An Analysis of the Trends and Variability of Hepatic and Pancreatic Surgery in Australia

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Thesis Abstract

For many general surgical procedures, quality of care does not differ greatly between providers or hospitals. However, the outcomes of complex surgical procedures such as those performed on the liver or pancreas have been shown to vary by hospital, surgeon and their respective volume or experience.

This research sought to provide an assessment of the current state of hepatic and pancreas surgery in Australia with identification of potential areas for improvement. A systematic search for studies investigating the determinants of mortality and morbidity for hepatic resection and pancreaticoduodenectomy (PD) was performed. A particular focus on Australian studies revealed gaps in the current available evidence.

The first objective was to evaluate the mortality due to hepatic resection in Australia. Publication 1 (Variability of perioperative mortality of hepatic resection in Australia) reflected this aim. Australian Institute of Health and Welfare (AIHW) data was interrogated for hepatic resection. The overall POMR for hepatic resection in Australia was 1.6% with significant interstate variability but without significant variability over time.

Publications 2 (Peer review of mortality after pancreaticoduodenectomy in Australia) and 3 (Peer review of mortality after hepatectomy in Australia) used the data collected from the Australian and New Zealand Audit of Surgical Mortality (ANZASM) to examine the factors leading to mortality post hepatic or pancreas resection. This was a unique approach not previously employed to examine the drivers of mortality for a specific procedure. For each patient death following PD or hepatic resection, the ANZASM Assessor's determination of whether patient care could have been improved was reviewed and summarised using thematic analysis. ANZASM assessors determined that a poor decision to operate contributed to 17% of deaths post PD and 25% of deaths post hepatic resection. Delay in the recognition of serious complication was considered relevant in 21% and 18% of PD and hepatic resection deaths respectively. Multi-disciplinary decision making has been strongly recommended in deciding which patients to offer these complex procedures. Optimal care includes early recognition of complications and enactment of an adequate rescue plan.

Finally, mortality data from the Victorian Admitted Episodes Database was interrogated for patients who underwent PD in public hospitals and reported in publication 4 (The short-term outcomes of pancreaticoduodenectomy in the state of Victoria – Hospital resources are more important than volume). Risk adjusted perioperative outcomes were reported and compared for hospital volume and hospital peer group. The overall inpatient mortality for PD in Victoria was 2.7% with a significant difference in mortality between hospital peer groups and not hospital volume. This finding highlights the importance of resource availability in the care of these complex patients.

The results seen in this group of studies contribute new evidence into the current status and variability of hepatic and pancreatic surgery in Australia. Furthermore, the two studies investigating the determinants of perioperative mortality provide a new perspective to the current international literature on hepatobiliary surgery.

Thesis Declaration

I certify that this work contains no material which has been accepted for the award of any other degree or diploma in my name, in any university or other tertiary institution and, to the best of my knowledge and belief, contains no material previously published or written by another person, except where due reference has been made in the text. In addition, I certify that no part of this work will, in the future, be used in a submission in my name, for any other degree or diploma in any university or other tertiary institution without the prior approval of the University of Adelaide and where applicable, any partner institution responsible for the joint-award of this degree.

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C. Stevens

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Published Works

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Stevens CL, Babidge WJ, Maddern GJ. Variability of perioperative mortality of hepatic resection in Australia. ANZJ Surg 2018; 88(10):1022-1027

Stevens CL, Reid JL, Babidge WJ, Maddern GJ. Peer review of mortality after pancreaticoduodenectomy in Australia. HPB 2019; 21(11):1470-1477

Stevens CL, Reid JL, Babidge WJ, Maddern GJ. Peer review of mortality after hepatectomy in Australia. HPB 2019 DOI 10.1016/j.hpb.2019.09.001 [Epub ahead of print]

Stevens CL, Watters, DAK. The short-term outcomes of pancreaticoduodenectomy in the state of Victoria – Hospital resources are more important than volume. ANZJ Surg 2019; 89(12):1577-1581

