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REVIEW

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Centralization and prospective audit of cystectomy are necessary: a commentary on the case for centralization, supported by a contemporary series utilizing the ANZUP cystectomy database

Pravin Viswambaram[1,2,3] | Steve P. McCombie[1,2,3] | Cynthia Hawks[1,2,3] | D. Michael A. Wallace[1] | Shomik Sengupta[3,4,5,6] | Dickon Hayne[1,2,3]

[1]UWA Medical School, The University of Western Australia, Crawley, Washington, Australia

[2]Fiona Stanley Hospital, Murdoch, Washington, Australia

[3]Australian and New Zealand Urogenital and Prostate (ANZUP) Cancer Trials Group, Camperdown, New South Wales, Australia

[4]Department of Urology, Eastern Health, Box Hill, Victoria, Australia

[5]Eastern Health Clinical School, Monash University, Melbourne, Victoria, Australia

[6]Department of Surgery, University of Melbourne, Parkville, Victoria, Australia

Correspondence
Dickon Hayne, Fiona Stanley Hospital, 11 Robin Warren Drive, Murdoch, WA 6150, USA.
Email: dickon.hayne@uwa.edu.au

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Abstract

Bladder cancer (BC) outcomes are unacceptably poor. In Australia, BC survival is actually deteriorating. There is an urgent need to improve outcomes in BC patients, which requires a multipronged approach. One area deserving closer scrutiny is radical cystectomy. Audit is necessary to identify areas for improvement and without it, outcomes remain unknown. Evidence convincingly shows high-volume surgeons and centers improve cystectomy outcomes including overall survival, yet centralization has still not occurred. The Australia and New Zealand Urogenital and Prostate (ANZUP) Cancer Trials Group cystectomy database has been established to facilitate cystectomy audit in Australia and New Zealand. We present initial data from the ANZUP cystectomy database from a single high-volume center, discuss the benefits of centralization and its challenges in the Asia-Pacific context.

1 | INTRODUCTION

Bladder cancer (BC) is lethal, and its outcomes have not improved in recent years. It is the tenth most common cancer in the world with an incidence of 5.7 per 100,000 people in 2020.[1] The global age-standardized mortality rate was 1.9 per 100,000 population.[1] Fortunately, mortality rates in Asia (apart from Western Asia), Australia, and Zealand were lower than the global rate.[1] However, BC survival in Australia has deteriorated over the last 30 years, from 67% in 1986–1990 to 54% in 2011–2015.[2,3] There is an urgent need to do more for BC patients both internationally and in the Asia-Pacific region, and we need to tackle this issue from multiple fronts.

One area, which needs to be addressed, is cystectomy outcomes. Radical cystectomy (RC) with pelvic lymph node dissection (PLND) +/− neoadjuvant chemotherapy (NAC) is the current gold standard in the treatment of nonmetastatic muscle invasive BC.[4] Furthermore, it has a role in the management of high-risk, nonmuscle invasive BC. Five to 10-year recurrence-free survival after open radical cystectomy (ORC) and PLND is estimated to be between 58% and 66% in centers averaging between 15–40 ORC per year.[5,6] These outcomes may be improved by 5%–10% with the addition of NAC.[7,8] RC with PLND is a morbid

procedure with significant risks. Contemporary studies report 30-day postoperative complication and mortality rates of 56.3% and 3.23%, respectively, in patients undergoing RC.[9]

Centralization of complex surgeries such as RC at high-volume centers (HVCs) with high-volume surgeons (HVSs) has demonstrated improved perioperative and long-term outcomes; these include reduced complications, oncologic outcomes, length of stay, perioperative mortality, and overall survival.[10–17] There may be challenges to centralization, but strategies can be implemented to overcome them. Audit of perioperative outcomes is also necessary to identlify areas for improvement and to implement changes. National clinical quality registries (CQR) have prospectively collected data, which could potentially alter clinical practice and enhance patient outcomes.[18] We discuss the issues surrounding centralization in the Asia-Pacific region and present the initial data from an HVC obtained from the national cystectomy registry in Australia and New Zealand, the Australia and New Zealand Urologential and Prostate (ANZUP) Cancer Trials Group cystectomy database.

