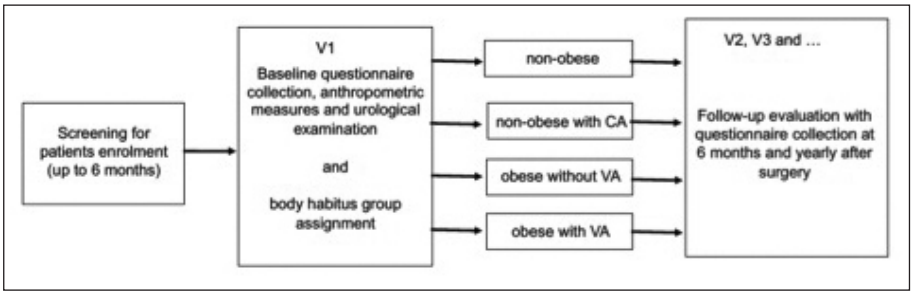
Outcome measures

The main outcome measures were change in questionnaire score, the urinary and sexual function recovery at the end of the follow-up evaluation in each body habitus groups.

Statistical analysis

For statistical purposes, independent variables included all patient- and tumor-related data available in our institutional database. First, descriptive statistics were obtained reporting medians and *interquartile range* (IQR, 25th and 75th percentiles) for continuous variables, and frequencies and proportions for categorical variables, as appropriate.
Continuous variables were compared using the Student t test. Categorical variables were tested with the chi-square test. BMI and waist circumference were examined as continuous variables using crude and adjusted logistic regressions to evaluate their association with the recov-

Figure 1.
Follow-up schedule.



ery of sexual function and continence. Multivariable Cox regression analysis to evaluate clinical and surgical predictors for continence and sexual recovery was performed.
Statistical analyses were performed using SPSS v. 24 (*IBM SPSS Statistics for Mac, Armonk, NY, IBM Corp*). A significance level of $p < 0.05$ was set for all tests. According to the nature of the study, we consider the following sample size to enroll: all patients attending a single Centre in the same period between January and December 2012 represent our patients' population.

Results

Overall, 78 patients were considered for this study. Median age was 68 (IQR: 62-77) and median pre-operative PSA was 9.9 ng/ml (IQR: 3.2-14.7). Nerve sparing RP was performed in 36 (46.1%) patients. At final histopathological examination pT2a, pT2b and pT2c were assessed in 26 (33.3%), 15 (19.2%) and 37 (47.5%) patients, respectively.

Table 1.
Demographic, clinical and pathological patients' data at the enrolment time.

Patients (n°)	78
Age (median; IQR*)	68 (62-77)
Educational qualification	
Primary school	55 (70.5)
High school	21 (26.9)
University	2 (2.6)
Pre-operative evaluation	
PSA (median; IQR*)	9.9 (3.2-14.7)
Clinical stage	
cT2	74 (94.9)
cT3	4 (5.1)
Prostate volume, ml (median; IQR*)	48 (32-78)
DRE# - positive	19 (24.3)
BMI§ (median; IQR*)	26.3 (20.8-34.3)
Waist circumference, cm	91 (89-105)
IPSS$	13 (12-14)
IIEF-5'	25 (24-26)
Surgical approach	
Nerve-sparing	36(46.1%)
Unilateral	21 (58.3)
Bilateral	15 (41.7)
Pathological findings	
pT2a	26 (33.3)
pT2b	15 (19.2)
pT2c	37 (47.5)
Gleason score	
3+3	10 (12.8)
3+4	35 (44.9)
4+3	33 (42.3)
Positive margins	15 (19.2)
NCEP: ATP III"	
Group A	23 (29.4)
Group B	9 (11.5)
Group C	26 (33.4)
Group D	20 (25.7)

The table shows all baseline characteristics, clinical and pathological parameters. n°= number; IQR = Interquartile range; DRE# = Digital rectal examination; BMI§ = Body Mass Index; IPSS$ = International Prostatic Symptoms Score; IIEF-5' = International Index of Erectile Function; NCEP: ATP III" = National Cholesterol Education Program Adult Treatment Panel III.*

Anthropometric measures and questionnaires results at baseline

Baseline median BMI was 26.3 (IQR: 20.8-34.3), while median WC was 91.6 cm (IQR: 89.3-105.4). Pre-operative IPSS and IIEF-5 were 13 (IQR: 12-14) and 25 (IQR: 24-26), respectively. In line with the NCEP: ATP III, 23 patients were included in the Group A, 9 in the Group B, 26 in the Group C and 20 in the Group D. No differences among the four groups have been showed in terms of pre-operative IIEF-5, IPSS scores or pathological data. All clinical, demographic, instrumental and pathological data have been showed in Table 1.

