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The Australian Laparoscopic Non Robotic Radical Prostatectomy Experience – Analysis of 2943 Cases (USANZ Supplement)

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Abstract: Objectives:

To analyse the Australian experience of high-volume Fellowship-trained Laparoscopic Radical Prostatectomy (LRP) surgeons.

Materials and Methods:

2943 LRP cases were performed by nine Australian surgeons. The inclusion criteria were a prospectively collected database with a minimum of 100 consecutive LRP cases. The surgeons' LRP experience commenced at various times from July 2003 to September 2009. Data were analysed for demographic, peri-operative, oncological and functional outcomes.

Results:

The mean age of patients were 61.5 years and mean preoperative PSA 7.4ng/ml. Mean operating time was 168 minutes with conversion to open surgery in 0.5% and a blood transfusion rate of 1.1%. Overall mean length of stay was 2.5 days. 73.6% of pathological specimens were pT2 and 86.3% had Gleason Score >7. Overall positive surgical margins (PSM) occurred in 15.9% with pT2 PSM 9.8%, pT3a PSM 30.8% and pT3b PSM 39.2%. Mean urinary continence at 12 months was 91.4% (data available from five surgeons). Mean 12 months potency after bilateral nerve spare was 47.2% (data

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available from four surgeons). Biochemical recurrence occurred in 10.6% (mean follow up 17 months).

Conclusion:

The Australian experience of Fellowship trained surgeons performing LRP demonstrates favourable peri-operative, oncological and functional outcomes in comparison to published data for open, laparoscopic and robotic assisted radical prostatectomy. In our Australian centres, LRP remains an acceptable minimally invasive surgical treatment for prostate cancer despite the increasing use of robotic assisted surgery.

Introduction

Since Schuessler first described the technique over 20 years ago [1], Laparoscopic Radical Prostatectomy (LRP) has been established as an effective and trainable minimally invasive surgical treatment option for localised prostate cancer with the advantages of decreased blood loss, decreased analgesic requirements and earlier hospital discharge and convalescence compared with Open Radical Prostatectomy [2-6].

However, first generation pioneer surgeons have suggested that several hundred cases are required before the learning-curve is overcome [2, 7]. As such, the widespread dissemination of LRP has been limited with 'de novo' learning of the technique not recommended without formal 'immersion' fellowship training [8]. It is well recognised, however, that Fellowship programs in LRP shorten this learning curve [3, 9-11].

Although the steep learning curve may have diminished the enthusiasm for LRP, this minimally invasive surgical technique continues to be performed in Australian centres due to local surgeon experience, geographical and financial barriers to robotic access. In this study, we analyse the Australian experience of high volume Fellowship-trained LRP surgeons and compare it to a published review of outcomes from high-volume open, laparoscopic, and robotic assisted prostatectomy series [12]. This is the largest multi-centre radical prostatectomy series with any technique from Australia, and is one of the largest published LRP series internationally [13]

Materials and Methods

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All surgeons performing laparoscopic radical prostatectomy in Australia were invited to participate in this study with the entry requirement being a prospectively collected database with a minimum of 100 consecutive LRP cases collected from the start of their LRP experience.

With ethics approval [Hunter New England 14/07/16/5.07 (HNE), Human Research Ethics Committee (HREC) LNR/14/HNE/263], data from 2943 LRP cases were collected from nine surgeons from around Australia including three in regional areas (Figure 1). Eight of the nine surgeons had LRP Fellowship training overseas and all surgeons perform an extra-peritoneal descending approach [14].

The surgeons' LRP experience commenced at various times from July 2003 to September 2009. Six of the nine surgeons continue to perform LRP as of August 2014. Mean surgeon annual case load was 45, ranging from 22 to 95 cases per year (Table 1). Data were analysed for demographic, peri-operative, oncological and functional outcomes and compared to the weighted means of data from a published review article on high volume open, laparoscopic and robotic assisted prostatectomy centres [12].