2 | REASONS FOR CENTRALIZATION

In 2015, the Global Cancer Surgery Commission highlighted that surgical volume was an important factor influencing cancer surgery outcomes.[19] Multiple studies have demonstrated that centralization of surgery, particularly that of low-volume, high-risk cancer surgery, leads to improved patient outcomes.[10–16,20,21] This has been noted in a variety of oncological surgeries, including RC. Centralization of other major oncologic surgeries is supported by convincing evidence of reduced complication rates and mortality.[20] Centralization is recommended by clinical guidelines. The National Institute for Clinical Excellence (NICE) Improving Outcomes in Urological Cancers Guidelines recommend that RC should be performed in centers by teams performing at least 50 RC or radical prostatectomy per year and not by cystectomists performing less than 5 RC/year.[22] The European Association of Urology (EAU) guidelines recommend that RC be done at sites performing at least 10 RC/year, with a preference for sites performing >20 RC/year.[23] The mechanisms by which centralization results in improved outcomes for RC are likely multifactorial but may include: increased familiarity with the procedure and peri-operative care, increased resource availability, and increased access to other relevant specialist and multidisciplinary services. Centralization of RC in the Asia-Pacific region could potentially be achieved through open dialogue between local institutions, or governmental mandate.

3 | BETTER SURVIVAL AND LOWER MORTALITY

Afshar et al. analyzed data from the Hospital Episodes Database in the United Kingdom and found that despite having slightly older and comorbid patients, centers and surgeons complying with the NICE guidelines had lower 30-day (2.1% vs. 2.9%; $p = .003$), 90-day (5.2% vs. 7.2%; $p < .001$), and 1-year (21.5% vs. 25.6%); $p < .001$) mortality rates compared to those who did not comply.[24] Similarly Waingankar et al. demonstrated lower 30-day (1.8% vs. 3.3%) and 90-day (5.8% vs. 9.6%) mortality rates at HVCs compared to low-volume centers (LVCs).[25]

Long-term mortality is also improved at HVCs compared to LVCs. Overall survival (OS) was improved at centers performing more than 10 RC/year (hazard ratio [HR] .95, 95% confidence interval [CI]: .91–.99).[26] Afshar et al. demonstrated that those complying with the NICE guidelines had a better median survival time of 5.41 years (95% CI: 5.05–5.85) versus 4.07 years (95% CI: 3.69–4.50) in those who did not.[24] After adjusting for age, comorbidities, gender, and indices of multiple deprivation, those who were noncompliant with the NICE guidelines had an increased risk of death (HR 1.17; 95% CI: 1.12–1.23).[24] Siemens et al. analyzed the Ontario Cancer Registry and concluded that passive centralization of RC occurred between 1994–2008 and 2009–2013 as the mean annual surgeon volume of RC had increased from 4.5 (95% CI: 4.4–4.7) to 6.8 (95% CI: 6.5–7.1), and the mean hospital volume of RC had increased from 12.2 (95% CI: 11.8–12.5) to 16.4 (95% CI: 15.8–16.9).[27] Over this time, cancer-specific survival improved considerably (HR .6; 95% CI: .53–.67).[27] Cole et. al assessed the impact of RC at HVCs on survival from the National Cancer Database and demonstrated that patients having RC at the top-decile centers (mean annual volume of 33.5 RC/year) had an OS of 57.0 months compared to 41.8 months at the bottom-decile centers (mean annual volume of 2.4 RC/year), equating to a 15-month survival advantage at HVCs.[21]