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Publication 1

Variability of perioperative mortality of hepatic resection in Australia

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Principal Author

Name of Principal Author (Candidate)	Claire Stevens		
Contribution to the Paper	Designed the study, performed the literature review, sourced and sorted the data, performed the statistical analysis and drafted the manuscript.		
Overall percentage (%)	80%		
Certification:	This paper reports on original research I conducted during the period of my Higher Degree by Research candidature and is not subject to any obligations or contractual agreements with a third party that would constrain its inclusion in this thesis. I am the primary author of this paper.		
Signature		Date	06 Dec 19.

Co-Author Contributions

By signing the Statement of Authorship, each author certifies that:

i. the candidate's stated contribution to the publication is accurate (as detailed above);

ii. permission is granted for the candidate in include the publication in the thesis; and

iii. the sum of all co-author contributions is equal to 100% less the candidate's stated contribution.

Name of Co-Author	Professor Wendy Babidge		
Contribution to the Paper	Sourced the data, assisted with drafting and review of the manuscript		
Signature		Date	1 Jan 20

Name of Co-Author	Professor Guy Maddern		
Contribution to the Paper	Generated the idea for the study and provided guidance on the design of the study, critically reviewed the manuscipt.		
Signature		Date	30/12/19

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Variability of perioperative mortality of hepatic resection in Australia

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Key words
hepatectomy, hepatic resection, perioperative mortality.

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Abstract

Background: Hepatic resection is a relatively young and complex specialized procedure. A strong relationship between volume and perioperative mortality has been reported internationally. However, there has been no multicentre study into hepatic resection in Australia. This retrospective, population-based cohort study was conducted to determine national, state and territory based volume and perioperative mortality rates (POMRs).

Methods: Australian Institute of Health and Welfare data was interrogated for the Australian Classification of Health Intervention codes for hepatic resection defined as extended hemi-hepatectomy (30421), hemi-hepatectomy (30418), segmental hepatic resection (30415) and sub-segmental hepatic resection (30414). Logistic regression analysis was performed using the de-identified data to investigate trends and differences between states/territories. Mortality rates were risk adjusted for age, gender and public or private admission. The data set included patients who underwent hepatic resection in the financial years 2005/2006 to 2012/2013.

Results: The overall POMR for all types of hepatic resection was 1.6% (201/12 562). There was no significant change in POMR over time. However, there was significant variation between the states and territories with two states having significantly higher POMR for major hepatic resections (regional range: 1.3–3.8%). POMRs increased with age with the highest mortality seen in the 75–79 year age group. The POMR was lower in private than in public hospitals.

Conclusion: The results of this study confirm that the overall Australian POMR for major hepatic resection is similar to results reported internationally. National and state/territory POMR has not varied significantly over time. The significant variation between states/territories warrants further investigation.

Introduction

For many general surgical procedures, quality of care does not differ significantly between providers or hospitals. However, the outcomes of complex surgical procedures such as those performed on the liver, pancreas or oesophagus have been shown to vary by hospital, surgeon and their respective volume of experience.[1,2]

Australia is relatively unique with its widely dispersed population. One-third of Australia's population live outside of a major city.[3] Centralization of liver resectional surgery has occurred in many Western countries with consistently good results.[4,5] Hepatic resection in Australia is known to be performed in relatively low-volume centres. The relationship between volume and outcome shown in the literature may represent the quality of care provided and not just be a function of throughput.

The perioperative mortality rate (POMR) is an indicator of access to and safety of surgery and the associated anaesthesia for a defined procedure. POMR is used as a tool to evaluate care at a population level and should be risk-adjusted to compare jurisdictions. The POMR is measured over a set time period and is expressed as the number of deaths per procedure.[6] The complexities of hepatic resection and the associated perioperative care are such that the POMR of this procedure should provide an adequate but broad marker of quality of care.