Pathological staging and positive surgical margins (PSMs) were reported in accordance with the guidelines of the International Society of Uropathologists (ISUP) [15]. Pre-operative potency was defined as an IIEF-5 of ≥ 17 and postoperative potency, the ability to achieve penetrative intercourse with or without oral PDE-5 inhibitors. We defined continence as dry and pad free or the use of a precautionary pad that remained completely dry over a 24-hour period. The data on functional outcomes were assessed by patient questionnaires (IIEF-5) together with clinician/practice nurse data collection.

Results

The mean age of patients were 61.5 (39-83) years and mean preoperative prostate specific antigen (PSA) was 7.4 (0.1-87) ng/ml (Table 2).

19%, 63% and 18% were preoperative D'Amico's low, intermediate and high risk respectively.

Mean operating time was 168 minutes (range of operator means 117-224 minutes) with conversion to open surgery in 0.5% (range of operator means, 0-1.5%) and a blood transfusion rate of 1.1% (range of operator means, 0-2.5%). The overall mean length of stay was 2.5 days (range of operator means 1.7 – 3 days) (Table 3).

Pathological specimens were 73.6% pT2, 20.7% pT3a, 5.5% pT3b and 0.1% pT4. Overall positive surgical margins (PSM) occurred in 15.9% of cases with pT2 PSM 9.8% (range of operator means 2.7%-18.5%), pT3a PSM 30.8% (range of operator means 16.7%-52.9%) and pT3b PSM 39.2% (range of operator means 0-75%). 86.3% had a final Gleason Score ≥ 7 with 12.1% Gleason Score ≥ 8 .

Mean urinary continence at 12 months was 91.4% (range of operator means 89-97%) with data available from five surgeons. Mean 12-month potency after unilateral and bilateral nerve spare was 35.2% and 47.2% respectively with data available from four surgeons (Table 4).

Biochemical recurrence occurred in 10.6% with a mean follow up of 17 months and data available from seven surgeons.

Discussion

The feasibility and reproducibility of LRP has been well established for close to two decades with functional and oncological outcomes comparable to open radical prostatectomy [4, 16 - 18], with the advantages of decreased blood loss, decreased analgesic requirements, and earlier hospital discharge and convalescence [5, 6, 19, 20].

However, the uptake of LRP has likely been limited by a steep learning curve. A large multi-centre analysis of high volume LRP surgeons showed the PSM rates plateaued only after 200-250 cases [7]. Also, Eden *et al.* (2009) have shown multiple learning curves exist with operating time and blood loss plateau after 100-150 cases,

complications and continence rates took 150-200 cases whilst potency outcomes plateaued after 700 cases [2]. Findings such as these have led to the recommendation that LRP training should be carried out only under the guidance of formal mentorship [2, 3, 9, 21].

A modular training approach, such as the Heilbronn and Leipzig models [21-23], allows for the step-wise mentoring of LRP. These dedicated immersion high volume Fellowship teaching programs have been shown to abbreviate the extensive learning curve [9, 10, 21, 24]. Most of these programs exist in high-volume centres outside of Australia [10], and in fact all except one of the surgeons from our series have been trained overseas. The difficulty however may lie in the recent increasing limited numbers of pure laparoscopic prostatectomy Fellowships available internationally, although these training programs still exist locally for mentoring LRP in Australia [8].

Whilst we also acknowledge one of the barriers to LRP training includes its long learning curve of several hundred cases by first generation surgeons [2,7], the shortened learning curve with Fellowship training can be seen from four of our surgeons that have published their initial experience with LRP with favourable outcomes [8,10, 11, 25]. We have also found no difference in PSM rate between the first 100 and second 100 cases from our cohort of nine surgeons [26], suggesting abbreviation of the learning curve for PSM rate with Fellowship training when compared to the 200-250 case learning curve found by Secin et al. [7].

Our current series represents the largest Australian radical prostatectomy series of any operative technique, and is one of the largest LRP series published [12-13]. As such, we have compared it to international high-volume open, laparoscopic and robot-assisted prostatectomy published series [12].

