Original Article

Safety, efficacy and cost of intra-operative cell salvage during open radical prostatectomy

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Background: We aim to examine the safety and efficacy of intra-operative cell salvage (ICS) in radical prostatectomy.

Methods: A retrospective cohort study was performed, enrolling consecutive patients undergoing open radical prostatectomy at two institutions during 01/01/18–31/12/19. Patients were grouped by ICS use. Primary outcomes were allogeneic transfusion rates, and biochemical recurrence (prostate specific antigen >0.2 mg/mL). Secondary outcomes were use of adjuvant therapies, Clavien-Dindo complications and transfusion-related cost (allogeneic transfusion + ICS setup + ICS reinfusion).

Results: In total, 168 men were enrolled. Patients were grouped based on whether they received no blood conservation technique (126 men) or ICS (42 men). Groups were similar in median age, pre- and post-operative haemoglobin and length of stay. They also had similar post-operative tumour Gleason score, TNM-stage and positive surgical margin rates. Compared with controls, the ICS group had shorter follow up (336 *vs.* 225 days; P=0.003). The groups had similar rates of biochemical recurrence (17% *vs.* 14%; P=0.90), adjuvant therapy use (30% *vs.* 29%; P=0.85) and complications (14% *vs.* 19% patients; P=0.46). There was no metastatic progression or cancer-specific mortality in either group. Although a similar proportion of patients received allogenic transfusion (2.4% *vs.* 4.8%; P=0.33) and units of packed red blood cells (PRBC) (9 *vs.* 5 units), transfusion-related costs were higher amongst the ICS group (AUD $11,422 *vs.* $43,227).

Conclusions: ICS use in radical prostatectomy was not associated with altered rates of allogeneic transfusion, complications, biochemical recurrence or adjuvant or salvage therapies. Transfusion related costs were higher in the ICS group.

Keywords: Prostatectomy; cell salvage; autologous; transfusion; blood; cost

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Introduction

Prostate cancer is the most commonly diagnosed non-cutaneous cancer in men. In 2020, incidence is expected to exceed 25,000 men in Australia, and 240,000 in the United States of America, with over one third undergoing prostatectomy (1-3). Traditionally, radical prostatectomy has been associated with significant operative blood loss. This has improved over recent decades, due to the introduction of minimally invasive technologies, improved anatomical understanding and advances in surgical technique. However,

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estimated blood loss in open prostatectomy remains significant at 900 mL, with allogeneic blood transfusion (ABT) rates of 4–14% in modern series (4-6).

The accessibility and safety of ABT in developed nations have dramatically improved in the past thirty years. However, patients undergoing transfusions remain exposed to a broad range of risks. These include fluid overload, transfusion reaction, ABO incompatibility, transfusion transmitted infections, storage errors, delayed administration and death (7). Additionally, ABT has been shown to induce transfusion related immuno-modulation and increased cancer recurrence, including urological (8,9). The cost of administering a single unit of packed red blood cells (PRBC) also continues to rise, recently exceeding AUD $1,100 (10,11).

Intra-operative cell salvage (ICS) offers a sound alternative to ABT and avoids many of its limitations. Spilled blood is scavenged from the operative field, washed, filtered and transfused back to the patient. ICS has repeatedly been demonstrated safe in oncological surgery, and effective in reducing ABT rates and transfusion-related cost (12-15). Despite these advantages, ICS has not found universal favour, due to concerns of unclear efficacy and tumour recurrence.

To date, the literature on ICS use in radical prostatectomy consists of twelve retrospective studies of median size 107 patients, with most published >15 years ago (10,14). Therefore, this study aims to undertake a large and contemporary assessment of patients undergoing open radical prostatectomy, examining the effect of ICS use on safety, efficacy and cost. We present the following article in accordance with the STROBE reporting checklist (available at http://dx.doi.org/10.21037/tau-20-1265).

Methods

In this retrospective cohort study, consecutive patients undergoing open radical prostatectomy at either of our two institutions between 01/01/18–31/12/19 were enrolled. Data were collected from hospital and private practice electronic and hard copy records. Post-operative surveillance for biochemical recurrence (BCR) was performed at least every six months, based on tumour stage and grade. BCR was defined as a post-operative prostate specific antigen of >0.2 ng/mL. Data census occurred at 30/03/20. Last follow-up data was determined from date of last clinical appointment.

