Early Experience in Extraperitoneal Robotic Assisted Radical Prostatectomy with HUGO RAS System: A Comparative Analysis with Laparoscopic Radical Prostatectomy

Experiência Inicial na Prostatectomia Radical Extraperitoneal Assistida por Robot com o HUGO RAS: Análise Comparativa com a Prostatectomia Radical Laparoscópica

Miguel Marques Monteiro[1], David Teixeira[2], Diogo Nunes-Carneiro[1,2], João Cabral[1], Frederico Teves[1,2], José Soares[1,2], Avelino Fraga[1,2]

Abstract

Introduction: The Hugo™ RAS system represents a novel robotic platform recently implemented in our department. Despite its introduction, there is still a scarcity of data regarding extraperitoneal robot-assisted radical prostatectomy (eRARP) carried out using this system. Our primary aim is to compare perioperative, early functional, and oncological outcomes of eRARP with the Hugo RAS System during our centre's initial foray into robotic surgery with our standard three-dimensional extraperitoneal laparoscopic radical prostatectomy (eLRP).

Methods: We conducted a retrospective analysis, comparing men diagnosed with localized prostate cancer who underwent either eRALP or eLRP at a tertiary referral centre in Portugal. These procedures were carried out by the same major surgeons between 2022 and 2023. Urinary continence was defined as no pads used and was assessed up to 3 months post-surgery. Oncologic outcomes were determined by evaluating the positive surgical margin (PSM) rate and PSA levels ≥0.1 ng/mL at 6 weeks. Secondary outcomes included the usage of protective pads at 6 weeks and 3 months post-surgery, total operative time, estimated blood loss, length of hospital stay, and catheterization time. Complications within 3 months post-surgery were classified according to the Clavien-Dindo system. Statistical analysis was conducted using SPSS Statistics 28®, with significance set at a two-sided *p*-value <0.05.

Results: Patients who underwent eRALP (n=50) and eLRP (n=59) were analysed and compared. Postoperative continence rates at 6 weeks and 3 months after surgery were 52.0% and 70.0% for eRALP and 42.4% and 64.4% for eLRP, respectively ($p>0.05$). PSA persistence was observed in 16.7% and 23.7% for the eRALP and eLRP, respectively ($p=0.369$). There was no statistically significant difference in the rates of positive surgical margins (PSM) between the two surgical modalities. Regarding perioperative outcomes, the median total operative time was greater for eRALP compared to eLRP (261 min (238-294) *vs* 177 min (157--200), $p<0.001$). For eRALP, the median console time was 137 min (119-196), and the mean docking time was 4.6 min (IQR 4.1–5.2). The median estimated blood loss was 200 mL (250-575) *vs* 150 mL (100-200) for eRALP and eLRP, respectively ($p=0.151$). The median time to remove the vesical catheter was lower for eRARP (7 days (7–8) *vs* 8 days (8–10), $p<0.001$). A percentage of 92% of patients undergoing eRALP had a length of stay less than or equal to two days, while only 52.5% of those undergoing eLRP met this criterion ($p<0.001$). The only intraoperative complication registered was mechanical failure in one robotic arm, which required conversion to laparoscopy. No intraoperative complications for eLRP were registered. There was also no statistically significant difference in the rates of complication frequency within 3 months after surgery (eRALP 10.0% *vs* eLRP 10.2%, $p=0.459$).

Conclusion: Robotic-assisted extraperitoneal radical prostatectomy with the Hugo™ RAS demonstrates comparable oncological outcomes and early urinary continence to our standard laparoscopic extraperitoneal radical prostatectomy. eRARP with this novel robotic system seems to allow a seamless transition into robotic surgery.

Keywords: Laparoscopy; Prostate/surgery; Prostatectomy/methods; Prostatic Neoplasms/surgery; Robotic Surgical Procedures

Resumo

Introdução: *O sistema Hugo™ RAS representa uma plataforma robótica inovadora, recentemente implementada no nosso departamento. Apesar da sua introdução, ainda existe uma escas-*

1 – Urology Service, Unidade Local de Saúde de Santo António, Porto, Portugal
2 – Instituto Ciências Biomédicas Abel Salazar – Universidade do Porto, Porto, Portugal

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sez de dados relativamente à prostatectomia radical extraperitoneal assistida por robot realizada com este sistema. O nosso principal objetivo é comparar os resultados perioperatórios, funcionais e oncológicos durante a nossa experiência inicial da prostatectomia radical assistida por robot (eRARP), utilizando o Sistema Hugo™ RAS, com a tradicional prostatectomia radical laparoscópica tridimensional extraperitoneal (eLRP).

Métodos: Realizamos uma análise retrospetiva, comparando homens diagnosticados com cancro da próstata localizado, que foram submetidos a eRALP ou eLRP num centro de referência terciário em Portugal. Estes procedimentos foram realizados pelos mesmos cirurgiões entre 2022 e 2023. A continência urinária foi definida como a não utilização de pensos e foi avaliada aos 3 meses após a cirurgia. Os resultados oncológicos foram determinados através da taxa de margens cirúrgicas positivas (PSM) e da avaliação da persistência de PSA (PSA=0,1 ng/mL às 6 semanas). Os resultados secundários incluíram o uso de pensos protetores às 6 semanas e aos 3 meses após a cirurgia, o tempo operatório total, a perdas sanguíneas estimadas, o tempo de internamento e o tempo de cateterização. As complicações até 3 meses após a cirurgia foram classificadas de acordo com o sistema Clavien-Dindo. A análise estatística foi realizada utilizando o SPSS Statistics 28®, com significância definida para um valor de p de duas caudas <0,05.