Progressive advances in multiple aspects of hepatic resection have resulted in improved outcomes.[7,8] A recent analysis of greater than 4000 resections for malignant disease in a high-volume centre in the United States concluded that the trend towards parenchymal preservation and a consequent reduction in major hepatectomy rates is the most recent significant factor.[9] The authors found an overall

30-day mortality rate of 1% and a 90-day mortality rate of 3%. The 90-day mortality rates associated with extended hepatectomy and right hemi-hepatectomy for malignant disease were 6% and 3%, respectively. Perioperative mortality has been reported by other international studies as between 3% and 3.5%.[7,10,11]

This retrospective, population-based cohort study was conducted to determine national, state and territory based volume and POMRs for hepatic resection. A nationwide study examining hepatic resection in Australia will enable comparison across regions and with the outcomes reported internationally.

Methods

Australian Institute of Health and Welfare data from all admissions to public and private Australian hospitals from 1 July 2005 to 30 June 2013 was interrogated for the Australian Classification of Health Intervention codes for the four types of hepatic resection: extended hemi-hepatectomy (30421), hemi-hepatectomy (30418), segmental resection (30415) and sub-segmental resection (30414). Extraction of data was based upon the first 10 procedural codes and where there were multiple hepatic resection codes, the most extensive was recorded. De-identified data included year of operation, age group (5 year bands), gender, state/territory of admission, private/public admission and mode of separation (deceased, transferred, discharged etc). POMR was defined as the number of deaths that occurred during the same hospital admission as the procedure (including after 30 days) divided by the total number of admissions for that procedure.

Binary logistic regression models were used to investigate trends and differences between states/territories. This was performed separately for all resections (extended hemi-hepatectomy, hemi-hepatectomy, segmental and sub-segmental hepatic resection) and major resections (extended hemi-hepatectomy and hemi-hepatectomy). Patient status was the binary response variable (discharged or deceased) and predictor variables included year of admission (linear effect where year 2005/2006 = 0 to 2012/2013 = 7). The model was run by state/territory and as a nation, with each state/territory as a predictor variable.

Risk was adjusted by including patient age, gender and private or public admission in the model. Age was considered as a continuous variable based upon the starting age of each bracketed group (e.g. 55–59 = 55). The Wald test was used to assess significance of the model variables with $P < 0.05$ considered significant. Non-significant terms were removed stepwise until significant variables remained.

The procedural admission distribution for the states/territories was compared to population density at June 2013.[12] The distribution was tested for independence using the chi-square test. POMR trends for age were reviewed for states with higher POMR to reveal at-risk age groups; the significance of the findings was tested using the chi-square test of association.

Results

During the period from 1 July 2005 to 30 June 2013, there were 12 562 hepatic resections performed in Australian hospitals; 5006 (39.9%) of these were major hepatic resections. Figure 1 shows the number of admissions for all types of hepatic resection and the proportion of major resections by year. There was a 46% increase in the total number of procedures across the study period. There were more males than females at 52.9% and 47.1%, respectively. Peak procedural incidence was in the 65–69 year age group (14.4%). More procedures were performed in public hospitals (56.3%) than in private hospitals (42.6%).

The overall POMR for all hepatic resections over the study period was 1.6% (Table 1). There was no significant change in POMR over time ($P = 0.095$). POMRs increased with age (non-linear effect, $P < 0.001$), with the highest mortality seen in the 75–79 year age group at 3.9% (39/995) (Fig. 2). POMR was lower in private versus public hospitals (odds ratio (OR): 0.706, 95% CI: 0.526, 0.949; $P = 0.021$). The POMR for males was 1.9% and 1.3% for females (OR: 1.608, 95% CI: 1.203, 2.150; $P = 0.001$).

