Descriptive Information	
Condition	Prostate cancer (PCa)
Official Title	Modified posterior reconstruction of the rhabdosphincter by iliopectineal ligament suspension during robot-assisted laparoscopic radical prostatectomy: description of the technique & implications on early recovery of urinary continence (Randomized Controlled Trial)
Brief Summary	The robot-assisted laparoscopic radical prostatectomy (RALP) is a widespread and rapidly expanding procedure around the world. Several studies have shown that RALP is feasible with lower positive surgical margin rates, shorter hospitalizations, lower post-operative leakage rates, lower transfusion requirements and a shorter period of urinary catheterization. However, functional outcomes in terms of continence, and erection still lag behind ,markedly reducing the quality of everyday life for patients, especially those who are younger and more active The proportion of continent patients at 12 mo after surgery ranges from 69% to 96% However, the early recovery of urinary continence remains a challenge to be overcome. The functional outcomes in the first 3 mo after radical prostatectomy (RP) are still variable, which has been attributed to differences in the surgical technique and variations in the definition and assessment of continence Based on this information, some technical variations have been described to improve the early urinary continence rates after RRP, such as preservation of the bladder neck, nerve-sparing (NS) techniques, preserving maximum length of the urethra, preserving the puboprostatic ligament and endopelvic fascia, posterior rhabdosphincter reconstruction, anterior reconstruction, and suture of the arcus tendineus to the bladder neck. Among these techniques, PR is currently the most widely adopted by the highest-volume RARP centers. However, the results are controversial. This study was motivated by our technique for performing the reconstructive phase of RALPP, combines the benefits of the Rocco technique with reinforcing rhabdosphincter by iliopectineal ligament suspension to create a hammock to support the vesicourethral anastomosis .We believe that the suspension of the rhabdosphincter complex can provide additional posterior support to the vesicourethral anastomosis stabilizing the posterior urethra in its anatomical position in the pelvic floor. This restores the normal posterior urethrovesical angle during the increase of abdominal pressure. The use of this suspension technique and their outcomes in RALP, however, has not been described. In this study, we report the application of this technique and its impact on early recovery of urinary continence in comparing with the posterior reconstruction (PR) of the rhabdosphincter technique, as described by Rocco and colleagues

<table>
<tr><th colspan="4">Study Design</th></tr>
<tr><td>Study Type</td><td colspan="3">Interventional (Clinical Trial)</td></tr>
<tr><td rowspan="4">Study Design</td><td>Intervention Model:</td><td colspan="2">Parallel Assignment</td></tr>
<tr><td>Allocation:</td><td colspan="2">Randomized</td></tr>
<tr><td>Masking:</td><td colspan="2">None (Open Label)</td></tr>
<tr><td>Primary Purpose:</td><td colspan="2">Treatment</td></tr>
<tr><td>Estimated sample</td><td colspan="3">200 patients</td></tr>
<tr><td>Sampling Method</td><td colspan="3">Non-Probability Sample</td></tr>
<tr><td>Study Population</td><td colspan="3">It will include patients diagnosed with locally advanced prostate adenocarcinoma treated at the Hôtel-Dieu de Québec (HDQ) by Robot-assisted Radical Prostatectomy with pelvic lymph node dissection. Subjects without previous radiotherapy and / or Hormotherapy</td></tr>
<tr><td rowspan="3">Study Groups</td><td>1: Group</td><td colspan="2">Intervention</td></tr>
<tr><td>Robot-assisted radical prostatectomy (RARP) / technique urethrovesical anastomosis (UVA) 1</td><td colspan="2">The posterior reconstruction (PR) of the rhabdosphincter technique, as described by Rocco.</td></tr>
<tr><td>2 : Group
Robot-assisted radical prostatectomy (RARP) / technique urethrovesical anastomosis (UVA) 2</td><td colspan="2">The posterior reconstruction (PR) of the rhabdosphincter technique, as described by Rocco with iliopectineal ligament suspension.</td></tr>
<tr><td>Biospecimen</td><td colspan="3">Non</td></tr>
<tr><td rowspan="4">Eligibility Criteria</td><td>Ages Eligible for Study</td><td colspan="2">45 Years to 80 Years (Adult, Senior)</td></tr>
<tr><td>Sexes Eligible for Study</td><td colspan="2">Male</td></tr>
<tr><td>Inclusion Criteria</td><td colspan="2">Exclusion Criteria</td></tr>
<tr><td>Patients with prostate cancer (PCa) of clinical stage T3 or less with no evidence of metastasis were considered candidates for RALP</td><td colspan="2">• patients not suitable for RARP
• any neoadjuvant hormonal treatment
• prior radiation therapy
• Prior transurethral resection of the prostate previous history of urethral stricture
• Previous history of urinary incontinence.</td></tr>
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Outcome Measures	
Primary Outcome	Impact on early recovery of urinary continence. (< 3 mo)
Secondary Outcome	Impact on recovery of urinary continence. (12 mo)