Resultados: Foram analisados e comparados pacientes submetidos a eRALP (n=50) e eLRP (n=59). As taxas de continência pós-operatória às 6 semanas e 3 meses após a cirurgia foram de 52,0% e 70,0% para eRALP e 42,4% e 64,4% para eLRP, respetivamente (p>0,05). A persistência do PSA foi observada em 16,7% e 23,7% para a eRALP e a eLRP, respetivamente (p=0,369). Não houve diferença estatisticamente significativa nas taxas de margens cirúrgicas positivas entre as duas modalidades cirúrgicas. Em relação aos resultados perioperatórios, a mediana do tempo operatório total foi maior para a eRALP comparado com eLRP (261 min (238-294) vs 177 min (157-200), p<0,001). Para a eRALP, a mediana do tempo de consola foi de 137 min (119-196), e o tempo médio de ancoragem foi de 4,6 min (IQR 4,1-5,2). A mediana de perdas sanguíneasestimadas foram de 200 mL (250-575) vs 150 mL (100-200) para a eRALP e eLRP, respetivamente (p=0,151). O tempo mediano para a remoção do cateter vesical foi menor para aeRARP (7 dias (7-8) vs 8 dias (8-10), p<0,001). Dos pacientes submetidos a eRALP, 92% tiveram um tempo de internamento inferior ou igual a dois dias, enquanto apenas 52,5% dos submetidos a eLRP cumpriram este critério (p<0,001). A única complicação intraoperatória registada foi a falha mecânica de um braço robótico, que exigiu a conversão para laparoscopia. Não foram registadas complicações intraoperatórias para a eLRP. Também não houve diferença estatisticamente significativa nas taxas de frequência de complicações até 3 meses após a cirurgia (eRALP 10,0% vs eLRP 10,2%, p=0,459).

Conclusão: A prostatectomia radical extraperitoneal assistida por robot com o Hugo™ RAS demonstra resultados oncológicos e continência urinária comparáveis com a prostatectomia radical laparoscópica extraperitoneal. A eRARP com este sistema robótico parece permitir uma transição suave para a cirurgia robótica com resultados favoráveis.

Palavras-chave: Laparoscopia; Neoplasias da Próstata/cirurgia; Próstata/cirurgia; Prostatectomia/métodos; Procedimentos Cirúrgicos Robóticos

Introduction

Prostate cancer (PCa) is the second most prevalent malignancy affecting men worldwide.[1,2] Despites, it is a complex disease with a diverse spectrum of treatment modalities. In the context of clinically localised disease, radical prostatectomy remains the preeminent primary curative intervention. Historically, this procedure was primarily performed through open surgery, typically via a retropubic approach. Nevertheless, the notable incidence of post-prostatectomy complications, including urinary incontinence, sexual dysfunction, considerable haemorrhage, postoperative pain and long convalescence[3] has catalysed the introduction of minimally invasive approaches to optimise functional outcomes and recovery period.

The advent of minimally invasive techniques, such as robotic-assisted approaches, has emerged as a viable alternative to open radical prostatectomy (ORP). Robotic-assisted radical prostatectomy (RARP) has gained increasing acceptance, establishing itself as the dominant surgical modality for prostatectomy due to its ability to combine the minimally invasive advantages of laparoscopic RP with enhanced technical proficiency in vesicourethral anastomosis reconstruction.[4] Consequently, RARP has become the preferred minimally invasive approach when available. RARP was initially introduced using the Da Vinci® Surgical system (Intuitive Surgical, Inc.) in 2002, which played a significant role in shaping the landscape of robotic surgery. However, the pace of technological advancement has led to the introduction of new robotic systems within the scientific community.[5]

One of the recent additions to the robotic surgical arena is the HUGO™ RAS System, developed by Medtronic. This system comprises an “open” surgical console with an HD–3D passive display, a system tower, and four independent, extendable modular portable arm carts. The open console facilitates the transition from laparoscopy to robotic surgery, while the independent robotic arms offer flexibility and innovative possibilities for configuring operative rooms and techniques. These characteristics allow a magnified three-dimensional vision, heightened precision and improved ergonomics.[3,6-8]

Despite the enthusiasm surrounding RARP, no evidence exists to conclusively demonstrate its superiority over open and laparoscopic radical prostatectomy (LRP).[9]

Given our extensive experience in laparoscopic radical prostatectomy, questions persist regarding the advantages of RARP over LRP. Drawing from our prior investigations, our study aims to compare perioperative, oncologic, and early functional outcomes between RARP utilising this novel HUGO™ RAS System and LRP in a high-volume centre without prior robotic surgical experience.[10]

Methods

1. Study Design and Participants

We conducted a single-centre study within the high-volume urology department of Centro Hospitalar Universitário de Santo António, Porto, Portugal. We retrospectively reviewed patients diagnosed with newly localised prostate cancer who had opted for radical prostatectomy (RP) as their primary treatment, with or without pelvic lymphadenectomy (PLND). The decision to perform PLND was based on a preoperative risk of nodal involvement of 5%.[11]

The objective of our trial was to compare two distinct modalities of minimally invasive radical prostatectomy. This included the recently introduced extraperitoneal robotic-assisted radical prostatectomy (eRARP) using the novel Hugo RAS System and our established standard approach, the three-dimensional extraperitoneal laparoscopic radical prostatectomy (eLRP).