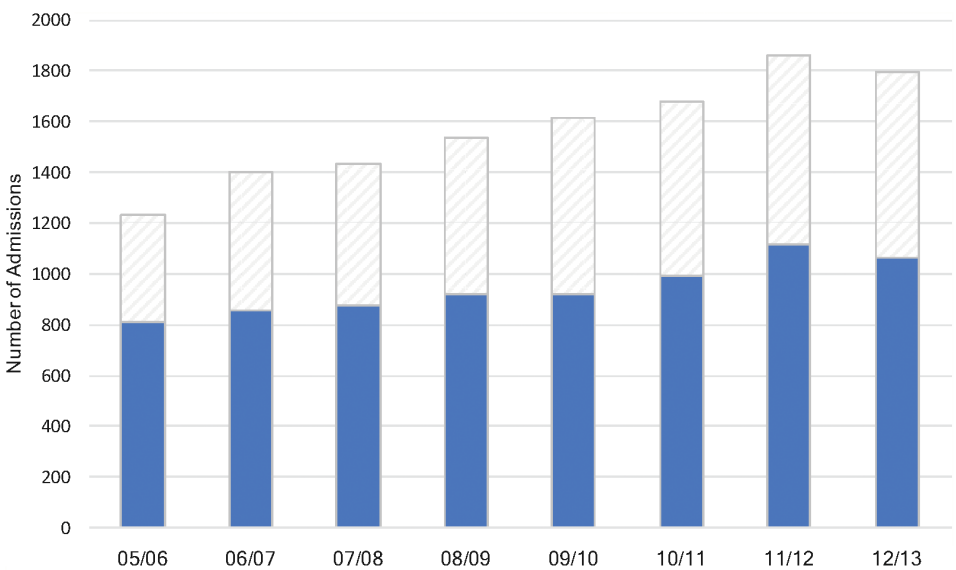

Fig. 1. Total number of hepatic resection admissions and the proportion of major hepatic resection in Australian hospitals between 1 July 2005 and 30 June 2013. ■, Minor hepatic resection; ▨, major hepatic resection.

Across Australia, there were approximately 25 perioperative deaths per year following hepatic resection with 16 of these having undergone a major resection (Table 2).

The POMR for major hepatic resections was 2.6% (Table 2). As was the case when including all hepatic resections, examining major resections separately revealed no significant change in POMR over time ($P = 0.170$). POMRs increased with age (non-linear effect, $P < 0.0001$) (Fig. 2) and were lower in private versus public hospitals (OR: 0.583, 95% CI: 0.396, 0.858; $P = 0.006$).

The POMR for each state and territory are shown in Tables 1 and 2 for all resections and major resections, respectively. There was a significant POMR variation between the states and territories (all hepatic resections: $P < 0.001$, major hepatic resection: $P = 0.001$), ranging from 0.6% to 2.5% for all types of hepatic resection and 1.3% to 3.8% for major resections.

The procedural admission distribution across the states/territories showed statistically significant variation. The number of resections per million population per year for each state or territory is shown in Table 3.

Both New South Wales (NSW) and Western Australia (WA) had the highest POMR out of the states/territories for major hepatic resection with POMR of 3.77% and 3.80%, respectively. Within NSW, patients over 60 years of age undergoing major resection had a mortality rate of 5.4% compared with 2.8% for the rest of the nation for this age group ($P = 0.002$). The relatively high POMR in WA is almost entirely accounted for within the 70–79 year age group. Across all regions outside of WA, this age group had a POMR of 5.4%. In WA, the mortality rate of 70–79 year olds was 12% ($P = 0.036$). No patients over 80 years of age died in the perioperative period after major hepatic resection in WA.

Discussion

The results of this study show that Australia's national hepatic resection perioperative mortality compares favourably with that seen internationally. However, international studies consistently show evidence of improvement over 5–12 year periods.[7,9] Neither the national nor the state/territory POMRs showed improvement over the 8 years of the data collection period. This was the case for all types of hepatic resection and overall. The reason for this may be that improvements are made less obvious by increasing complexity of cases and/or an increase in the number of procedures performed on chemotherapy-affected livers across the study period. However, this same trend would have been expected to be seen overseas. While Australian POMRs are reasonable, reasons for our lack of improvement over time should be further investigated.

