Which Factors Affect Short-Term Urinary Continence and Erectile Function Recovery Following Robotic-Assisted Radical Prostatectomies (RARP)?-A Retrospective Cohort Study

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Introduction

Robotic-Assisted Radical Prostatectomy (RARP) is currently a gold standard treatment for localised prostate cancer [1]. Variations in prostatectomy technique include nerve-sparing, limited or extended Pelvic Lymph Node Dissection (PLND). During nerve-sparing, the closely associated neurovascular bundles are preserved to allow for spontaneous penile erections to be maintained postoperatively. A limited PLND refers to only the lymph nodes surrounding and in close association to the prostate found in the external iliac and obturator fossa areas, meanwhile extended PLND remove nodes further away including hypogastric, pre-sacral and pre-sciatic regions [2].

Development of the DaVinci (Intuitive®) surgical system and preliminary trialling of its application in a urological setting led to the first documented RARP occurring in early 2000 [1,3,4]. Following this,
use of the DaVinci system has been adopted in many centres worldwide. Guy’s and St Thomas’ Hospitals was one of the first to pioneer the use of robotic assistance in the urology setting in the United Kingdom in 2004, which is now practiced across the globe. Comparative to Laparoscopic Radical Prostatectomy (LRP), RARP is highly effective with increased precision and accuracy, leading to improved patient outcomes. The odds of biochemical recurrence, urinary incontinence and Erectile Dysfunction (ED) are lower following RARP compared to LRP, as found in systematic reviews by Ficarra V, et al. and Montorsi F, et al. [5,6]. Although outcomes have improved since the introduction and use of RARP, postoperative Prostate Specific Antigen (PSA) levels, continence and erectile function are still concerning to patient’s disease-free survival and quality of life.

This study aims to evaluate perioperative variables in men undergoing RARP, to establish any significant correlations affecting these short-term postoperative outcomes of PSA levels, continence and ED. By doing so we hope to develop our understanding and aid patient management and postoperative care to ensure optimal patient recovery is achievable.

Patients and Methods

This was a retrospective analysis of all RARPs performed at a high volume tertiary robotic centre between January 2016 and April 2017. A total of 382 RARPs were performed of which 331 were statistically analysed. 51 cases were excluded from analysis due to insufficient postoperative data or follow-up was not received at our trust.

Each patient received a standard preoperative workup; PSA, MRI and appropriate prostate biopsies were taken within 14 days of first referral. The Briganti nomogram forms the basis for lymphadenectomy with a 5% threshold for lymph node involvement alongside PSMA-PET code scanning results. All patients were discussed at the Multi-Disciplinary Team (MDT) meeting in which tumour grade, stage and lymph node dissection was decided, with a management plan agreed and as per the network target by day 62 from initial presentation to the Disciplinary Team (MDT) meeting in which tumour grade, stage and lymph node dissection was decided, with a management plan agreed and as per the network target by day 62 from initial presentation to the Postoperative Day (POD) 1.

All operative procedures were carried out according to local trust protocol. Patients received prophylactic gentamycin and intravenous co-amoxiclav at induction. Patients were positioned in the Reverse Trendelenburg position with end docking and standard 6 port access for the dual console Da Vinci Xi (Intuitive®) Surgical System. Postoperatively, all patients were mobilized on the 1st postoperative day with their urethral catheter in situ and discharged with low molecular weight heparin injections for 28 days. Patients then had a nurse-led trial without catheter at week 1 and surgeon review at 6 weeks post-RARP.

Data was collected on 15 perioperative variables and was correlated to three short-term postoperative outcomes: PSA levels at 6 weeks, urinary continence and ED at 6 months. An undetectable PSA was defined as <0.03ng/L. Continence endpoints were defined by individuals either fully continent or using a security pad for light leakage followed by increased number of pad usage per day, at 6 months postoperatively, and the endpoint defining complete ED was ED refractory to oral agent, pump or injections. The perioperative variables examined included: patient demographics; operating consultant; preoperative PSA, Gleason score, amount of nerve sparing (none, unilateral or bilateral); tumour staging; distance of surgical margins; presence of seminal vesicle invasion and grading of nodes removed.