Data analysis	
Preoperative	Age, BMI, PSA, ASA score IPSS score, IIEF-5 score, TRUS prostate volume GS Positive DRE
Intraoperative	Operative time, min Anastomosis time (min) Estimated blood loss, ml Lymph node dissection Nerve-sparing procedure • Non–nerve sparing • Bilateral nerve sparing • Unilateral nerve sparing Transfusion Catheterization time, day complications (Clavien grade)
Perioperative	Duration of hospital stay (days) Urethral catheterization time (days) complications before hospital discharge (Clavien grade) Urine leakage on cystography
Follow up 1,3,6,12 mo	• Continence ○ Expanded Prostate Cancer Index Composite [EPIC] at 1, 3, 6, and 12 mo after the procedure. ○ the 24-h pad weight test for 3 days ▪ 1st test: The patients who were still incontinent at 3 mo ▪ 2nd test: The patients who were still incontinent at 6 mo ▪ 3rd test: The patients who were still incontinent at 12 mo • ED ○ IIEF-5 score at 1, 3, 6, and 12 mo after the procedure. • complications (Clavien grade) • Histopathological data: ○ Positive margins ○ Prostate volume ○ Stage ○ Pathological GS

Administrative Information

Investigators	Principal Investigator: Dr. Thierry Dujardin	
Study Sponsor	HDQ-CERCO	
Collaborators		
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Ethics committee approval	Status: Approved No. 2019-4193	
References	Menon M, Tewari A, Baize B, et al. Prospective comparison of radical retropubic prostatectomy and robot-assisted anatomic prostatectomy: the Vattikuti Urology Institute experience. Urology. 2002;60:864-868. Menon M, Tewari A, Peabody J, et al. Vattikuti Institute prostatectomy: technique. J Urol. 2003;169:2289-2292. Menon M, Shrivastava A, Sarle R, et al. Vattikuti Institute prostatectomy: a single-team experience of 100 cases. J Endourol. 2003; 17:785-790. Van Velthoven RF, Ahlering TE, Peltier A, et al. Technique for laparoscopic running urethrovesical anastomosis: the single knot method. Urology. 2003;61:699-702. Rocco B, Gregori A, Stener S, et al. Posterior reconstruction of the rhabdosphincter allows a rapid recovery of continence after transperitoneal videolaparoscopic radical prostatectomy. Eur Urol. 2007; 51:996-1003. Rocco F, Carmignani L, Acquati P, et al. Restoration of posterior aspect of rhabdosphincter shortens continence time after radical retropubic prostatectomy. J Urol. 2006;175:2201-2206. Kaul S, Sammon J, Bhandari A, et al. A novel method of urethrovesical anastomosis during robot-assisted radical prostatectomy using a unidirectional barbed wound closure device: feasibility study and early outcomes in 51 patients. J Endourol. 2010;24:1789- 1793. Liberati A, Altman DG, Tetzlaff J et al. The PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate healthcare interventions: explanation and elaboration. BMJ 2009; 339: b2700 Tewari A, Jhaveri J, Rao S et al. Total reconstruction of the vesicourethral junction. BJU Int 2008; 101: 871–7 Gautam G, Rocco B, Patel VR, Zorn KC. Posterior rhabdosphincter reconstruction during robot-assisted radical prostatectomy: critical analysis of techniques and outcomes. Urology 2010;76:734–41. De La Rosette JJ, Abbou CC, Rassweiler J, Laguna MP, Schulman CC (2002) Laparoscopic radical prostatectomy: a European virus with global potentials. Arch Esp Urol 55:603–609 Rassweiler J, Stolzenburg J, Sulser T, Deger S, Zumbe J, Hofmockel G et al (2006) Laparoscopic radical prostatectomy— the experience of the German Laparoscopic Working Group. Eur Urol 49:113–119	

	Patel VR, Thaly R, Shah K. Robotic radical prostatectomy: outcomes of 500 cases. BJU Int 2007;99:1109–12. Noguchi M, Shimada A, Nakashima O, Kojiro M, Matsuoka K. Urodynamic evaluation of a suspension technique for rapid recovery of continence after radical retropubic prostatectomy. Int J Urol 2006;13:371–6.