For laparoscopic radical prostatectomy, we retrospectively collected data from January 2021 to December 2022, while data for RARP were gathered following its implementation in our department, from March 2023 to December 2023.

eRARP procedures were conducted by two surgeons (J.C. and F.T.) during their initial experience with robotic surgery. eLRP was performed by the same surgeons (J.C and F.T), both of whom had large LRP experience. We retrieved demographic, clinical, and disease-specific clinical data from the hospital's electronic clinical records, which were then extracted through a review of medical records. Ethical approval for the study was obtained from the relevant ethical committees and written informed consent was acquired from all participating patients. The study protocol received approval from the Ethics Committee of our university hospital (Reference Number: 2023.257(219-DEFI/209-CE). All procedures adhered to the principles of the Declaration of Helsinki, and patients provided their informed consent to participate.

2. Procedures and Postoperative Care

Extraperitoneal robot-assisted radical prostatectomies (eRARP) were conducted in accordance with previously published methods, as described.[9] Extraperitoneal laparoscopic radical prostatectomy (eLRP) followed the same procedural technique. Vesical catheter removal was supervised by nursing staff and all patients received instructions to perform pelvic floor muscle exercises postoperatively.

3. Outcomes

Continence and oncological outcomes were assessed by analysing subjective data collected at baseline, at 6 and at 12 weeks postoperatively. Intraoperative data were recorded as per usual practice by the surgical and anaesthetic teams and subsequently obtained by the research team through a review of medical records. Postoperative complications were ascertained via medical records and patient interviews throughout the trial. Data were retrieved from the hospital's electronic clinical process and extracted by medical records review.

3.1 Perioperative Data

Surgical variables were assessed and compared as total intraoperative time (total duration that a patient spent in the operating room), operative time (duration of surgery), console time, estimated total blood loss, incidence of intraoperative adverse events, and need for technical conversion. We also closely examined the duration of indwelling catheter placement, length of hospital stays, postoperative complications (classified according to the modified Clavien-Dindo system) and readmission rates within 90 days following surgery.

3.2. Urinary Continence

Continence data were collected via patient-reported incontinence and the number of pads used at both 6 weeks and 12 weeks after RP. Patients were defined to be continent if they reported no pad usage during the specified periods.

3.3. Oncological Outcomes

Positive surgical margin (PSM) status and postoperatively PSA total levels served as surrogate markers for evaluating oncologic outcomes. PSA persistence was defined as PSA >0.1ng/mL at 6 weeks. Furthermore, the need for postoperative radiotherapy and localization, extension, and focality of surgical margins was documented.

4. Statistical Analysis

To characterise the study cohort, means and standard deviations were calculated for continuous variables, while numbers and percentages were determined for categorical data. Non-normally distributed samples were summarised using the median and quartiles. Shapiro-Wilk and histogram were used to assess normality and the Levene test for variance equality. For the comparison of categorical variables, $\chi 2$ and Fisher's exact tests were utilised, while independent samples t-test and Mann-Whitney U-tests were employed for quantitative variables as appropriate. Uni and Multivariate logistic regression analysis were used to identify independent clinical and pathological predictors. Data preparation and descriptive statistics were performed using IBM SPSS version 29.0 Edition statistical software (IBM Corp., Armonk, NY, USA). The reported *p*-values were two-sided, and values <0.05 were taken to indicate statistical significance.

Results

Patients who underwent eRALP (n = 50) and eLRP (n = 59) were analysed and compared. Baseline, demographic, clinical, and histologic characteristics of radical prostatectomy specimens between the groups were well-balanced and are found in Table 1.

1. Perioperative Outcomes

Regarding perioperative outcomes, the median total operative time was significantly longer for eRALP compared to eLRP (261 min (238-294) *vs* 177 min (157–200), *p*< 0.001). For eRALP, the median console time was 137 min (119–196), and the mean docking time was 4.6 min (IQR 4.1–5.2). The median estimated blood loss was 200 mL (250-575) *vs* 150 mL (100-200) for eRALP and eLRP, respectively (*p*=0.151). The median time to remove the vesical catheter was lower for eRARP (7 days (7–8) *vs* 8 days (8–10), *p*<0.001). Ninety-two percent of patients undergoing eRALP had a length of stay of two days or less, while only 52.5% of those undergoing eLRP met this criterion (*p*<0.001). The sole intraoperative complication registered was a mechanical failure in one robotic arm, which required conversion to laparoscopy. No intraoperative complications were registered for eLRP. There was also no statistically significant difference in the postoperative readmissions and complications within 3 months after surgery (eRALP 10.0% *vs* eLRP 10.2%, *p*=0.459). Detailed perioperative outcomes are presented in Table 2.

2. Continence

Postoperative continence rates at 6 weeks and 12 weeks after surgery were 52.0% and 70.0% for eRALP and 42.4% and 64.4% for eLRP, respectively (*p*>0.05), according to the 0 pads definition at 3-mo FU (*p*=0.341 and *p*=0.548). Among incontinent patients, 52.2% and 55.9% for eRALP and eLRP, respectively only used one pad at 6 weeks and these patients' difference increased at 12 weeks (eRALP 60.0% *vs* eLRP 90.5%, *p*<0.01). These results are described in Table 3 and Fig. 1.