Patients were grouped and compared based on whether they did (ICS group) or did not (control) receive ICS. Primary outcomes were oncological safety (assessed by biochemical recurrence with post-operative prostate specific antigen of >0.2 ng/mL) and efficacy (assessed by allogeneic transfusion rates). Secondary outcomes were use of adjuvant or salvage therapies, Clavien-Dindo complications of any grade (16) and transfusion-related cost. The study had Institutional Ethics Review approval (LNR/62339/BHSSJOG-2020-206251).

ICS practice

In our department, the decision to utilise ICS for a procedure is based on surgeon preference, taking into account anticipated blood loss and personal preference. At both sites, the ICS machine is a Sorin Xtra® (LivaNova, London), using a Imugard® III-RC leukocyte depletion filter (Terumo Corporation, Tokyo).

As recommended by other authors, our institutions both use ICS in a financially tiered system. Initially only equipment required for the blood salvage, anticoagulation and collection are opened. When desired, further equipment is opened to allow blood processing and reinfusion. This allows costs savings, with the ICS processor set and other items not wasted when blood is not reinfused.

The decision to reinfuse salvaged blood is made jointly by the surgeon and anaesthetist, based on patient pre-operative haemoglobin, cardiorespiratory comorbidities, intra-operative heart rate and blood pressure, volume of blood salvaged and anticipated future haemorrhage risk.

Transfusion related cost calculations

Costs were calculated as of 30/03/20 (*Table 1*). Transfusion related costs were calculated as allogeneic transfusion cost + ICS setup cost + ICS reinfusion cost. Costs related to length of stay and complications were not included.

Allogeneic transfusion incurs both product and process costs. The product cost of one PRBC unit at our institution is AUD $416.15, purchased from the National Blood Authority (17). Process costs of transfusion include hospital overheads, staffing, pre-infusion laboratory testing and in-hospital logistics. These are known to be three to five times higher than the product cost (18,19). Australian process costs were first estimated in 2006 at AUD $370 per unit of allogeneic red blood cells infused (20). Several authors have subsequently applied the Australian Bureau of Statistics consumer price index for hospital and medical services to

Table 1 The cost of intra-operative cell salvage set up and reinfusion in Australian dollars, as of 31 March 2020

Item	Cost
Ballarat Base Hospital	
ICS collection reservoir alone	$160.00
Dual suction tubing	$25.00
Anticoagulant	$7.40
Waste Bag	$36.40
Sub-total, ICS setup cost	$228.80
ICS combined collection + processing kit	$380.00[†]
Leucocyte depletion filter	$31.24
Blood reinfusion bag	$9.90
3x1 L 0.9% normal saline	$2.97
Intra-venous infusion tubing	$8.90
Sub-total, ICS reinfusion cost	$433.01
St John of God Hospital	
ICS collection reservoir alone	$160.00
Dual suction tubing	$25.00
Anticoagulant	$10.25
Sub-total, ICS setup cost	$195.25
ICS combined collection + processing kit	$140.00[†]
Leucocyte depletion filter	$31.24
Blood reinfusion bag	$14.00
3x1 L 0.9% normal saline	$3.27
Intra-venous infusion tubing	$9.64
Sub-total, ICS reinfusion cost	$198.15

[†], cost of reservoir alone subtracted from the cost of the combined ICS kit, as the latter equipment bundle includes a reservoir. amp., ampoules; ICS, intra-operative cell salvage; mL, millilitres.

derive modern re-estimates of this cost, updated in 2010 to AUD $536 (10,11,21). We applied this same method to estimate a 59.1% increase from end-of-financial-year 2010 to 2019 (22). This resulted in a current process cost of AUD $853, and a total cost of AUD $1,269.15 per unit allogeneic red blood cells infused.

ICS costs were calculated by pricing each item involved. At both centres, sufficient capacity in routine theatre technician staffing and the existence of only one ICS machine per site mean that no additional staffing costs were incurred to deliver ICS.

Statistical analysis

Most primary and secondary outcomes were categorical measures, including number of patients per group experiencing biochemical recurrence, allogeneic transfusion and complications. These categorical measures were summarized as proportions and assessed with Pearson's chi-square test, unless zero values were encountered, in which case Fisher's exact test was used. Continuous data such as serum haemoglobin were summarized as medians, and groups were compared using the Wilcoxon (Mann–Whitney) test. All tests were two-tailed and significance was assessed at the 5% alpha level. Data were analysed using SAS v9.3 (SAS Institute Inc., Cary, NC, USA).

Ethics

This study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the Ballarat Health Services and St John of God Healthcare Human Research Ethics Committee (LNR/62339/BHSSJOG-2020-206251) and individual consent for this retrospective analysis was waived.