Data collection and analysis was performed using RStudio (Version 1.1.456). Multiple logistic regression analyses were performed to identify predictors for each of the three endpoints. In order to increase power to the test, endpoints for the analysis were defined as:

- Post-operative PSA 0 ≤ 0.03ng/L, 1 ≥ 0.03ng/L
- Continence 0=Fully Continent 1=any incontinence
- Post-operative erectile Function 0=no ED 1=any ED

For descriptive purposes, endpoints with subcategories are also presented in graphs and tables. If a variable did not have enough number of events for the outcomes of interest, then it was excluded from the analysis.

This study has been registered as an audit at our institution (Ref: 8077) and all work has been reported in line with the STROCSS criteria [8]. No ethical approval or funding was required for this study.

Results

A total of 382 RARPs were carried out between January 2016 to April 2017 (mean 24/month), of which 331 underwent full analysis. 51 cases were excluded due to insufficient postoperative data or follow-up was not received at our trust. Cases were performed by five experienced Urologists at a single institution.

Mean patient age was 62.22 ± 7.45 years (IQR: 38.7-87.8 years). Mean preoperative PSA was 10.12 ± 7.86 ng/mL (SD: 1.20-68.00 ng/mL), and using the new Epstein Gleason scoring system the modal grade group was 2 indicative of a Gleason score 3+4=7 [9].

Of 71 patients whom had a lymphadenectomy, 63 were benign (88.7%), 3 (4.22%) had micrometastasis and 5 (7.04%) were metastatic. Documented complications were minimal, 6/331 (1.81%), and Clavien-Dindo I/II only.

Urinary and patients’ characteristics can be found in table 1.

Associations between perioperative and short-term postoperative outcomes

PSA level at 6 weeks: At 6 weeks post RARP, a routine PSA level was performed. 278 (84.0%) patients had an undetectable PSA at 6 weeks (PSA <0.03ng/L), thus indicating biochemical cure. Twenty-eight patients (8.4%) had PSA 0.03 to <0.1 and the remainder 25 (7.55%) had PSA 0.1 to <0.6.

On analysis we found increased preoperative PSA level to be significantly associated to increased postoperative PSA levels at 6 weeks (OR=1.05, p=0.01). We also found positive surgical margins less than or equal to 3mm in length associated with increased postoperative PSA levels at 6 weeks (OR=4.70, p=0.00) compared to negative surgical margins. Metastatic lymph nodes removed were additionally found to be significantly associated to increased postoperative PSA levels (OR=4.74, p=0.05). Whilst unilateral and bilateral nerve sparing were identified as significantly protective factors in reducing postoperative PSA levels at 6 weeks comparative to non-nerve sparing RARP (OR=0.37,0.30 and p=0.03,0.01 respectively) (Table 2).

Urinary continence at 6 months: At 6 months, 75.8% (251/331) patients were either fully continent or using a security pad (Figure 1).

When performing the multiple logistic regression analysis all perioperative variables were included. The results found firstly

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Table 1: Tumour and patient characteristics.