There are two strong themes from the available literature on population-based studies of hepatic resection. The first is the reported value of centralization and the second around parenchymal preservation and decreasing major hepatectomy rates to reduce mortality and morbidity.

The volume effect for hepatic resection was summarized in a 2013 meta-analysis and suggested a strong volume outcome relationship for mortality. However, while the included studies defined the cut-off value between high and low as 10–20 resections per year, low-volume centres were extremely low (1–4 cases per year) and high-volume centres were between 11 and 63 cases per year.[4] The low volumes in this study are very low and any unit doing this would struggle to maintain proficiency. Considering this, the finding that mortality was twice as high in the low-volume centres should not be unexpected. In a recent paper out of Italy, Torzilli *et al.*[13] have produced a good commentary on the ideal centre for hepatic resection. They describe the inherent variability in the definition of resectability and the use of a simple volumetric criteria to define a type of hepatic resection. Torzilli *et al.*[13] have proposed centralization of hepatic resection in Italy to centres that can maintain an operative volume of greater than 20 procedures per year with <3% 90-day mortality. Centralization has already occurred in the United Kingdom, United States and Canada. In one state of Australia, Victoria, there are nine specialist liver surgery units performing between 7 and 40 resections per year (C. L. Stevens, unpubl. abstract, 2017), volumes that are not dissimilar to those

Table 1 Mortalities, admissions and post-operative mortality rates for hepatic resection (July 2005 to June 2013)

Year		NSW	VIC	QLD	WA	SA	TAS	ACT	NT	AUS
2005/2006	*n*	11/448	6/252	3/265	1/119	0/111	0/23	1/15	0/2	22/1235
	POMR (%)	2.5	2.4	1.1	0.8	0.0	0.0	6.7	0.0	1.8
2006/2007	*n*	7/510	2/271	7/315	3/159	0/98	0/21	0/25	0/3	19/1402
	POMR (%)	1.4	0.7	2.2	1.9	0.0	0.0	0.0	0.0	1.4
2007/2008	*n*	10/532	4/284	3/306	5/133	1/139	1/24	0/15	0/0	24/1433
	POMR (%)	1.9	1.4	1.0	3.8	0.7	4.2	0.0	0.0	1.7
2008/2009	*n*	16/587	3/294	4/327	3/104	1/165	1/26	1/30	0/3	29/1536
	POMR (%)	2.7	1.0	1.2	2.9	0.6	3.8	3.3	0.0	1.9
2009/2010	*n*	20/638	4/323	5/366	5/111	0/120	1/23	1/33	0/0	36/1614
	POMR (%)	3.1	1.2	1.4	4.5	0.0	4.3	3.0	0.0	2.2
2010/2011	*n*	20/631	2/369	4/347	2/135	2/125	1/31	0/41	0/1	31/1680
	POMR (%)	3.2	0.5	1.2	1.5	1.6	3.2	0.0	0.0	1.8
2011/2012	*n*	10/660	7/455	1/381	1/152	0/133	0/42	0/40	0/0	19/1863
	POMR (%)	1.5	1.5	0.3	0.7	0.0	0.0	0.0	0.0	1.0
2012/2013	*n*	12/610	2/472	2/383	0/119	2/127	0/44	3/44	0/0	21/1799
	POMR (%)	2.0	0.4	0.5	0.0	1.6	0.0	6.8	0.0	1.2
Total	*n*	106/4616	30/2720	29/2690	20/1032	6/1018	4/234	6/243	0/9	201/12562
	POMR (%)	2.3	1.1	1.1	1.9	0.6	1.7	2.5	0.0	1.6

ACT, Australian Capital Territory; AUS, Australia; NSW, New South Wales; NT, Northern Territory; POMR, perioperative mortality rate; QLD, Queensland; SA, South Australia; TAS, Tasmania; VIC, Victoria; WA, Western Australia.

