## A LITERATURE-BASED ANALYSIS OF THE LEARNING CURVES OF LAPAROSCOPIC RADICAL PROSTATECTOMY

## \*Daniel W. Good,<sup>1,2</sup> Grant D. Stewart,<sup>1,2</sup> Jens-Uwe Stolzenburg,<sup>3</sup> Stuart A. McNeill<sup>1,2</sup>

Department of Urology, Western General Hospital, Edinburgh, UK
Edinburgh Urological Cancer Group, University of Edinburgh, Edinburgh, UK
Department of Urology, University of Leipzig, Leipzig, Germany
\*Correspondence to daniel.good@ed.ac.uk

Disclosure: No potential conflict of interest. Received: 07.01.14 Accepted: 07.03.14 Citation: EMJ Urol. 2014;1:90-96.

### ABSTRACT

There is a trend for the increased adoption of minimally invasive techniques of radical prostatectomy (RP) - laparoscopic (LRP) and robotic assisted (RARP) - from the traditional open radical retropubic prostatectomy (ORP), popularised by Partin et al. Recently there has been a dramatic expansion in the rates of RARP being performed, and there have been many early reports postulating that the learning curve for RARP is shorter than for LRP. The aim of this study was to review the literature and analyse the length of the LRP learning curves for the various outcome measures: perioperative, oncologic, and functional outcomes. A broad search of the literature was performed in November 2013 using the PubMed database. Only studies of real patients and those from 2004 until 2013 were included; those on simulators were excluded. In total, 239 studies were identified after which 13 were included. The learning curve is a heterogeneous entity, depending entirely on the criteria used to define it. There is evidence of multiple learning curves; however the length of these is dependent on the definitions used by the authors. Few studies use the more rigorous definition of plateauing of the curve. Perioperative learning curve takes approximately 150-200 cases to plateau, oncologic curve approximately 200 cases, and the functional learning curve up to 700 cases to plateau (700 for potency, 200 cases for continence). In this review, we have analysed the literature with respect to the learning curve for LRP. It is clear that the learning curve is long. This necessitates centralising LRP to high volume centres such that surgeons, trainees, and patients are able to utilise the benefits of LRP.

Keywords: Learning curve, laparoscopic radical prostatectomy, prostate cancer.

#### INTRODUCTION

Radical prostatectomy is a recognised method of curative treatment for localised prostate cancer. Since the first laparoscopic radical prostatectomy (LRP) in 1997,<sup>1</sup> there has been a trend towards an increase in adoption of more minimally invasive techniques of radical prostatectomy (LRP and robotic assisted radical prostatectomy, RARP) from the traditional open radical retropubic prostatectomy (ORP), popularised by Partin et al.<sup>2</sup> This trend has been pioneered and driven by urologists in Europe.<sup>3-5</sup>

The purported advantages of LRP over ORP are reduced blood loss, reduced blood transfusion, improved cosmetic outcome, shorter time to resumption of normal activities, and shorter hospital stay.<sup>5-7</sup> Despite these advantages, the 2011 British Association of Urological Surgeons (BAUS) radical prostatectomy audit revealed that of the cases contributed, 26% were still performed by ORP.<sup>8</sup> Recently there has been a dramatic expansion in the rates of RARP being performed<sup>9</sup> and there have been some reports postulating that the learning curve for RARP is shorter than for LRP,<sup>10,11</sup> however this is still open to debate.

Coinciding with a similar rise in the rate of RARP being performed in the US, there has been a dramatic decline in the rates of prostatectomy performed by the laparoscopic route. Much of the reason for this change is the presumed longer learning curve for LRP over RARP, however this still is the subject of fierce debate. Aside from the long learning curve, the marketing pressures - more severe in the US than elsewhere - have placed pressures on surgeons to offer the latest technology.<sup>12,13</sup>

The recent systematic review and economic modelling of benefit and cost-effectiveness of RARP and LRP showed that RARP is more expensive than nationalised healthcare services, like the NHS in the UK, compared to LRP; however, this could be offset if there were lower positive surgical margin (PSM) rates and a higher volume (100-150 cases/year).<sup>14</sup> These studies, however, did not take into account the length of the learning curve, which could dramatically alter the cost-effectiveness of RARP during this period.