|                        | Urinary Incontinence | Erectile Dysfunction | Post-Operative PSA |
|-----------------------|----------------------|----------------------|--------------------|
|                       | No (n=207)           | Yes (n=124)          | Overall (n=331)    |
|                       | No (n=31)            | Yes (n=300)          | Overall (n=331)    |
|                       | <0.03                | >=0.03               | Overall (n=331)    |
| **Age**               |                      |                      |                    |
| Mean(SD)              | 61.4(7.93)           | 63.6(6.39)           | 62.2(7.45)         |
| Median [Min, Max]     | 62.0 [38.0,78.0]     | 64.0 [46.0,77.0]     | 63.0 [38.0,78.0]   |
| **Consultant**        |                      |                      |                    |
| Consultant 1          | 18(8.7%)             | 18(14.5%)            | 36(10.9%)          |
|                       | 1(3.2%)              | 35(11.7%)            | 36(10.9%)          |
|                       | 34(12.2%)            | 2(3.8%)              | 36(10.9%)          |
| Consultant 2          | 42(20.3%)            | 12(9.7%)             | 54(16.3%)          |
|                       | 6(19.4%)             | 48(16.0%)            | 54(16.3%)          |
|                       | 50(18.0%)            | 4(7.5%)              | 54(16.3%)          |
| Consultant 3          | 13(6.3%)             | 10(8.1%)             | 23(6.9%)           |
|                       | 0(0%)                | 23(7.7%)             | 23(6.9%)           |
|                       | 20(7.2%)             | 3(5.7%)              | 23(6.9%)           |
| Consultant 4          | 78(37.7%)            | 55(44.4%)            | 133(40.2%)         |
|                       | 18(58.1%)            | 115(38.3%)           | 133(40.2%)         |
|                       | 107(38.5%)           | 26(49.1%)            | 133(40.2%)         |
| Consultant 5          | 56(27.1%)            | 29(23.4%)            | 85(25.7%)          |
|                       | 6(19.4%)             | 79(26.3%)            | 85(25.7%)          |
|                       | 67(24.1%)            | 18(34.0%)            | 85(25.7%)          |
| **Pre-Op PSA**        |                      |                      |                    |
| Mean(SD)              | 10.6(8.64)           | 9.83(7.37)           | 10.2(8.05)         |
| Median [1.80-68.0]    | 8.00[1.20-64.5]      | 8.00[1.20-68.0]      | 6.00[2.07-31.6]    |
| **Gleason ISUP**      |                      |                      |                    |
| 1                     | 10(4.8%)             | 9(7.3%)              | 19(5.7%)           |
|                       | 1(3.2%)              | 18(6.0%)             | 19(5.7%)           |
|                       | 18(6.5%)             | 1(1.9%)              | 19(5.7%)           |
| 2+3                   | 170(82.1%)           | 95(76.6%)            | 265(80.1%)         |
|                       | 26(83.9%)            | 239(79.7%)           | 265(80.1%)         |
|                       | 227(81.7%)           | 38(71.7%)            | 265(80.1%)         |
| 4+5                   | 27(13.0%)            | 20(16.1%)            | 47(14.2%)          |
|                       | 4(12.9%)             | 43(14.3%)            | 47(14.2%)          |
|                       | 33(11.9%)            | 14(26.4%)            | 47(14.2%)          |
| **T stage groups**    |                      |                      |                    |
| 0-1                   | 143(69.1%)           | 83(66.9%)            | 226(68.3%)         |
|                       | 24(77.4%)            | 202(67.3%)           | 226(68.3%)         |
|                       | 196(70.5%)           | 30(56.6%)            | 226(68.3%)         |
| 2,3,4                 | 64(30.9%)            | 41(33.1%)            | 105(31.7%)         |
|                       | 7(22.6%)             | 98(32.7%)            | 105(31.7%)         |
|                       | 82(29.5%)            | 23(43.4%)            | 105(31.7%)         |
| **Seminval vesicles invasion** |            |                      |                    |
| 0                     | 195(94.2%)           | 115(92.7%)           | 310(93.7%)         |
|                       | 29(93.5%)            | 281(93.7%)           | 310(93.7%)         |
|                       | 263(94.6%)           | 47(88.7%)            | 310(93.7%)         |
| 1                     | 12(5.8%)             | 9(7.3%)              | 21(6.3%)           |
|                       | 2(6.5%)              | 19(6.3%)             | 21(6.3%)           |
|                       | 15(5.4%)             | 6(11.3%)             | 21(6.3%)           |
| **Positive nodes**    |                      |                      |                    |
| None                  | 191(92.3%)           | 113(91.1%)           | 304(91.8%)         |
|                       | 29(93.5%)            | 275(91.7%)           | 304(91.8%)         |
|                       | 262(94.2%)           | 42(79.2%)            | 304(91.8%)         |
| Benign                | 10(4.8%)             | 9(7.3%)              | 19(5.7%)           |
|                       | 2(6.5%)              | 17(5.7%)             | 19(5.7%)           |
|                       | 12(4.3%)             | 7(13.2%)             | 19(5.7%)           |
| Micrometastasis-Metastasis | 6(2.9%)         | 2(1.6%)              | 8(2.4%)            |
|                       | 0(0%)                | 8(2.7%)              | 8(2.4%)            |
|                       | 4(1.4%)              | 4(7.5%)              | 8(2.4%)            |
| **Margins**           |                      |                      |                    |
| Negative              | 168(81.2%)           | 99(79.8%)            | 267(80.1%)         |
|                       | 26(83.9%)            | 241(80.3%)           | 267(80.1%)         |
|                       | 234(84.2%)           | 33(62.3%)            | 267(80.1%)         |
| <=3mm                 | 26(12.6%)            | 20(16.1%)            | 46(13.9%)          |
|                       | 4(12.9%)             | 42(14.0%)            | 46(13.9%)          |
|                       | 28(10.1%)            | 18(34.0%)            | 46(13.9%)          |
| >3mm                  | 13(6.3%)             | 5(4.0%)              | 18(5.4%)           |
|                       | 1(3.2%)              | 17(5.7%)             | 18(5.4%)           |
|                       | 16(5.8%)             | 2(3.8%)              | 18(5.4%)           |
| **Nerve Sparing**     |                      |                      |                    |
| None                  | 40(19.3%)            | 30(24.2%)            | 70(21.1%)          |
|                       | 4(12.9%)             | 66(22.0%)            | 70(21.1%)          |
|                       | 49(17.6%)            | 21(39.6%)            | 70(21.1%)          |
| Unilateral            | 72(34.8%)            | 37(29.8%)            | 109(32.9%)         |
|                       | 7(22.6%)             | 102(34.0%)           | 109(32.9%)         |
|                       | 94(33.8%)            | 15(28.3%)            | 109(32.9%)         |
| Bilateral             | 95(45.9%)            | 57(46.0%)            | 152(45.9%)         |
|                       | 20(64.5%)            | 132(44.0%)           | 152(45.9%)         |
|                       | 135(48.6%)           | 17(32.1%)            | 152(45.9%)         |