Results

Demographics

One hundred and sixty-eight consecutive patients underwent open radical prostatectomy during the study period and were enrolled. No blood conservation technique occurred for 126 men, while ICS was employed for 42. Patient characteristics, tumour characteristics, primary outcomes and secondary outcomes are summarised in *Table 2*.

Primary outcome 1—oncological safety

The control and ICS groups had similar rates of biochemical recurrence (21 *vs.* 6 patients; P=0.90). There was no metastatic progression or cancer-specific mortality in either group.

Primary outcome 2—efficacy

The control and ICS groups had equivalent use of allogeneic transfusion (3 *vs.* 2 patients; P=0.33). This included nine and five units of allogeneic red blood cells

Table 2 Patient characteristics and outcomes

Patient characteristics	No cell salvage	Intra-op. cell salvage	P value
Patients	126	42	n/a
Age [years]; med. [mean]	66 [64.9]	67 [65.8]	0.42
Pre-op. Hb [g/L]; med. [mean] [missing]	154 [153] [2]	152 [151] [1]	0.18
Discharge Hb [g/L]; med. [mean] [missing]	118 [117] [13]	119 [114] [0]	0.35
Hb drop [g/L]; med. [mean] [missing]	37 [36] [15]	35 [37] [1]	0.99
Charlson comorbidity index; med. [mean]	4 [4.6]	5 [4.9]	0.26
Length of stay [days]; med. [mean]	3 [3.3]	3 [3.5]	0.73
Follow-up [days]; med. [mean]	321 [336]	176 [225]	0.003
Tumour characteristics			
Prostatectomy ISUP score			0.92
1	1	1	
2	50	17	
3	29	9	
4	5	1	
5	41	14	
T stage			0.78
T2	62	24	
T3a	37	10	
T3b	26	8	
T4	1	0	
Node positive	2	1	0.74
Metastatic pre-op	0	0	n/a
Margins positive [%]	66 [52%]	25 [60%]	0.42
Primary outcomes			
Biochemical recurrence [%]	21 [17%]	6 [14%]	0.90
Allogeneic transfusion units [patients]	9 [three]	5 [two]	0.33
Secondary outcomes			
Adjuvant or salvage therapies	38 [30%]	12 [29%]	0.85
Complications	18 [14%]	8 [19%]	0.46
Transfusion related cost [AUD]	$11,422	$43,227	n/a

NB. Continuous variables: Mann Whitney U. Categorical variables with no zero values: chi square test. Categorical variables with any zero values: Fisher exact test. Data given as median [interquartile range]. AUD, Australian dollars; Hb, haemoglobin; ISUP, International Society of Urological Pathology; n/a, not applicable; Op, operative.

Table 3 Complications

Complications	Clavien-Dindo grade	No.
Traditional group		
Hypoglycaemia, ward based care with electrolytes	I	1
Hypotension, ward based care with electrolytes	I	7
Ileus, ward based care with electrolytes, no NGT	I	1
Pain due to self-resolving superficial haematoma	I	1
High drain output requiring extended period with drain	I	3
Delirium, ward based care with medications	II	1
Fever & pelvic abscess, requiring antibiotics only	II	1
Hypotension, requiring inotropes in recovery only, no ICU	II	1
Urinoma with return to theatre & revision of anastomosis	IIIb	1
Respiratory distress requiring ICU admission	IV	1
Intra-operative cell salvage group		
Hypotension, ward based care with electrolytes	I	2
Ileus, ward based care with electrolytes, no NGT	I	1
High drain output requiring extended period with drain	I	1
Rectal perforation repaired during prostatectomy	IIIb	1
Arrhythmia requiring ICU admission	IV	1
Hypotension requiring ICU admission	IV	1
Bowel injury + urinoma, requiring return to theatre & ICU admission	IV	1

ICU, intensive care unit; IUC, indwelling urethral catheter; NGT, naso-gastric tube.

transfused, respectively.

Secondary outcomes

Adjuvant or salvage therapies were used in 38 and twelve patients respectively (P=0.85). The groups had similar rates of complications (18 *vs.* 8 patients; P=0.46) (*Table 3*), with no deaths at time of data census. Regarding costs, 19 and 45 patients had salvaged blood collection alone at our public and private institution respectively. A separate 27 and 15 men had reinfusion of salvaged blood at these sites. Including costs of the units of allogeneic blood transfusion described in '*Primary outcomes*', transfusion related costs were higher for the ICS group (AUD $11,422 *vs.* $43,227).