4 | LOWER COMPLICATION RATES

Several studies have demonstrated lower complication rates at HVCs.[28] Vetterlein et al. found that HVCs performing more than 44 RC/year had lower major complications (Clavien Dindo classification grade 3 or more) with an odds ratio (OR) of .34 (95% CI: .17–.68).[29] Another study found that inpatient complication rates were lower at HVCs (50–55 RC/year) compared to LVCs (<5 RC/year); OR .61 (95% CI: .46–.79).[30] Leow et al. analyzed the effect of surgeon volume on complication rates and noted that very low-volume surgeons (LVS) (less than 1 RC/year) had the highest major complication rates of 18.3%, while very HVS (more than 28 RC/year) had the lowest rates of 11.3% ($p < .001$).[13] Furthermore, overall complication rates were lower when performed by very HVSs (OR .67, 95% CI: .5–.89).[13] Afshar et al. showed that those who were compliant with the NICE guidelines had reduced re-intervention rates; 30.0% versus 33.6% ($p < .001$).[24] HVSs and HVCs have lower blood transfusion rates compared to LVSs and LVCs.[28] Siemens et al. demonstrated less blood transfusion rates in HVCs (34% of those not requiring blood tranfusions were from HVCs compared to 15% in LVCs, $p < .001$) and HVSs (34% of those not requiring blood transfusions had their surgery by HVSs compared to 15% who had their surgery performed by LVSs, $p < .001$).[31] There are limited studies analyzing the effects of centralization in Asia. Takada et al. assessed the perioperative morbidity at multiple institutions in Japan and found that only one of the 21 centers could be classified as an HVC (perfoming an average of 10 or more RC/year).[32]

One significant long-term complication of RC is uretero-ileal stricture formation. This can cause significant morbidity. Surgical reconstruction is highly complex and is frequently not attempted, leaving patients with life-long replacement of ureteric stents. Goh et al. demonstrated a reduced rate of uretero-ileal strictures in HVCs (mean annual volume of more than 13.1 RC) and HVSs (more than 25 ORC or 11 robot-assisted radical cystectomy [RARC] over 6 years) compared to LVCs (mean annual volume of less than 3.6 RC) and LVSs (less than 7 ORC or 5 RARC over 6 years), respectively.[33]

5 | SHORTER INPATIENT LENGTH OF STAY

A few studies have demonstrated a statistically significant reduction in length of stay (LOS) with RC performed at HVCs.[30,34] In particular, Groeben et al. found the mean LOS at LVCs (<4 RC/year) versus HVCs (>50 RC/year) was 11.4 +/− 8.8 days versus 10.3 +/− 9.2 days in USA, and 24.5 +/− 14.6 days versus 23.3 +/− 13.8 days in Germany, respectively.[34] Moreover, Afshar et al. reported lower LOS in the group compliant with the NICE guidelines; 14 versus 16 days ($p < .001$).[24]

6 | HIGHER CONTINENT URINARY DIVERSIONS RATES

Neobladder or continent urinary diversions are techinically more complex to perform than ileal conduit urinary diversion. HVCs are more likely to offer continent urinary diversion to appropriate patients. Udovicich et al. and Joice et al. found greater continent urinary diversion rates at HVCs (>10 and > 30 RC/year, respectively) on unadjusted analyses (11% vs. 3%, $p = .02$ and 14% vs. 5%, $p < .001$, respectively).[35,36] On adjusted analysis, Lin-Brande et al. demonstrated that HVCs had higher rates of continent urivary diversions (OR 1.86, 95% CI:1.46–2.36).[37]

7 | BETTER ONCOLOGICAL OUTCOMES

Oncological outcomes at HVCs are better with lower positive surgical margins (PSM) and higher lymph node yield (LNY). A few studies have demonstrated lower PSM rates at HVCs compared to LVCs. Sabir et al. compared RC performed at HVCs (≥10 RC/year) versus LVCs (<10 RC/year) based on data from the Swedish Bladder Cancer Registry between 1997 and 2002.[38] Their study showed that HVCs had significantly lower PSM rates compared to LVCs (12% vs. 32%, $p < .001$).[38] This study also showed that the risk of local recurrence was higher at LVCs compared to HVCs (26% vs. 19%, $p < .004$).[38] Similarly, Scarberry et al. demonstrated significantly lower PSM rates at HVCs (≥10 RC/year) with an OR of .88 (95% CI: .81–.97).[26]