Operative and peri-operative complications

Only two patients required conversion to open surgery due to intraoperative bleeding, that, however, did not require other emergent managements or intensive care. In 76 cases (97.4%) no complications occurred that required an emergent return to the operating room. Even if an increased blood loss has been observed in Group B and D when compared with Group A and C, there was not statistically significant difference. No statistically significant difference has been showed among the Groups in terms of operative median time or hospital stay. No statistically significant differences have been reported among the Groups in terms of peri-operative complications (such as thrombosis, prolonged compression nerve injury or bladder neck disruptions).

Follow-up data

Survival outcome

At a median follow up of 86 months (82-95), 12 patients reported a biochemical recurrence showing a biochemical-recurrence free survival of 84.7%. The overall survival rate at the end of follow-up period was 96.1%. No difference has been reported among the Groups in terms of cancer-specific survival and overall survival, according to the baseline model with adjustments for age and year at cancer diagnosis. The Figure 2 shows the Kaplan-Meier curve analysis on the survival probability of patients with prostate cancer by Group.

Figure 2.
Kaplan-Meier curve analysis on the survival probability of patients with prostate cancer by body habitus.

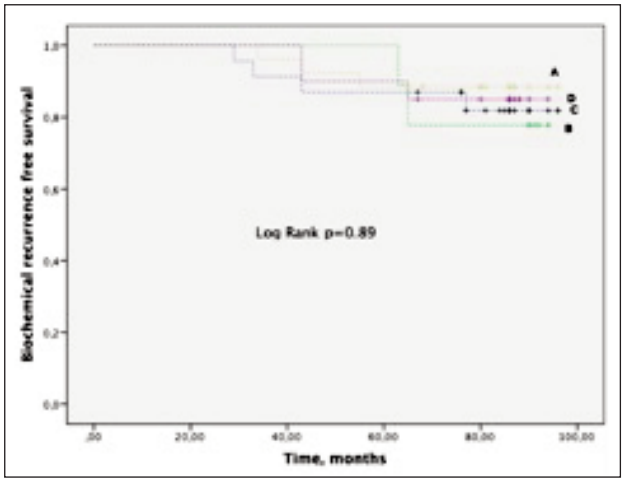


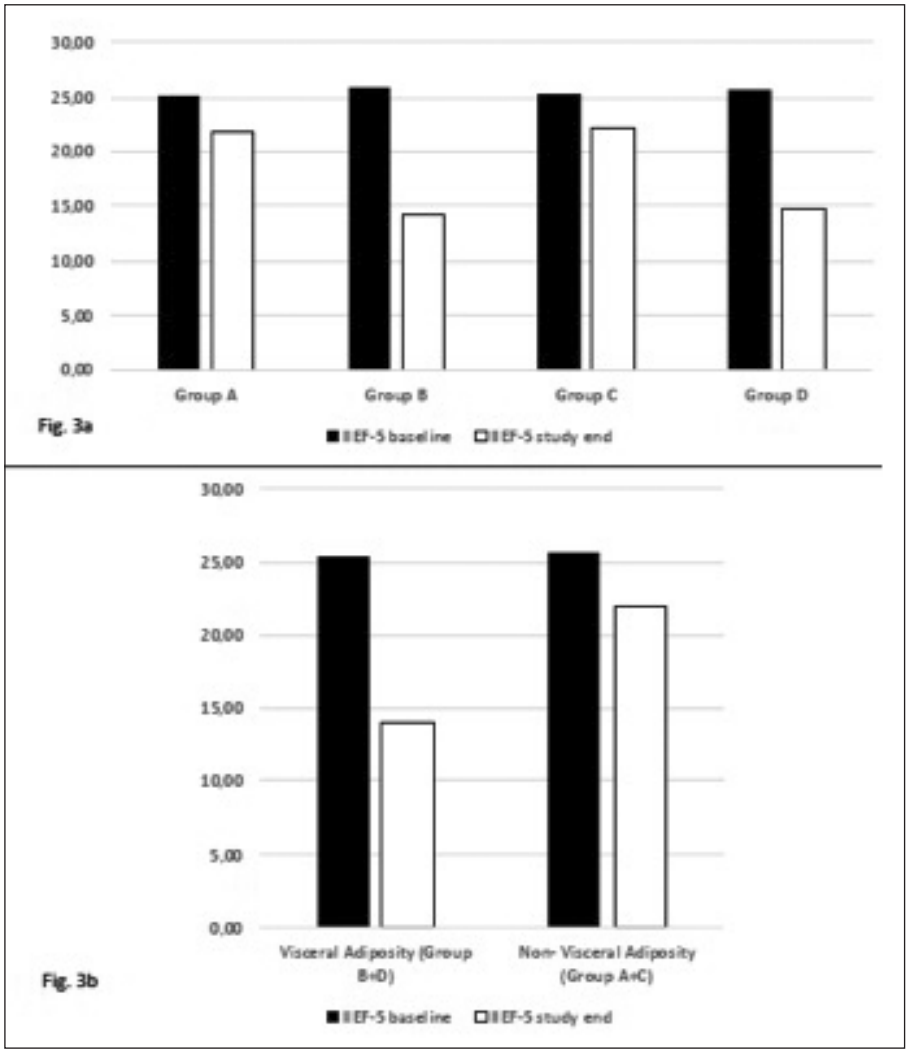
Table 2.
Functional findings at the follow-up evaluation according to the body habitus.