3. Oncological outcomes

Summary data concerning oncological outcomes are presented in Table 4. There were no significant differences in PSA values between eRARP and eLRP groups across all tumour stages.

PSA persistence was observed in 16.7% and 23.7% for the eRALP and eLRP, respectively (*p*=0.369). Further analysis can be found in Table 4. There was also no statistically significant difference in positive surgical margins rates between the two surgical modalities. Oncologic outcomes according to stratification in stages and EAU risk classification were reported in Table V.

PSM (OR 3.8 95% CI 1.2-12.2, *p*=0.024), extraprostatic disease (OR 7.8 95% CI 2.4-25.3 *p*<0.001) and histologic ISUP grade 3-5 of specimen (OR 6.4 95%CI 2.0-20.6, *p*=0.002) were independent predictors of PSA persistence at 6 weeks (PSA ≥01). However, in the multivariable analysis only extraprostatic disease (OR 3.9 95% CI 1.1-13.7 *p*=0.034) and higher ISUP grade of the specimen (OR 4.6 95%CI 1.3-15.8, *p*=0.019) remained as independent predictors compared to PSM (OR 2.9 95% CI 0.8--10.5, *p*=0.10). Only extraprostatic disease (OR 4.8, 95% CI 1.8--13.4, *p*<0.001) emerged as an independent predictor of positive surgical margins in multivariable analysis adjusted for ISUP. Table 5 displays the rates of PSM localization as well.

Discussion

The management of localised prostate cancer remains challenging and controversial. Existing evidence does not definitively establish one method as superior to another in terms of long-term functional and oncological outcomes. Thereby, the choice of therapeutic approach is typically determined collaboratively by a multidisciplinary team takinginto the patient's preferences. In the context of radical surgery, there is an ongoing debate regarding the adoption of robotic surgery to minimise functional complications and achieve superior oncologic outcomes, compared to the existing results of laparoscopic or open procedures.[4]

Multiple studies have compared minimally invasive surgical therapies with the classic open retropubic approach, but the only outcomes consistently distinguishing them have been reduced blood loss and length of stay, and safer early catheter removal in minimally invasive approaches.[11-15]

In addition, comparisons between robotic-assisted radical prostatectomy and laparoscopic procedures have yielded disparate conclusions across the literature.[16-18] Hence, the aim of this study was to compare the outcomes of the recently introduced extraperitoneal robotic-assisted laparoscopic prostatectomy using the novel Hugo RAS System with our conventional extraperitoneal LRP. The goal was to assess whether the initial experience affected the oncological outcomes and continence.

There is a lack of high-quality studies comparing biochemical recurrence rates, prostate-specific mortality, and overall survival between the existing different approaches.[19] Although two RCTs have attempted to compare these outcomes between RARP and LRP, they have not been able to show a statistical difference in this regard.[16,20] A more recent RCT aimed to address these outcomes in a larger, more inclusive sample, but also failed to reach a statistically significant conclusion.[18]

Our results revealed a persistence of PSA (16.7% in the eRARP group *vs* 23.7% in the eLRP group, *p*=0.369) similar to those reported by Stolzenburg *et al* (23% RARP *vs* 21% LRP) but higher than those reported by Asimakopoulos *et al* (8% RARP vs 3% LRP) and Porpiglia *et al* (2% RARP *vs* 7.5% LRP).[6,16,20] These discrepancies may be attributed, first of all, to the elevated percentage of high-risk patients that constituted our sample. In fact, 53.1% of our RARP group and 37.3% of the LRP group were classified as high-risk patients, which means an increased risk of

Table 1 – Baseline and histologic characteristics of radical prostatectomy specimens.

Variable	eRARP (n=50)	eLRP (n=59)	*p* value
Median age, years (IQR)	70 (64-73)	67 (62-71)	0.257
Mean body mass index, kg/m^2 (SD)	26.12 (± 3.12)	26.12 (± 3.12)	0.410
Median preoperative PSA level, ng/mL (IQR)	9.7 (6.3–14.4)	7.4 (6.4-11.6)	0.176
Biopsy ISUP grade group			
Grade group 1, n (%)	10 (20.0)	16 (27.1)	0.385
Grade group 2, n (%)	23 (46.0)	24 (40.7)	0.576
Grade group 3, n (%)	13 (26.0)	12 (20.3)	0.484
Grade group 4-5, n (%)	4 (8.0)	7 (11.9)	0.505
EAU Risk Stratification			0.221
Low risk, n (%)	7 (14.3)	14(23.7)	
Intermedium risk, n (%)	16 (32.7)	23(39.0)	
High-risk, n (%)	26 (53.1)	22(37.3)	
cT stage, n (%)			0.095
Impalpable (cT1)	21 (42.0)	41 (69.5)	
Palpable (cT2–3)	17 (34.0)	16 (27.1)	
Tumour stage on preoperative MRI			0.789
T2, n (%)	38 (76)	45 (76.3)	
T3, n (%)	5 (10)	7 (12.4)	
Median prostate volume on preoperative MRI, cm^3 (IQR)	43 (30-57)	43 (33-64)	0.986
Median prostate weight, g	38 (32-49)	42 (33-56)	0.272
Pathologic ISUP grade group			
Grade group 1, n (%)	0 (0.0)	2 (3.4)	0.499
Grade group 2, n (%)	28 (56.0)	25 (42.4)	0.156
Grade group 3, n (%)	17 (34.0)	21 (35.6)	0.862
Grade group 4-5, n (%)	5 (10.0)	11 (18.6)	0.204
pT stage, n (%)			0.580
pT2	27 (54.0)	32 (54.2)	
pT3a	12 (24.0)	18 (30.5)	
pT3b	11 (22.0)	9 (15.3)	
Extraprostatic extension, n (%)	18 (36.0)	26 (44.1)	0.392
Median of lymph nodes yielded, n (IQR)	2 (0-4)	5 (3-8)	0.012
N+, n (%)	1 (2.0)	0 (0.0)	0.428