Our demographic data of patient age, preoperative PSA and clinical stage (Table 2) are comparable to those of other series. Our lower case load per year reflects single surgeon data rather than multisurgeon data from other centres. The lower population density in Australia may also impact on surgical volumes (Fig 1).

Although only 13.7% of radical prostatectomy specimens had a Gleason score ≤ 6 , we would expect even a lower percentage of Gleason ≤ 6 in future cohorts given the increasing use of active surveillance in low risk patients. In fact, there is published data on Australian men with prostate cancer on active surveillance having low levels of anxiety and maintained health-related quality of life [27, 28]. In addition, with the new prostate cancer grading system, there may be further shift towards surveillance for more patients with Gleason 3+4 disease and thus a higher percentage of patients undergoing intervention for ISUP 2014 Grade ≥ 3 [29].

Our overall mean operating time is similar to open and robotic published data and shorter compared to published LRP data (Table 3) [12]. Our transfusion rates, open conversion rates and length of stay are also similar (Table 3). This suggests that Australian LRP surgeons are comparable to those of international series.

Whilst these results confirm satisfactory peri-operative outcomes from our patients undergoing LRP, it is acknowledged that the important outcomes for RP regardless of the technique are oncological and functional [30]. Our overall PSM rate of 15.9% is acceptable. In 30 high volume open radical prostatectomy publications the overall PSM rate was 24% [12]. In the largest LRP analysis of PSM by Secin *et al.* (2010) of over 8500 patients their overall PSM rate was higher at 22% [7]. The weighted mean of robotic papers on overall PSM rate was slightly lower at 13.6% but there was a higher rate of organ confined disease (pT2) compared to our series 78.7% vs 73.6%. Our pT2 and pT3 PSM rate of 9.8% and 32.6% are more than acceptable compared to the published literature [12].

The assessment of functional outcome results of continence and potency is known to be more difficult to compare due to varying definitions and lack of standardisation [31]. Only five of nine surgeons had data on continence and four had data on potency. With our definition of continence of dry or a precautionary pad that remained completely dry our continence rate was 91% and at least equivalent to other high volume centres regardless of technique. Similar to other papers, the overall data collection on potency from our series was poor. Although preoperative IIEF-5 scores were collected not all had postoperative IIEF-5 scores and as such we have used the definition commonly used for postoperative potency as penetrative intercourse with

or without oral PDE5 inhibitors. Whilst it appears our 12 month potency data is inferior to robotic series (47% vs 71%) it is to be noted that only five of 14 robotic papers had data on potency and these were from units with some of the highest robotic volume data in the world [32, 33] and as such may not be a true indication of the “average” robotic potency results.

Although this paper represents the largest collaboration on RP data from Australia there are limitations. Similar to any multi-centre analysis there is incomplete data highlighted by the functional outcomes described above. Also, although some centres collected data on complications including Clavien-Dindo Scores, readmission rates, long term complications such as anastomotic strictures, it was incompletely collected prospectively and as such no meaningful conclusion could be drawn from the data we had available for analysis. We also did not have data from most surgeons on pelvic lymphadenectomy and lymph node yield which may also have served as a measure of surgical quality. We acknowledge the omission of this data may weaken the overall favourable LRP outcomes we publish here.

Another criticism could be the selection bias in that the results from our nine surgeons may not be an overall reflection of all Australian Fellowship trained LRP surgeons. This analysis reflects the results of nine highly motivated surgeons who maintained a prospective database from the start of their LRP practice and results may be different to those that have not collected their data or did not want to submit their data for analysis. Also, although this paper includes a significant proportion of Fellowship trained LRP surgeons in Australia, it does not include some surgeons’ data due to our strict inclusion criteria. Surgeons who had collected their data after their initial LRP learning curve, or selected with ORP during their LRP experience (that is non-consecutive cases) or had not collected their data prospectively were not included in this analysis (Table 1). The LRP experience from three surgeons during their transition to RALP where there was an overlap with LRP and RALP were however still included (Table1).