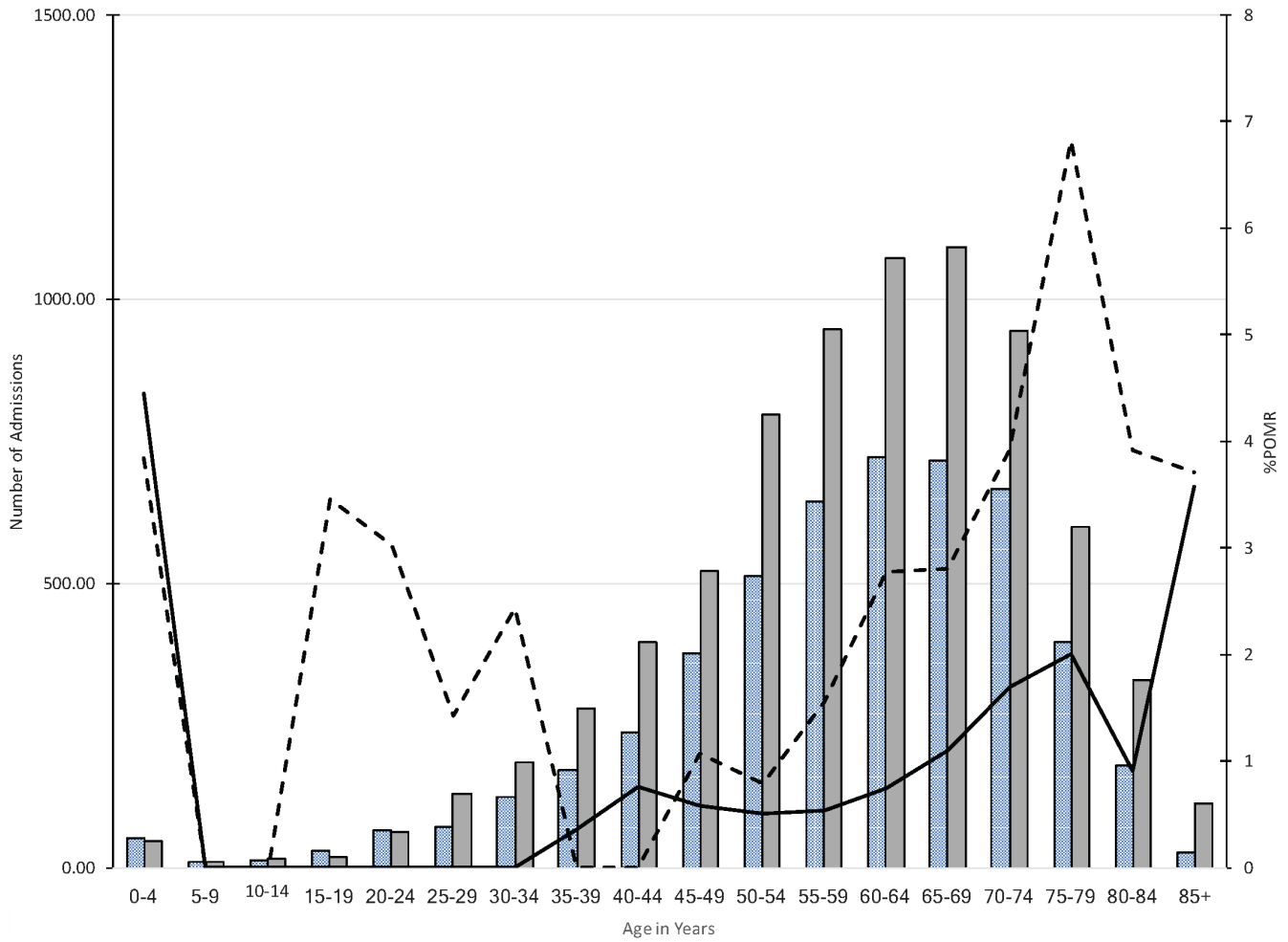

Fig. 2. Number of minor and major hepatic resection admissions graphed with perioperative mortality rate (POMR) for Australian hospitals between 1 July 2005 and 30 June 2013. ▨, Major hepatic resection; ▭, minor hepatic resection; – – –, major hepatic resection POMR; ——, minor hepatic resection POMR.

Table 2 Mortalities, admissions and post-operative mortality rates for major hepatic resection (July 2005 to June 2013)

		NSW	VIC	QLD	WA	SA	TAS	ACT	NT	AUS
2005/2006	*n*	10/150	3/96	1/85	1/49	0/29	0/10	0/4	0/0	15/423
	POMR (%)	6.7	3.1	1.2	2.0	0.0	0.0	0.0	0.0	3.5
2006/2007	*n*	4/186	1/111	5/126	2/56	0/40	0/10	0/16	0/0	12/545
	POMR (%)	2.2	0.9	4.0	3.6	0.0	0.0	0.0	0.0	2.2
2007/2008	*n*	5/195	2/107	1/135	4/56	1/48	0/8	0/10	0/0	13/559
	POMR (%)	2.6	1.9	0.7	7.1	2.1	0.0	0.0	0.0	2.3
2008/2009	*n*	11/225	1/134	3/139	2/38	0/65	0/5	0/11	0/0	17/617
	POMR (%)	4.9	0.7	2.2	5.3	0.0	0.0	0.0	0.0	2.8
2009/2010	*n*	12/266	3/146	3/158	3/37	0/55	1/11	1/17	0/0	23/690
	POMR (%)	4.5	2.1	1.9	8.1	0.0	9.1	5.9	0.0	3.3
2010/2011	*n*	12/252	1/150	4/157	2/55	2/49	0/9	0/16	0/0	21/688
	POMR (%)	4.8	0.7	2.5	3.6	4.1	0.0	0.0	0.0	3.1
2011/2012	*n*	7/271	6/197	1/160	0/43	0/50	0/11	0/15	0/0	14/747