Figure 1: A graph showing the frequency of continence levels 6 months postoperatively.
Table 2: Showing the multiple logistic regression analyses between the perioperative variables analysed comparative to the postoperative PSA levels at 6 weeks. (Ref=reference group, OR=odds ratio).

| Post-Operative PSA | OR   | 2.5%CI | 97.5%CI | P-value |
|--------------------|------|--------|---------|---------|
| Age                | 1.00 | 0.96   | 1.04    | 0.86    |
| Consultant         |      |        |         |         |
| Consultant 1       | Ref  | Ref    | Ref     | Ref     |
| Consultant 2       | 0.96 | 0.17   | 7.46    | 0.97    |
| Consultant 3       | 2.68 | 0.41   | 21.85   | 0.31    |
| Consultant 4       | 3.52 | 0.94   | 22.90   | 0.10    |
| Consultant 5       | 3.33 | 0.84   | 22.31   | 0.13    |
| Pre-Op PSA         | 1.05 | 1.01   | 1.09    | 0.01*   |

Table 3: Showing the multiple logistic regression analyses between the perioperative variables analysed comparative to the postoperative urinary incontinence outcomes at 6 months. (Ref=reference group, OR=odds ratio).

| Urinary Incontinence | OR   | 2.5%CI | 97.5%CI | P-value |
|----------------------|------|--------|---------|---------|
| Age                  | 1.04 | 1.01   | 1.08    | 0.02*   |
| Consultant           |      |        |         |         |
| Consultant 1         | Ref  | Ref    | Ref     | Ref     |
| Consultant 2         | 0.33 | 0.13   | 0.82    | 0.02*   |
| Consultant 3         | 0.85 | 0.29   | 2.46    | 0.77    |
| Consultant 4         | 0.83 | 0.39   | 1.80    | 0.64    |
| Consultant 5         | 0.53 | 0.23   | 1.23    | 0.14    |
| Pre-Op PSA           | 1.02 | 0.99   | 1.05    | 0.19    |

increasing age to be significantly associated with increased urinary incontinence outcomes (OR=1.33, p=0.02) and we also found one consultant out of the five to be significantly associated to reduced incontinence outcomes (OR=0.33, p=0.02) (Table 3).

Erectile Dysfunction (ED) at 6 months: At 6 months patients’ responses were categorized into the following outcomes: no ED; minimal or improving spontaneous erections; erections managed well with oral agents and/or a pump device; trial period with the same or another oral agent; erections not managed with oral agents and pump, hence trial injections; erections managed well with injections; erections not managed well with oral agents, pump and injections; and finally, certain patients did not wish to pursue treatment for ED. At 6 months of 35.2% (116/331) patients were found to have no ED, minimal or improving spontaneous erections or were managing erections well with oral agents and pump (Figure 2).