Although RALP is increasingly the favoured minimally invasive option for RP, possibly due to a shorter learning curve and arguably better functional outcomes [12, 34], we have shown good results can be achieved by Fellowship trained Australian LRP

surgeons. Formalised laparoscopic simulation which is often incorporated within these laparoscopic Fellowship programs may contribute to shortening this learning curve [35]. The limited availability and cost of RALP also likely precludes the complete transition to this technique especially in smaller regional centres that are still achieving comparable results. Furthermore, the skill set used in “pure” LRP would be transferable to other advanced laparoscopic urological procedures requiring suturing such as laparoscopic pyeloplasty and laparoscopic partial nephrectomy. The ongoing training and dissemination of LRP will mean our future urological surgeons will have higher likelihood at being trained to perform these other procedures laparoscopically without robotic assistance.

Centralisation to high volume RALP centres remains an option. This pattern, already exhibited in the US, has resulted in patients needing to travel longer distances to receive care. From 2000 to 2009, the median distance traveled in the US to receive care increased by 54% [36]. However, as observed in the treatment of other cancers in Australia, the travel distance required to receive care significantly affects patient treatment choices [37].

In conclusion, the Australian experience of Fellowship trained surgeons performing LRP demonstrates favourable perioperative, oncological and functional outcomes in comparison to published data for open, laparoscopic and robotic assisted radical prostatectomy. This represents the largest Australian publication on RP regardless of technique and in our Australian centres, LRP remains an acceptable minimally invasive surgical treatment for prostate cancer despite the increasing use of robotic assisted surgery.

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Centre	Total Cases	Mean Cases/year	Still Performing LRP?	Fellowship Trained Overseas	Consecutive Cases from 1 st LRP
Gosford, Wyong and Gosford Private Hospitals	234	47	Yes	Yes	Yes
Epworth Healthcare, Melbourne	208	36	No	Yes	Yes*
The Wesley Hospital, Brisbane	122	35	No	Yes	Yes*
Barwon Health University Hospital, Geelong	233	35	Yes	No	Yes (except 2 open cases early in experience)
Pindara Private Hospital, Benowa	256	54	No	Yes	Yes*
Royal Perth Hospital, Perth	347	49	Yes	Yes	Yes
St. Vincent's Private Hospital, East Melbourne	160	22	Yes	Yes	Yes
Hollywood Private Hospital, Perth	1049	95	Yes	Yes	Yes
Bethesda Hospital, Perth	334	35	Yes	Yes	Yes

* RALP (not included in database) started while still performing LRP

Variable	Our Series	ORP*	LRP*	RALP*
Papers	9 surgeons	30	14	14
Patients	2943	340-9035	250-5824	294-2766
Publication Date	2015	1994-09	2003-08	2006-09
Volume/year	45	55-769	74-370	120-461
Mean Age (years)	62	61	63	60
Mean Pre-Operative PSA (ng/ml)	7.4	7.0	8.8	7.23
Clinical Stage T1c (%)	61	47	69	76

* Coelho *et al.*, 2010

Variable	Our Series	ORP *	LRP*	RALP*
Mean operation time (min)	168	165	205	163
Transfusion (%)	1.1	20.1	3.5	1.4
Open Conversion (%)	0.5	NA	1.76	0.34
Mean length of Stay (days)	2.5	3.48	4.87	1.43

* Coelho *et al.*, 2010

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Variable	Our Series	ORP *	LRP*	RALP*
pT2 (%)	73.6	64.3	64	78.7
pT3 (%)	26.2	31.5	32.6	20.5
pT2 PSM (%)	9.8	16.8	12.4	9.6
pT3 PSM (%)	32.6	42	39.2	37.1
Overall PSM (%)	15.9	24	21.3	13.6
Mean 12 month continence	91 ^α	80	85	92
Mean 12 month potency	47 ^β	29	55	71

^α Data on 5 surgeons

^β Data on 4 surgeons

* Coelho *et al.*, 2010