The aeronautical industry was the first to describe the 'learning curve' (LC) effect, where the amount of hours required to produce a product decreased in a uniform manner as the experience of workers increased.<sup>15</sup> The same is true of surgeons, however, the exact way to define the LC, the measures to use or indeed the definition of the completion of the LC varies widely and is the subject of debate.<sup>16</sup>

There is clearly much interest in the LC for minimally invasive radical prostatectomy for trainees, urologists, and healthcare providers around the world. It is also of importance to patients especially with the advent of new technologies (RARP) which affect the learning curve, something which was brought to the forefront by the UK General Medical Council Enquiry into the Bristol Paediatric Surgical Unit, where concerns were raised about patient exposure to early LCs of surgeons.<sup>17</sup>

The aim of this study was to review the literature and analyse the length of the LRP LCs for the various outcome measures: perioperative (blood loss, operative time, complications), oncologic PSM rate, biochemical recurrence [BCR]), and functional outcomes (urinary continence and potency). Finally, we will look at the LC for pentafecta attainment.

#### MATERIALS AND METHODS

A broad search of the literature was performed in November 2013 using the PubMed database. The following search terms were used during the literature search: "laparoscopic radical prostatectomy" and "learning", and "curve" or "proficiency", and "gain" and "curve". Reference lists of relevant articles were also searched for additional articles. The selection was limited to English language articles only. Only studies of real patients and those from 2004 until 2013 were included: those on simulators were excluded. Article abstracts were reviewed for suitability and further reviewed in full if they had information pertaining to LCs of urological procedures. 239 studies were identified after which 13 were included.

#### DISCUSSION

The LC is a heterogeneous entity, depending entirely on the criteria used to define it. The literature varies widely with respect to these criteria, the first question which arises is: what variable to use?<sup>16</sup> For radical prostatectomy these key performance indicators are relatively easy to define and represent the pentafecta outcomes as coined by Patel et al.<sup>18</sup> It is important within these variables that there is consistency in the definition of these variables, allowing comparison in a wider context. Clearly it is also important that other confounding factors are taken into consideration when comparing variables during the LC as these can have significant effects on learning. This includes D'Amico risk grouping, organisational factors (equipment/facilities), the surgical team experience, case mix etc.<sup>16,19,20</sup>

Perhaps one of the greatest debates and the greatest variability in the literature is the definition of the completion of the learning curve. Many authors define completion of the LC as: 'the time to achieve skills necessary to satisfactorily perform a surgical procedure.<sup>21</sup> Using this definition, improvements in various outcomes (such as operative time) in consecutive cases are demonstrated, where there is a statistically significant difference between the last group and first group of patients.<sup>22,23</sup> Various statistical methods used to demonstrate the LC include simple linear regression, CUSUM, and fitting curve methods (e.g. locally weighted scatterplot smoothing [LOESS], negative exponential curves etc).<sup>22,24,25</sup>

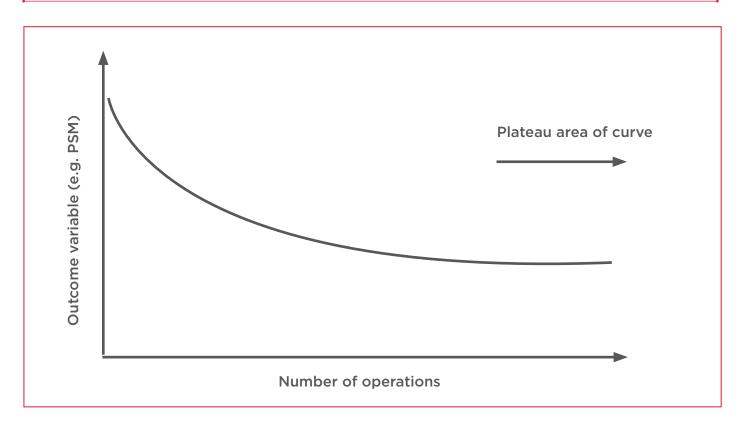


Figure 1: Graphical illustration of a learning curve, with the area of the curve showing the plateauing of the learning curve (denoted with an arrow).

These studies generally tend to use these methods of analysis as there are insufficient numbers of patients to show a plateauing of the LC.<sup>16</sup> This, however, does not reflect the true length of time required to complete the LC as there is no plateau (Figure 1). A better definition of completion of the LC may be: 'time to reach a level of experience after which repetition of technique yields no further improvement (LC plateau).'<sup>21</sup> Whilst showing a plateau in a performance indicator is taken as the best level achieved by a surgeon, it is imperative that this end plateau level is viewed within an acceptable 'expert' level, which is hard to define but is generally taken from the worldwide literature.

Due to the heterogeneity of the literature with regard to the definition used, we have used both of these definitions.

#### The Perioperative Learning Curve:

Table 1 summarises the evidence for the length of the perioperative LC (blood loss, operative time, and complications).

The perioperative LC is the most frequently published LC in the literature. This is the easiest

for surgeons to gather and is often uploaded into databases immediately after the operation. As such, these are the most likely variables to be completely recorded in a database, and therefore, most commonly published on. That said, it is important to ensure that the definitions of when operative time is calculated from are standardised to allow comparisons between studies.