EAU=European Association of Urology; ISUP = International Society of Urological Pathology; MRI = magnetic resonance imaging; PSA = prostate-specific antigen; SD= standard deviation; IQR= interquartile range; eRARP= extraperitoneal robotic assisted radical prostatectomy; eLRP= extraperitoneal laparoscopic radical prostatectomy; N+= metastasis in regional lymph node

Table 2 – Postoperative results for the study cohort

Variable	eRARP (n=50)	eLRP (n=59)	*p* value
Median total intraoperative time, min (IQR)	261 (238-294)	177 (157-200)	<0.01
Median operative time, min (IQR)	190 (145-200)	120 (99-141)	<0.01
Median console time, min (IQR)	137 (114-161)	–	–
Underwent PLND, n (%)	19 (38.0)	28 (47.5)	0.365
Median estimated blood loss, ml (IQR)	200 (250-575)	150 (100-200)	0.151
Median time to catheter removal, d (IQR)	7 (7-7)	8 (8-10)	<0.01
Median length of hospital stays, days (IQR)	2 (2-2)	2 (2-3)	<0.01
Length of stay ≤2 days, n (%)	46 (92.0)	31 (52.5)	<0.01
Intraoperative complications, n (%)	1 (2)	0 (0)	0.459
90-days complications, n (%)	5 (10.0)	6 (10.2)	0.729
90-days readmission, n (%)	1 (2)	2 (3.4)	1

eRARP= extraperitoneal robotic assisted radical prostatectomy; eLRP= extraperitoneal laparoscopic radical prostatectomy; IQR= interquartile range; PLND= pelvic lymph node dissection

Table 3 – Urinary continence results for the study cohort

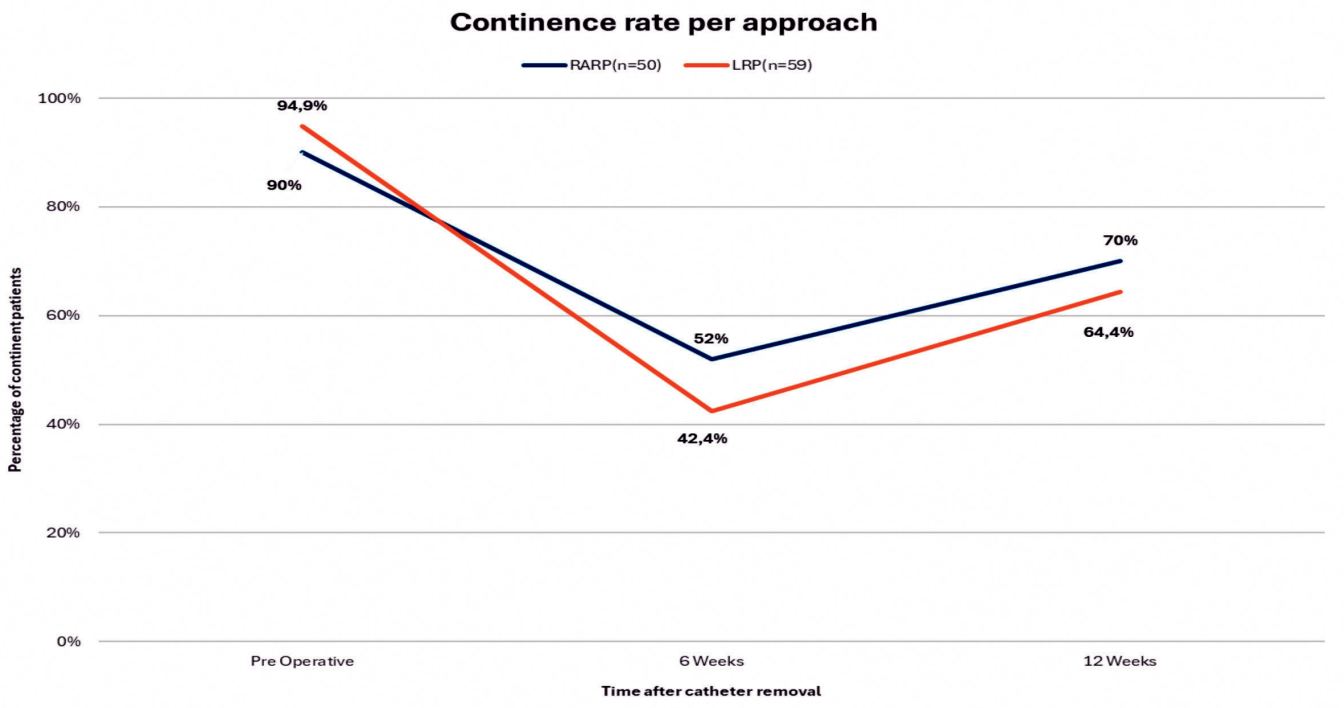
Variable	eRARP (n=50)	eLRP (n=59)	*p* value
Continence Rates			
Pre-operative urinary continence, n (%)	45 (90.0)	56 (94.9)	0.525
Urinary continence at 6 weeks, n (%)	26 (52.0)	25 (42.4)	0.341
Urinary Continence at 12 weeks, n (%)	35 (70.0)	38 (64.4)	0.548
Non-continent patients			
Pads number at 6 weeks ≤1, n (%)	13 (52.2)	19 (55.9)	0.897
Pads number ≤1 at 12 weeks, n (%)	9 (60.0)	19 (90.5)	<0.01

eRARP= extraperitoneal robotic assisted radical prostatectomy; eLRP= extraperitoneal laparoscopic radical prostatectomy