Patients (n°)	78			
NCEP: ATP III# (body habitus)	**Group A**	**Group B**	**Group C**	**Group D**
Patients (n°)	23 (29.4)	9 (11.5)	26 (33.4)	20 (25.7)
Urinary continence				
No pad/die	19	7	20	12
No or 1 pad/die	4	1	5	3
2 or more pads/die	0	1	1	5
IIEF-5§ (median; IQR*)	22 (18-23)	14 (7-16)	22 (17-24)	14 (8-18)
IPSS'	11 (6-14)	12 (7-13)	10 (6-11)	11 (6-13)

The table shows all follow up data according to the body habitus. n° = number; NCEP: ATP III# = National Cholesterol Education Program Adult Treatment Panel III; IIEF-5§ = International Index of Erectile Function; IQR = interquartile range; IPSS' = International Prostatic Symptoms Score.*

Functional outcomes
Overall, 71 (91%) patients reported complete continence, while 7 (8.9%) used ≥ 2 pads per day. Median postoperative IIEF-5 was 18 (IQR: 7-24). Twelve patients (15.4%) reported spontaneous erection without any pharmacological support. Conversely, 38 (48.7%) and 10 (12.8%) reported sexual function recovery with the use of oral support and/or PGE1 administration, respectively, while 18 patients (23.1%) reported complete absence of erections. The median IIEF-5 in 29 patients with VA (Group B+D) was 14 (IQR 7-18) while was 22 (IQR 17-24) in 49 non-VA patients (Group A+C) (62.8%), with a statistically significant difference between the two groups ($p < 0.001$) (Figure 3). Twenty-three patients (79.3%) with VA reported complete continence, while 6 (20.7%) used ≥ 2 pads per day. On the other hand, 48 patients (97.9%) without VA reported complete continence. All follow-up data stratified for body habitus groups have been showed in Table 2.

Figure 3.
a) Median IIEF-5 in patients by body habitus at baseline and at the end of the study. b) Median IIEF-5 in patients with and without visceral adiposity at baseline and at the end of the study.



Multivariate analysis findings
At multivariable analysis, visceral adiposity was confirmed as a strong independent predictor for worse continence (Group B: HR 3.67; 2.75-4.51 CI 95%; p = 0.003; Group D: HR 2.03; 1.81-3.14 CI 95%; p = 0.04) and sexual function recovery (Group B: HR 4.51; 3.09-5.63 CI 95%; p = 0.001; Group D: HR 3.33; 3.04-5.09 CI 95%; p = 0.001) (Table 3).

Discussion

Main findings
It is widely known that functional outcomes have a non-negligible impact on health-related quality of life after RP.
The impact of obesity on the outcomes of RP, irrespective of surgical approach, has been extensively investigated but we are still far from drawing definitive conclusions (7). Yet there is a strong need for further investigation to explore association between continence and sexual recovery and obesity, assessed not only by BMI but also evaluating district adiposity parameters such as WC, subcutaneous and abdominal fat volume.
To address this unmet need, we conducted the current longitudinal, cohort study to further pose a little cornerstone towards an in-depth knowledge of this critical issue.
On the basis of this background, we demonstrated that obesity with central adiposity was associated with worse continence and sexual function recovery after laparoscopic RP.