The blood loss LC is the earliest to be completed out of the variables. Most of the studies published, however, observe falling blood losses as experience increases rather than a plateauing of the LC.<sup>23,26,27</sup> There are, however, two studies which have shown a plateauing of the LC. The first, by Rodriguez et al.,<sup>28</sup> showed a plateau of blood loss that was constant over the first 200 cases; this however plateaued at 500 ml, highlighting the importance of identifying the value at which blood loss plateaus, as the systematic review of blood loss outcomes for LRP showed a much lower level.<sup>29</sup> Another study of the LC, by Good et al.,<sup>25</sup> showed a plateauing of the blood loss LC after 150 cases.

The next LC to be completed is that of the complications. This is dependent on the generation

Table 1: Studies evaluating the perioperative learning curve. Where plateau was achieved, the number of cases is indicated.

Blood loss	Blood loss	Operative Time	Operative Time	Complications	Complications
No Plateau	Plateau	No Plateau	Plateau	No Plateau	Plateau
Vasdev et al. <sup>24</sup>	Good et al. <sup>25</sup> - 150 cases	Ghavamian et al. <sup>31</sup>	Good et al. <sup>25</sup> - 250 cases	Ghavamian et al. <sup>31</sup>	Good et al. <sup>25</sup> - 150 cases
Hellawell et al. <sup>23</sup>	Rodriguez et al. <sup>28</sup> - O cases*	Poulakis et al. <sup>32</sup>		Hellawell et al. <sup>23</sup>	Hruza et al. <sup>30</sup> - 250 cases**
Sultan et al. <sup>27</sup>		Hellawel et al. <sup>23</sup>			
		Rodriguez et al. <sup>28</sup>			

\* Plateau from 0 cases, but plateaued at 500 ml blood loss.

\*\* 250 cases for third generation laparoscopic radical prostatectomy surgeons, 700 cases for first generation surgeons.

# Table 2: Studies evaluating the oncologic learning curve. Where plateau was achieved, the number of cases is indicated.

PSM	PSM	BCR	BCR	
No Plateau	Plateau	No Plateau	Plateau	
Baumert et al. <sup>33</sup>	Good et al. <sup>25</sup> - pT2 200 cases, pT3 200 cases	Vickers et al. <sup>35</sup>	Good et al. <sup>25</sup> - 150 cases	
Hellawell et al. <sup>23</sup>	Secin et al. <sup>34</sup> - 200 - 250 cases			
	Rodriguez et al. <sup>28</sup> - 200 cases			

PSM: positive surgical margin; BCR: biochemical recurrence.

of surgeon that is being investigated. A large study by Hruza et al.,<sup>30</sup> with over 2,200 patients, found that first generation LRP surgeons had a significantly longer LC (700 cases) to plateau than third generation surgeons, who had a much shorter learning curve of 250 cases. Another study, by Good et al.,25 found the plateauing of the curve occurred after 150 cases. Both of these studies used the standardised Clavien-Dindo classification for grading of complications. Other studies that did not show a plateauing of the curve, but instead showed falling rates, demonstrated this after a similar numbers of cases; however, these studies did not use the standardised Clavien-Dindo classification.<sup>23,31</sup>

The time to complete the Operative time (Op time) LC is variable in the literature. Many studies that do not show plateauing due to lack of numbers do show a continuous falling LC throughout their series.<sup>23,31,32</sup> Op time, however, was found to be more lengthy to achieve by Good et al.,<sup>25</sup> likely due to the introduction of a nerve sparing technique after 100 cases. This, the authors concluded, was likely the reason for the curve to plateau at a later stage (after 250 cases).

#### The Oncologic Learning Curve:

Table 2 summarises the evidence for the lengthof the oncologic LC (PSM rates and BCR).

The oncologic LC consists of two variables: the PSM rate and the BCR rate. The PSM rate features more commonly in the literature with BCR rate exceedingly rare in the LC context, likely due to the difficulties in collecting PSA levels to provide meaningful follow-up data in large tertiary referral centres.

Baumert et al.<sup>33</sup> showed a declining PSM rate for both pT2 disease and pT3 disease after 100 cases, however, these authors did not have sufficient numbers to show a plateauing of the LC. Good et al.<sup>25</sup> showed a plateauing of both the pT2 and pT3 PSM LCs after 200 cases. Rodriguez et al.<sup>28</sup> also showed a plateauing of the pT2 LC after 200 cases. Further to this evidence, Secin et al.,<sup>34</sup> in an international multicentre study involving 51 different surgeons and 1,862 patients, showed a similar plateauing of the PSM LC of approximately 200-250 cases. The authors found that prior open experience or the generation of surgeon did not influence the time to achievement of the LC.