Discussion

Intra-operative blood loss remains a challenge in radical prostatectomy despite modern advances. In addition to ABT and ICS, several other blood-conservation management strategies exist, including pre-operative autologous blood donation and acute normovolaemic haemodilution. However, these both have significant limitations and are rarely practiced. Pre-operative autologous blood donation is twice as expensive as autologous blood, requires several pre-operative visits to prepare, decreases pre-operative haemoglobin and 50% of pre-donated units are discarded (15). Conversely, despite being more cost effective compared to pre-operative autologous blood donation, acute normovolaemic haemodilution is often complicated by intra-operative hypotension (15,23). ICS avoids these pitfalls and offers many additional benefits. It does not require pre-operative visits, nor cause pre-operative anaemia or intra-operative hypotension. Fresh salvaged red cells have greater oxygen carrying capacity than stored red cells (24).

Despite its multiple advantages, ICS remains controversial due to misconceptions regarding its efficacy and safety, particularly in tumour surgery. In 1986, the American Medical Association of Scientific Affair recommended against the use of ICS in cancer surgery following publication of a 1975 case report, in which a patient with lung cancer died from diffuse metastasis four weeks post pneumonectomy with ICS use (25,26). However, multiple studies have since generated strong and robust scientific evidence to contradict this hypothesis and validate the safety of ICS in oncological surgery (13,14). Part of this success has been the routine incorporation of a leukocyte depletion filter to eliminate almost all tumour cells scavenged from the operative field (27). Subsequently, use of ICS in radical prostatectomy is supported by multiple healthcare institutions such as the National Blood Authority Australia (28), the American Association of Blood Banks (29), the United Kingdom's National Institute for Health and Care Excellence (NICE) (30) and the Association of Anaesthetists of Great Britain and Ireland (31), whose guidelines are endorsed by the Royal College of Surgeons.

This study represents the largest assessment to date of ICS in prostatectomy in the Southern Hemisphere. Findings from our study show that ICS use does not affect rates of biochemical recurrence, use of adjuvant therapies or complication rates. This is in keeping with evidence from three large audits previously reporting complication rates associated with ICS use to be as low as <0.3% (32-34). Indeed, existing meta-analysis of blood conservation strategies in oncological surgery have revealed higher rates of disease recurrence with allogeneic transfusion (8,9), but not ICS (13,14). Amongst all twelve comparative studies to date of ICS in radical prostatectomy, with study follow up ranging 0–64 months (median 36 months), groups receiving ICS have experienced similar or decreased rates of biochemical recurrence compared with controls (10,14).

In this study, ICS use did not affect rates of ABT. This is consistent with similar works. While three prior studies of ICS in prostatectomy have reported significantly reduced ABT rates (35-37), most have not (10,37-45). In our patients, we believe this is related to the high median pre-operative haemoglobin (152–154 g/L), low rates of transfusion in both groups (2–5%) and small sample size.

Additionally, this study showed that transfusion related costs were higher in the ICS group compared to control. This is likely due to the low transfusion rates in the control arm, with subsequent limited capacity to deliver savings. This result was surprising given the absence of ICS-related staffing costs in our centre, in contrast to other studies (10,11). Amongst pre-existing studies of ICS in prostatectomy, only one found increased cost associated with ICS use (38), while all others have reported reduced expense (10,37,46). These findings have prompted reconsideration of patient selection in our centre. In future, the decision to salvage blood will be based on body habitus, pre-operative haemoglobin and intra-operative findings after dissection of the space of Retzius.

This study is limited by its small sample size and retrospective nature. While our group's median follow-up was short at 6 to 11 months, the authors do not expect a longer observation period to change the study's findings. However, we remain optimistic that the shorter period of follow up amongst the ICS group represents higher uptake in the latter half of the enrolment period and highlights a growing confidence among employing use of ICS. Despite similarities in patient and disease characteristics between the comparison groups, the non-randomised methodology may be associated with a degree of selection bias. Given the increasing utilisation of robot assisted radical prostatectomy, future studies are needed to investigate the relevance of ICS in this arena.

Conclusions

Within the limitations of this small retrospective study, ICS use in radical prostatectomy was not associated with altered rates of allogeneic transfusion, complications, biochemical recurrence or adjuvant or salvage therapies. Transfusion related costs were higher in the ICS group.

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Footnote

Reporting Checklist: The authors have completed the STROBE reporting checklist. Available at http://dx.doi.org/10.21037/tau-20-1265

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Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at http://dx.doi.org/10.21037/tau-20-1265). The authors have no conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). This study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by the Ballarat Health Services and St John of God Healthcare Human Research Ethics Committee (LNR/62339/BHSSJOG-2020-206251) and individual consent for this retrospective analysis was waived.

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