Table 3.
Multivariate analysis results of factors associated with worse functional outcome (urinary and sexual function).

Categories (variables)	Multivariate analysis (p) (HR; 95% CI)
Urinary function	
Age (< 65, ≥ 65 years)	(0.57) (HR 1.01; 0.75-1.34)
Body Mass Index (kg/m^2, continuous)	(0.07) (HR 1.62; 0.91-1.92)
Waist (cm, continuous)	(0.32) (HR 1.13; 0.55-1.87)
Body habitus	
Non-obese	(0.08) (HR 0.95; 0.63-0.99)
Non-obese with central adiposity	(0.04) (HR 2.03; 1.81-3.14)
Obese without central adiposity	(0.09) (HR 1.19; 0.69-1.90)
Obese with central adiposity	(0.003) (HR 3.67; 2.75-4.51)
Charlson Comorbidity Index (0-1, > 2)	(0.89) (HR 1.12; 0.70-1.56)
American Society of Anesthesiologists Score (≤ 2, ≥ 3)	(0.09) (HR 1.33; 0.90-1.60)
Sexual function	
Age (< 65, ≥ 65 years)	(0.63) (HR 1.07; 0.43-1.65)
Body Mass Index (kg/m^2, continuous)	(0.11) (HR 1.82; 0.90-1.96)
Waist (cm, continuous)	(0.28) (HR 0.91; 0.34-1.23)
Body habitus	
Non-obese	(0.12) (HR 0.80; 0.58-1.12)
Non-obese with central adiposity	(0.001) (HR 3.33; 3.04-5.09)
Obese without central adiposity	(0.08) (HR 1.20; 0.71-1.87)
Obese with central adiposity	(0.001) (HR 4.51; 3.09-5.63)
Charlson Comorbidity Index (0-1, > 2)	(0.77) (HR 1.93; 0.77-1.60)
American Society of Anesthesiologists Score (≤ 2, ≥ 3)	(0.93) (HR 1.42; 0.84-1.79)

The table shows the multivariate analysis results of factors associated with worse functional outcome (urinary and sexual function) in all enrolled patients. HR = Hazard risk; CI = Confidence interval.

Results in the context of previous studies

First key point of our study is that visceral obesity was confirmed to be independently associated with worse sexual function recovery. Of course, the presence of a greater amount of periprostatic adipose tissue may be associated with a higher risk of injury to the neurovascular bundle. Moreover, metabolic syndrome itself is linked with worse potency and higher rates of endothelial dysfunction (21). Actually, several previous studies showed no impact of obesity on sexual domain after open and/or robotic RP (22-24), while other series reported adverse effects (25) or impact with the metabolic and systemic disease (26, 27). However, we would like to point out that in all the above-mentioned health-related quality of life studies, the definition of potency and its measurement was mostly subjective, meaningfully undermining reliability of reported finding. In our study, we tried to overcome this limit by objectively defining pre- and postoperative erectile function with IIEF-5 questionnaire. Second, visceral obesity resulted an independent predictor also of delayed continence recovery. Consistently with our findings, *Wiltz et al.* (25) published one of the largest series, with 945 patients stratified according to BMI, reporting that obesity was associated with worse continence recovery at 12 and 24 months (25). Moreover, a systematic review and metanalysis by *Xu et al.* confirmed that obese patients are at higher risk of experiencing worse functional outcomes after RP (28). Of course, obesity might also bring about additional physical strain on the bladder, ultimately resulting in more preoperative urinary problems and a prolonged duration of return to continence. Considering these underlying issues unrelated to surgical expertise, suboptimal functional outcomes should be discussed with obese patients during preoperative counseling.

Strengths and limitations of this study

The present study was not devoid of limitations. First, this was a retrospective review of a prospectively collected database. Second, the relatively small sample size together might have undermined the evaluation of potential predictors of functional outcomes in our series. Even if all cases were performed by a single surgeon with extensive experience in LRP, our findings could not be applicable to all surgeon- or center-related scenarios. Acknowledged these limitations, our study represents the largest series so far exploring association between continence and sexual recovery and obesity, assessed not only by BMI but also evaluating district adiposity parameters such as WC, subcutaneous and abdominal fat volume. Further multi-institutional series are warranted to confirm our preliminary findings.

Conclusions

In our experience, visceral adiposity was associated with worse continence and sexual function recovery after laparoscopic RP, highlighting the need for an accurate pre-surgical evaluation of the body habitus and a detailed preoperative counselling before surgery.

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