PSA failure, need for secondary therapy, metastatic progression, and death from PCa. Nevertheless, radical prostatectomy is still an option for these patients with low volume tumors, but patients should be aware pre-operatively that surgery may be part of a multimodal treatment, with adjuvant or salvage radiotherapy androgen deprivation therapy.[4] In our study,we included pT3 patients, which accounted for 46.0% of the eRARP sample and 45.8% of the eLRP sample, as well as ISUP grade 4-5 patients, which are known predictors of PSA persistence. In addition, 36% of the eRARP group and 44.1% of the eLRP had extra prostatic extension, another established predictor of PSA persistence.[4] Upon analyzing the subgroup of patients with PSA persistence, we found that 75% of the patients in the eRARP group and 85.7% of patients in the eLRP group were classified as pT3, and 37.5% of patients on both groups had pathologic ISUP grade 4-5 tumors.

Our population appears to be like that of Stolzenburg *et al,*[18] who encompassed 35.8% of T3+ patients in their RARP sample and 38.5% in their LRP group. In contrast, Asimakopoulos *et al*[20] included only T1-T2 and Gleason scores =7, and Porpiglia *et al*[16] concentrated only on clinically staged T1–T2N0M0 patients.

Although our study did not find a statistically significant difference in positive surgical margins between eRARP and eLRP, we observed a higher overall percentage of PSM rates compared to similar studies. On the other hand, our PSA persistence results do



eRARP= extraperitoneal robotic assisted radical prostatectomy; eLRP= extraperitoneal laparoscopic radical prostatectomy

Figure 1 – Continence rate per approach

not appear to differ largely from the ones stated by Stolzenburg *et al,* who had similar inclusive parameters in sample selection to our study.[18] Also, in a multivariate analysis, only extraprostatic disease and higher ISUP grade remained as independent predictors. This finding was not observed for positive surgical margins. This can mean that the PSM rates observed in our study may not reflect true pathological findings but rather indicate poor manipulation of the prostatic specimen during surgical procedures. Therefore, a potential conclusion drawn from this trial is the importance of exercising increased caution during radical prostatectomies to minimise distortion of the original specimen.

The improved three-dimensional vision and ergonomics, as well as better precision, offered by the RARP, are generally accepted as potentially positively impacting continence rates. However, there appears to exist no difference between RARP and ORP either at early or long-term continence rates, according to different RCTs and meta-analyses.[15,21,22] A recently published multicentre RCT, the LAP-01, observed better early continence but found no difference at 12-months of follow-up between RARP and LRP.[18] Finally, although there is seemingly a lack of studies comparing LRP with ORP, the few available ones that we found suggest a superior early continence rate in ORP, with no difference observed in the long-term follow-up.[23]

Our study showed that 52% of eRARP patients and 42.4% of eLRP patients were continent at 6 weeks of follow-up, representing a 10.4% difference between groups. This difference decreased to 5.6% at 12 weeks, with continence rates of 70% and 64.4% in eRARP and eLRP patients, respectively. Although these results did not reach statistical significance, likely due to the limited patient population of this study, they align with the trends observed in previous studies. Our results regarding the difference in continence rates between groups over the follow-up period are similar to findings reported by the three RCTs mentioned above. These studies noted an initial superior continence rate in eRARP that tended to diminish over time, when compared to LRP.[16,18,20] Our results have also shown that, even in the incontinent patients, the majority of them need ≤1 PAD at 12 weeks. Possible explanations for the apparent superiority of RARP over LRP in early recovery continence may be related to the intrinsic characteristics of robotic-assisted procedures. For instance, improved manoeuvrability may enable better quality dissection and preservation of the neurovascular bundle. Additionally, the three-dimensional magnification allows an extremely precise apical/urethral dissection, resulting in an increasing preservation of the length of the membranous urethra.[6,16] Furthermore, the ability to perform an effective posterior reconstruction with or without the addition of anterior suspension techniques, alongside preservation of the and bladder neck and puboprostatic ligament, could aid in achieving an early return to baseline continence.[24,25] Likewise, the apparent similarity between ORP and RARP procedures observed in several trials regarding functional outcomes might be surpassed as experience with RARP progresses.[12,26]