Some studies have found increased PLND rates and LNY at HVCs. Vetterlein et al. demonstrated higher extended PLND rates at HVC (>22 RC/year) of 55% versus 42.3% at LVCs.[29] Similarly, Scarberry et al. found higher odds (OR 1.85 [95% CI: 1.74–196]) of extended PLND rates at HVCs (≥10 RC/year).[26] Xia et al. and Hermans et al. showed that HVCs (≥10 RC/year) were more likley to obtain an LNY of ≥10 (OR 2.59, 95% CI: 2.44–2.74 and OR 1.48, 95% CI: 1.22–1.80 respectively).[39,40]

Better oncological outcomes could also be achieved with higher rates of NAC use. Siemens et al. showed significantly higher rates of NAC with HVSs compared to LVSs (25% vs. 16%, $p = .009$)[27] while Xia et al. found a higher utilization of NAC of 23.6% at HVCs (median 20 RC/year) compared to 16.2% at LVCs (median 6 RC/year, $p < .001$).[39]

8 | BARRIERS TO CENTRALIZATION

Although studies such as Siemens et al. and Afshar et al. have demonstrated that some level of passive centralization has occurred, there are barriers to further centralization. Access to cancer care may be impeded as complex surgeries such as RC are shifted to HVCs, which are typically located in the metropolitan areas.[41] Longer travel distances may be required with centralization, and this may place an added burden on cancer patients. Xia et al. assessed the impact of centralization on travel distance and found that although travel distances increased with greater hospital RC volume, overall survival was higher in these patients who travelled longer distances for surgeries at HVCs.[39]

The lack of proper referral systems may prevent centralization. Establishing such systems requires funding, which may deter health departments.[42] However, there may be cost savings when complex cancer surgery is performed at HVCs. Leow et al. showed that the lower major complications rates observed with HVSs performing RC were associated with lower 90-day hospital costs.[13] Patients who did not experience any complications had significantly lower 90-day median hospital costs compared to those who had major complications ($24,341 vs. $43,965, $p < .001$).[13] Therefore, establishing a structured referral process to facilitate centralization may result in overall cost savings.

Another challenge to centralization is the lack of a clear definition on what constitutes an HVC for RC. Some studies have used cut-offs ranging from more than 10–50 RC per year, while others have divided annual RC volumes into quartiles and have defined HVCs as those in the top quartile.[28] Cut-offs also vary in different guidelines with the NICE guidelines suggesting >50 RC/year, while the EAU guidelines suggest >20 RC/year.[22,23]

LVSs or surgeons at LVC may be reluctant to refer patients to HVCs due to financial incentives or concerns over de-skilling.[42] RC is a complex procedure, which takes years to learn, and surgeons may be unwilling to stop performing a procedure they have invested a significant amount of time on. Furthermore, the training of future surgeons may be affected by centralization as only trainees at these HVCs would be able to learn this complex procedure. Their ability to manage the perioperative issues surrounding RC patients may also be compromised with centralization. However, ultimately the goal is to provide optimal patient care, and hence, centralization should be a priority.

9 | CQRs

CQRs are the next step in improving cancer care in the Asia-Pacific region.[43] Registries are a source of data for future research such as observational cohort studies and registry-based studies, and they can be used to answer-specific clinical questions.[44] More importantly, national CQRs are a tool for measuring and comparing surgical quality at different centers.[45] It allows us to assess the effect of centralization by comparing perioperative outcomes between low- and high-volume centers. CQRs provide a benchmark for surgeons and cystectomy centers to achieve.[45] RARC is being performed more widely and CQRs faciliate the comparison of RARC outcomes against that of ORC. Several countries including England, Sweden, Italy, Austria, and the Czech Republic have established national cystectomy CQRs.[46–50] Furthermore, in 2017, a multicenter, multinational RARC registry was set up in Asia and Australia. The ANZUP cystectomy database was set up to audit outcomes following RC in Australia and New Zealand.[51]