On multiple logistic regression analysis perioperative variables regarding Operating Consultants and the presence of metastatic nodes were removed to avoid redundancies. From the analysis we found increasing age to be significantly associated with increased PSA levels at 6 months (OR=1.78, p=0.00) (Table 4).

Discussion
This study provides interesting data relating to significant associations amongst perioperative variables and postoperative outcomes following RARP.

PSA levels
PSA levels after RARP are a significant marker in indication of operative success and oncological prognosis, the aim being to achieve undetectable levels of PSA [10,11]. Increased PSA prior to RARP would indicate a poorer general prognosis with a more advanced tumour staging and invasion of the cancer thus increasing the potential for treatment failure.
of metastases and remnants of the cancer post resection. Our data supports the preoperative PSA levels determining post op levels as has been reported in previous literature [12,13]. We have also identified metastatic lymph node involvement compared to benign were also significantly associated to increased postoperative PSA levels further substantiating the literature (OR=4.74, p=0.05).

Interestingly, multiple logistic regression analysis found unilateral and more so bilateral nerve sparing to be significantly associated to reduce PSA levels postoperatively at 6 weeks with odds ratios 0.37 and 0.30 respectively. This most likely is due to the reduced tumour stage of such patients as nerve sparing is only offered to non-metastasised compared to non-nerve sparing RARPs. The fine balance between the benefits of nerve sparing and the detriments of positive surgical margins as highlighted within this study should be further explored.

Positive margins less than 3mm in length with an odds ratio of 4.70 (1.87-11.81 95% CI) to be significantly associated to increased postoperative PSA levels at 6 weeks, compared to negative surgical margins. This may have also been true for positive margins greater than 3mm in length, however with only 18 such cases identified a significant association could not be stated, a larger study would be required to confirm. Nevertheless, if there are positive margins it is more likely that there is a localised spread of micrometastasis into the neighbouring structures, thus suggesting a higher PSA.

Table 4: Showing the multiple logistic regression analyses between the perioperative variables analysed comparative to the postoperative erectile function outcomes at 6 months.(ref=reference group, OR=odds ratio).

| Erectile Dysfunction | OR  | 2.5%CI | 97.5%CI | P-value |
|----------------------|-----|--------|---------|---------|
| Age                  | 1.78| 1.49   | 2.28    | 0.00*   |
| Pre-Op PSA           | 0.99| 0.84   | 1.18    | 0.95    |
| Gleason ISUP         |     |        |         |         |
| 1                    | Ref | Ref    | Ref     | Ref     |
| 2+3                  | 0.36| 0.01   | 4.24    | 0.45    |
| 4+5                  | 0.18| 0.00   | 4.63    | 0.32    |

| T stage groups       |     |        |         |         |
|----------------------|-----|--------|---------|---------|
| 0-1                  | Ref | Ref    | Ref     | Ref     |
| 2,3,4                | 1.38| 0.27   | 8.23    | 0.70    |

| Seminal vesicles invasion |     |        |         |         |
|---------------------------|-----|--------|---------|---------|
| 0                         | Ref | Ref    | Ref     | Ref     |
| 1                         | 0.15| 0.00   | 5.12    | 0.35    |

| Margins                  |     |        |         |         |
|--------------------------|-----|--------|---------|---------|
| Negative                 | Ref | Ref    | Ref     | Ref     |
| <=3mm                    | 3.08| 0.03   | 291.76  | 0.63    |
| >3mm                     | 0.93| 0.03   | 26.63   | 0.96    |

| Nerve Sparing            |     |        |         |         |
|--------------------------|-----|--------|---------|---------|
| None                     | Ref | Ref    | Ref     | Ref     |
| Unilateral               | 0.5 | 0.04  | 6.92    | 0.61    |
| Bilateral                | 0.64| 0.06   | 7.07    | 0.72    |

From the results achieved from this study the overall positive surgical margin rate was 19% compared to the national average of 31%. Once separated by tumour staging we found T2 (n=228) positive margin rates to be only 8% compared to the national average of 13%, whereas T3a (n=58) positive surgical margin rates were found to be significantly higher at 44.6% when the national average would aim for approximately 30% [7]. Following departmental consultant discussion, we believe the explanation were to aim to nerve spare and hence narrower excisions of T3a tumours. Regardless, we hope to further develop and implement quality assurance programmes as described by Cathcart P, et al. in 2015, whereby the use of monthly image-based surgical planning peer reviewed sessions will help us to understand how this discrepancy arose and provide solution on how to improve such outcomes in future [14].