Table 4 – Oncologic results for the study cohort

Variable	eRARP (n=50)	eLRP (n=59)	*p* value
PSM, n (%)	30 (60.0)	35 (59.3)	0.943
Non-Limited (>3 mm) PSM, n (%)	15 (35.7)	17 (53.1)	0.721
PSA at 6 weeks <0.05, n (%)	33 (68.8)	43 (72.9)	0.639
PSA at 6 weeks 0.05-0.1, n (%)	7 (14.6)	2 (3.4)	0.075
PSA at 6 weeks > 0.1, n (%)	8 (16.7)	14 (23.7)	0.369
Postoperative radiotherapy, n (%)	6 (12.5)	17 (28.8)	0.041
pT2			
PSM, n (%)	14 (51.9)	13 (40.1)	0.388
Non-Limited (>3 mm) PSM, n (%)	5 (35.7)	4 (36.4)	0.973
PSA >0.1, n (%)	2 (7.7)	23 (9.4)	1
Postoperative radiotherapy, n (%)	1 (3.9)	3 (9.4)	0.618
ISUP 4-5, n (%)	2 (7.4)	2 (6.3)	0.624
pT3			
PSM, n (%)	16 (69.7)	22 (81.4)	0.325
Non-Limited (>3 mm) PSM, n (%)	10 (83.3)	13 (61.9)	0.259
PSA >0.1 n (%)	6 (27.3)	12 (44.4)	0.215
Postoperative radiotherapy, n (%)	5 (29.4)	14 (51.9)	0.175
ISUP 4-5, n (%)	3 (13.0)	9 (33.3)	0.112
pT3a, n (%)			
PSM, n (%)	7 (58.4)	14 (77.8)	0.255
Non-Limited (>3 mm) PSM, n (%)	4 (80.0)	8 (57.1)	0.603
PSA >0.1, n (%)	2 (16.7)	6 (33.3)	0.312
Postoperative radiotherapy, n (%)	1 (8.33)	5 (27.7)	0.170
ISUP 4-5, n (%)	0 (0)	5 (27.7)	0.066
pT3b			
PSM, n (%)	9 (81.8)	8 (88.8)	1
Non-Limited (>3 mm) PSM, n (%)	6 (85.7)	6 (85.7)	1
PSA >0.1 n (%)	4 (40.0)	6 (66.7)	0.370
Postoperative radiotherapy, n (%)	4 (40.0)	9 (100)	<0.01
ISUP 4-5, n (%)	3 (27.3)	4 (44.4)	0.642

eRARP= extraperitoneal robotic assisted radical prostatectomy; eLRP= extraperitoneal laparoscopic radical prostatectomy; PSM= positive surgical margin; ISUP = International Society of Urological Pathology; PSA = prostate-specific antigen

Consequently, we posit that when exclusively conducted by a proficient surgical team and in select patient subsets, RARP may demonstrate superior oncologic and functional outcomes compared to ORP.

Lastly, the variability in the definition of continence across articles in the existing literature, as highlighted by Salazar *et al,* adds complexity to comparing continence outcomes.[27] These differences in sample characteristics and study methodologies

Table 5 – Analysis of PSA persistence, positive surgical margins and EAU Risk classification

PSA Persistence Variable	**eRARP**	**eLRP**	***p* value**
Pathologic stage ≥pT3, n (%)	6 (75.0)	12 (85.7)	0.602
Pathologic ISUP 4-5, n (%)	3 (37.5)	5 (37.5)	1
PSM, n (%)	6 (75.0)	12 (85.7)	0.602
Postoperative radiotherapy, n (%)	6 (75.0)	12 (85.7)	0.602
Positive Surgical Margins Variable	**eRARP**	**eLRP**	***p* value**
pT2	14 (51.9)	13 (40.1)	0.388
PSA>0.1, n (%)	1 (8.3)	1 (8.3)	1
Bilateral, n (%)	6 (42.9)	2 (16.7)	0.216
Multifocal, n (%)	9 (64.2)	2 (15.4)	<0.01
Apex, n (%)	7 (50.0)	6 (50.0)	1
Lateral, n (%)	5 (35.7)	5 (41.6)	0.756
Base, n (%)	5 (35.7)	2 (16.7)	0.275
pT3	16 (69.7)	22 (81.4)	0.325
PSA>0.1, n (%)	5 (31.3)	11 (50.0)	0.248
Bilateral, n (%)	6(37.5)	4 (18.2)	0.182
Multifocal, n (%)	7 (43.8)	10 (45.5)	0.942
Apex, n (%)	7 (46.7)	5 (22.7)	0.127
Lateral, n (%)	8 (53.3)	8 (36.4)	0.308
Base, n (%)	3 (20.0)	13 (59.1)	0.018
EAU Risk classification Variable	**eRARP**	**eLRP**	***p* value**
Low Risk			
Pathologic stage ≥pT3, n (%)	2 (28.6)	6 (42.3)	0.655
Pathologic ISUP 4-5, n (%)	0 (0.0)	0 (0.0)	1
PSM, n (%)	5 (71.4)	7 (50.0)	0.656
PSA >0.1, n (%)	0 (0.0)	1 (7.1)	1
Postoperative radiotherapy, n (%)	0 (0.0)	2 (14.3)	0.533
Intermedium Risk			
Pathologic stage ≥pT3, n (%)	6 (37.5)	9 (39.1)	0.918
Pathologic ISUP 4-5, n (%)	1 (6.25)	3 (13.0)	0.631
PSM, n (%)	9 (56.3)	5 (21.7)	0.061
PSA >0.1, n (%)	2 (12.5)	15 (65.2)	<0.01
Postoperative radiotherapy, n (%)	1 (6.3)	5 (21.7)	0.370
High Risk			
Pathologic stage ≥pT3, n (%)	15 (57.7)	12 (54.5)	0.825
Pathologic ISUP 4-5, n (%)	5 (19.2)	8 (36.4)	0.183
PSM, n (%)	16 (61.5)	13 (59.1)	0.862
PSA >0.1, n (%)	6 (23.1)	8 (36.4)	0.313
Postoperative radiotherapy, n (%)	5 (19.2)	10 (45.5)	0.051

EAU=European Association of Urology; eRARP= extraperitoneal robotic assisted radical prostatectomy; eLRP= extraperitoneal laparoscopic radical prostatectomy; ISUP = International Society of Urological Pathology; PSA = prostate-specific antigen; PSM= positive surgical margin

should be considered when interpreting and comparing the findings of these studies.