There is a paucity of data on the BCR LC, despite this being the most clinically important oncological outcome other than disease specific mortality. The study of Good et al.<sup>25</sup> showed a plateauing of the BCR LC after only 150 cases, however, after a plateau the BCR rate then continued to decrease. The authors postulated that this was likely due to the shorter follow-up time of the later cohort and not a lack of plateauing of the LC. Vickers et al.,<sup>35</sup> in another large international multicentre study involving 29 different surgeons and 4,702 patients, investigated the BCR LC. This study demonstrated a lower BCR rate as experience improves, however, it failed to plateau even after 1,000 cases. The authors demonstrated that this was slower than for ORP.

#### The Functional Learning Curve:

Table 3 summarises the evidence for the length of the LC associated with best functional recovery (urinary continence and potency). The functional LC is known to be the longest and most difficult to achieve, not only in achieving good outcomes consistently but also in data collection, as most studies use continence at 12 months and potency as the endpoints. These both require a length of follow-up which requires dedicated database managers to keep outcome recording updated. This is a major reason for the paucity of functional LC studies for LRP.

Huang et al.,<sup>36</sup> in their single surgeon series of 160 patients, showed a falling incontinence rate, which was better for the last group than the first group in the series; however, they were unable to show any plateau, likely due to the lack of patients in their series. Good et al.,<sup>25</sup> in their single surgeon series, were able to show a plateauing of the continence LC after 250 cases. Eden et al.,<sup>37</sup> in their study of their first 1,000 LRPs - whilst not specifically focusing on the functional LC - did suggest that it would take 200-250 cases to achieve it, except for potency, which continued to improve even after 700 cases.

Similarly, after 250 cases of bilateral nerve sparing endoscopic extraperitoneal radical prostatectomy (nsEERPE), the series by Good et al.<sup>25</sup> did not show a plateauing of the potency LC. Their series' potency rate at 12 months was 52% for bilateral nsEERPE. Both studies<sup>25,37</sup> commented that the potency LC is the longest and hardest to achieve.

The pentafecta attainment LC, the 'holy grail' for prostatectomists, is the least published. We were only able to find one publication on this in the literature by Good et al.<sup>25</sup> In this study the

Table 3: Studies evaluating the functional learning curve. Where plateau was achieved, the number	of
cases is indicated.	

Continence	Continence	Potency	Potency
No Plateau	Plateau	No Plateau	Plateau
Huang et al. <sup>36</sup>	Good et al. <sup>25</sup> - 250 cases	Good et al. <sup>25</sup> - no plateau after 250 cases	None found
		Eden et al. <sup>37</sup> - still improving after 700 cases	

authors were unable to demonstrate a plateauing of the LC, despite demonstrating plateauing for all curves except the potency LC. The authors identified that the pentafecta LC in their series closely matched that of the potency LC. In their series the overall pentafecta attainment was 47%, much lower than that previously demonstrated in an RARP series by Patel et al.,<sup>18</sup> who quoted a pentafecta attainment at 12 months of 70.8%. It is important to note that these were on different patient cohorts.

#### CONCLUSION

In this review, we have analysed the literature with respect to the LC for LRP. It is clear that the LC is long, approximately 200-250 cases for non-nerve sparing proficiency, however, much longer (in excess of 700 cases) for nerve sparing procedures, which deliver the best functional outcomes. Clearly much of this evidence comes from single surgeon series, which limits it, but nevertheless it gives us real insight into the length of experience required to achieve the LCs for this complex operation.

Given the long LC required, some countries such as the US have transferred to robotic surgery

with the promise that the LC is shorter,<sup>38-40</sup> however, recently with more rigorous studies, questions have been raised as to the true length of the LC required for RARP.<sup>41,42</sup> Studies comparing the plateauing of the pentafecta LCs between LRP and RARP are required as trainees and healthcare systems have made significant investments in robotics with hopes of shorter LCs and improved outcomes despite a lack of evidence.

One thing is certain from the evidence demonstrated, volume is critically important for surgeons and outcomes. A surgeon in training, performing 20-30 cases per year, may take over 10 years to achieve the LC, and may only achieve the potency LC and therefore pentafecta LC at retirement. It is critically important that both trainees and surgeons embarking on prostatectomy be situated in high-volume centres to ensure that patients do not suffer reduced quality of life whilst surgeons are on their LC. This will also help surgeons to develop quickly, as has been shown in large, pioneering centres such as Leipzig,43,44 where institutional experience, as opposed to individual experience, provides the quality assurance sought by patients.

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