10 | CONTEMPORARY ORC SERIES FROM A SINGLE HVS/HVC UTILIZING THE ANZUP CYSTECTOMY DATABASE

A total of 104 consecutive ORCs were performed between 2015 and 2020 at a tertiary centre in Australia by a single surgeon. Four ORCs (nonbladder or urethral cancer pathology) were excluded leaving 100 cases. Eighty-three were men, and mean age and body mass index were 68.1 years and 27.6 kg/m^2, respectively. Patients were highly comorbid (63 American Society of Anasethesiologits grade III or IV, median Charlson Commorbidity Index 3). Fifty-three patients had ORC for preoperative ≥T2 disease with 23 patients having NAC (43.4% of those with muscle invasive BC). Mean operative time was 439.8 min. Four had a neo-bladder urinary diversion, and 11 underwent a concurrent significant procedure (three male urethrectomies, four nephroureterectomies, one anterior resection, one total colectomy, one ultra-low Hartmann's procedure, and one ileostomy formation). Mean estimated blood loss was 712.8 ml with 12 having an intra-operative blood transfusion. Median LOS was 9 (range 4–27) days, while median LNY was 17 (0–52). Six patients had PSM (including focal positive margins/ureteric carcinoma-in-situ). Median follow-up time was 772 days, while one patient was lost to follow-up. Four patients developed complications related to their urinary diversion over this period (two parastomal hernias, one ureteroileal stricture, one urethral anastomotic stricture). Ninety-day major complications (Clavien Dindo 3–4) occurred in 16 patients. Postoperative mortality was zero at 30 and 90 days. All-cause mortality rates were 7.5% ($n = 6$) at 1 year and 27.6% ($n = 13$) at 3 years. All-cause mortality rates for those with invasive disease (≥T2) were 11.3% ($n = 6$) at 1 year and 38.5% ($n = 10$) at 3 years. These results appear highly favorable in comparison to other reported data. Table 1 shows a summary of the data from this HVC. The entire dataset can be accessed in Appendix 1–3 (hyperlink).

TABLE 1 Summary data from a single high-volume center (HVC) from the Australia and New Zealand Urogenital and Prostate (ANZUP) cystectomy database

		Total
Patients	*n* (%)	100 (100)
Age, years	mean (SD)	68.1 (9.3)
BMI, kg/m^2	mean (SD)	27.6 (4.9)
Gender	*n* (%)	
Male		83 (83)
Female		17 (17)
NAC	*n* (%)	23 (23)
Pre-ORC Path T Stage	*n* (%)	
<T2		44 (44)
≥T2		53 (53)
Urothelial adenocarcinoma of urethra		3 (3)
Urinary diversion	*n* (%)	
Ileal Conduit		96 (96)
Neobladder		4 (4)
Operation time, min	mean (SD)	439.8 (81.6)
Estimated blood loss, ml	mean (SD)	712.8 (465.7)
Transfusions	*n* (%)	34 (34)
Intraoperative		12 (12)
Length of stay	median (range)	9 (4-27)
Highest grade postoperative complications	*n* (%)	
Overall 90-day complications		85 (85)
Minor (CD Grade I-II)		69 (69)
Major (CD Grade III-IV)		16 (16)
Number of LN removed	median (range)	17 (0-52)
Positive Margins	*n* (%)	6 (6)
Ureteric (CIS only)		1 (1)
All-cause Mortality	*n* (%)	
30-day ($n = 100$)		0 (0)
90-day ($n = 100$)		0 (0)
1-year ($n = 80$)		6 (7.5)
≥T2		6 (11.3)
3-year ($n = 47$)		13 (27.6)
≥T2		10 (38.5)

Abbreviations: BMI, body mass index; CD, Clavien Dindo; CIS, carcinoma-in-situ; LN, lymph nodes; NAC, neoadjuvant chemotherapy; SD, standard deviation.

11 | CONCLUSION

Complex oncologic surgery requires surgical audit to determine outcomes and drive improved patient care. Centralization of cystectomy is achievable, rational, and necessary. It is supported by international guidelines and should be supported by the uro-oncologic community for the benefit of our patients.

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CONFLICT OF INTEREST

The authors do not have any conflict of interest to disclose.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

ORCID

Pravin Viswambaram https://orcid.org/0000-0002-9373-4024
Dickon Hayne https://orcid.org/0000-0002-4094-401X

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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