Regarding perioperative outcomes, our study revealed a longer operative time using the eRARP, compared to the eLRP (p=<0.01). However, the median operative time of 190 min (IQR 145-200) and median console time of 137 min (IQR 114-161) of the eRARP group where not far from what another study abording the HUGO™ RAS System has shown, with Bravi *et al* observing a median operative time of 180 min (IQR 145–200) and a median console time of 150 min (IQR 145–175).[28] On the other hand, Paciotti *et al* described a shorter median operative time of 150 min (IQR 130–170) and median console time of 120 min (IQR 110–150).[29]

There was no difference in the median blood loss between procedures, which contrasts with conclusions from a systematic review indicating that eRARP resulted in less blood loss compared to LRP.[12] This may also be justified by the learning curve experienced by our surgical team, or could potentially be attributed to alternative factors, such as the surgical technique itself.

The median time to catheter removal was found to be inferior in eRARP compared to eLRP (7 (IQR 7-7) *vs* 8 (IQR 8-10) days, respectively). These results differ from findings in other studies, where the median time for catheter removal was similar for RARP and LRP.[6,16,20] A possible explanation for this finding may lie in the technical superiority that robotic-assisted procedures offer, facilitating the creation of a watertight vesicourethral anastomosis, securing a greater safety in the early catheter removal. The variability between institution protocols and techniques used by the surgical teams may also justify the great differences observed in median time to catheter removal within the existing trials, with Develtere *et al* describing catheter removal date as early as 2 days, while Busby *et al* concluded the 7th day of post operation to be the ideal time for catheter removal.[29-31]

The median length of hospital stay was identical for both surgical approaches (2 days). However, the number of patients who were hospitalised under two days was significantly superior in eRARP (46 (92.0) days for RARP *vs* 31 (52.5) days for LRP). This suggests that RARP may lead to earlier patient discharge, potentially resulting in lower hospital inpatient costs, reduced overall postoperative complications and early return to work.

Despite early discharge, there were no differences relating to postoperative readmissions and complication rates in our study. These are different results from what the LAP-01 observed, where the LRP group had an increased rate of postoperative complications (21%), compared with the RARP group (15%).[6]

A strength of this study lies on the comparative analysis of the extraperitoneal technique using the Hugo™ RAS with the extraperitoneal laparoscopic radical prostatectomy, using real world data. The fact that there was no patient selection approximates this trial to the daily medical routine, therefore mimicking the results one might expect more accurately. As explained above, the robotic assisted radical prostatectomy, although without statistical value, seemed to follow the trend previous studies have shown of earlier recovery of continence in the eRARP group, as well as earlier hospital discharge and catheter removal, while maintaining oncological integrity compared to laparoscopic procedures. It is noteworthy that our surgical teams are still within the learning curve for manoeuvring the robotic equipment, underlining the potential for further improvement in outcomes with increased experience, and, despite the large experience operating via eLRP, the eRARP results show to be very promising.

Some limitations of our study include variations in experience levels between the analysed procedures, with a larger experience in laparoscopic surgery compared to the initial stages of robotic surgery, potentially affecting outcomes as the latter may still be within its learning curve. Additionally, the low sample size may underestimate differences in continence between the two groups and limit the use of other statistical methods, such as propensity score matching.

Also, the absence of questionnaires in the patient's follow-up and the retrospective nature of the study may lead to an underreporting of the non-favourable outcomes or an overestimation of the results. Finally, the influence of nerve-sparing was not investigated due to non-report, although it constitutes the preferred approach of our department.

Conclusion

Despite the initial experience, robotic-assisted extraperitoneal radical prostatectomy with the Hugo™ RAS demonstrates comparable oncological outcomes and tends to improve early urinary continence compared to our standard laparoscopic extraperitoneal radical prostatectomy. Also, the robotic approach leads to earlier hospital discharge compared to the laparoscopic one. Extraperitoneal RARP with this novel robotic system seems to prove to be safe and feasible, allowing for a seamless transition into robotic surgery.

Responsabilidades Éticas

Conflitos de Interesse: Os autores declaram a inexistência de conflitos de interesse na realização do presente trabalho.

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Confidencialidade dos Dados: Os autores declaram ter seguido os protocolos da sua instituição acerca da publicação dos dados de doentes.

Proteção de Pessoas e Animais: Os autores declaram que os procedimentos seguidos estavam de acordo com os regulamentos estabelecidos pela Comissão de Ética responsável e de

acordo com a Declaração de Helsínquia revista em 2024 e da Associação Médica Mundial.

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Autor Correspondente/*Corresponding Author:*
Dr. Miguel Marques Monteiro
Centro Hospitalar Universitário do Porto
Largo Prof. Abel Salazar – 4099-001 PORTO, Portugal
miguelmarquesmonteiro.urologia@chporto.min-saude.pt
https://orcid.org/0000-0002-8222-0511

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