Urinary continence

From the multiple logistic regression analysis, we found increasing age and the possibility of the operating consultant to significantly affect postoperative continence outcomes. The impact of increasing age has already been well documented in previous literature due to decline in nerve function/muscle strength alongside increasing comorbidities, such as heart conditions, arthritis, and diabetes with increasing age [15,16].

This study is one of the first to identify a possible affect the operating consultant can have on postoperative continence outcomes. In our cohort five experienced consultant urologists performed the operations, however one of the consultants was associated to significantly improved continence outcomes postoperatively. Similar to Pick et al we cannot confirm a learning curve effect to be the primary explanation for this finding [16]. This is because all surgeons were highly experienced, operating independently as consultants for an excess of 10 years each. Therefore, if the learning curve cannot be the sole explanation for our significant difference reported, other factors should be considered.

The surgeon with improved continence results had a varying surgical technique; aiming for maximal apical dissection and urethral length preservation; ensuring no endopelvic fascia dissection; meticulous bladder neck reconstruction; cold cutting of the dorsal venous complex and the use of larger urethral suture bites. He believes these techniques may have affected the continence outcomes and we therefore hope to explore the intricacies of the operative technique in future studies. Another potential variable factor may lie with the experience of the bedside operating assistant. Although the bedside assistant operates under close supervision of the consultant at the console, a learning curve also exists for the assistant, in addition to variations in the surgical technique which should be explored.

However, as the data was collected retrospectively, we cannot be completely certain if this association identified was limited by unintentional biases. This is firstly due to each consultant urologist operating upon a different volume of cases, ranging with the highest performing 133 RARPs and the lowest only 23. In addition, confounding variables such as age as identified in this study, alongside tumour staging and preoperative continence levels which could significantly affect postoperative continence outcomes were not controlled and thus could also affect this association identified.

Erectile dysfunction

Erectile function is a very important functional outcome for patients, allowing for improved recovery and quality of life postoperatively. Our study identified increasing age which is well
documented in the literature due to many factors such as declining nerve function, increasing co-morbidities, reduced testosterone levels and psychological distress [17]. The negative correlations are also useful to note whereby our results found perioperative variables such as preoperative PSA scores, presence of histopathological tumor invasion and increased tumour size and staging showed no statistically significant relationship with erectile function postoperative outcomes. We hope our results can help support the literature further and thus manage patient outcomes, especially amongst a more elderly population undergoing the RARP procedure [5,18].

Limitations of this study

Due to the retrospective nature of the study, we had a limited sample size, increasing this would increase our reliability. A formal ED assessment tool wasn’t used or a comment on the patient’s comorbidities. In the future we aim to implement this to aid patient counselling and management of expectations, whilst also providing additional explanation of these study findings. Also, for the outcomes concerning erectile dysfunction 10% of patients did not wish to pursue treatment which may have also altered our results as well.

Conclusion

Postoperative PSA levels were significantly increased in patients associated with high preoperative PSA levels, metastatic lymph nodes and those with positive surgical margins less than 3mm in length whilst significantly decreased amongst patients undergoing unilateral and bilateral nerve sparing RARPs. Increasing age and the effect of the operating consultant were also found to significantly affect continence outcomes postoperatively. We believe surgical technique impacts continence as detailed above and will look to explore this further. Overall this study will help predict postoperative functional outcomes in patients undergoing RARPs based on perioperative data allowing the urologist to be more informed of their patient's functional prognosis, aid counselling of patient expectations, in addition to oncological outcomes.

Acknowledgment and Disclosure Statement

No further acknowledgements or competing financial interests exist. Ethical approval was not required as this study focused on retrospective anonymised data analysis. This study has been registered with Research Registry under registration ID 5785.

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