	POMR (%)	2.6	3.0	0.6	0.0	0.0	0.0	0.0	0.0	1.9
2012/2013	*n*	7/257	2/199	0/150	0/34	2/62	0/14	2/21	0/0	13/737
	POMR (%)	2.7	1.0	0.0	0.0	3.2	0.0	9.5	0.0	1.8
Total	*n*	68/1802	19/1140	18/1110	14/368	5/398	1/78	3/110	0/0	128/5006
	POMR (%)	3.8	1.7	1.6	3.8	1.3	1.3	2.7	0.0	2.6

ACT, Australian Capital Territory; AUS, Australia; NSW, New South Wales; NT, Northern Territory; POMR, perioperative mortality rate; QLD, Queensland; SA, South Australia; TAS, Tasmania; VIC, Victoria; WA, Western Australia.

Table 3 Number of resections per million population per year by state or territory.

State	Population† (million)	Hepatic resections (*n*)	Resections per million population per year
NSW	7.408	4616	78
VIC	5.738	2720	59
QLD	4.659	2690	72
WA	2.517	1032	51
SA	1.671	1018	76
TAS	0.513	234	57
ACT	0.383	243	79
NT	0.24	9	5

†Population data from Australian Bureau of Statistics.[12] Chi-square test for independence (excluding NT) $P < 0.001$. ACT, Australian Capital Territory; NSW, New South Wales; NT, Northern Territory; QLD, Queensland; SA, South Australia; TAS, Tasmania; VIC, Victoria; WA, Western Australia.

throughout the nation. If mortality was a proxy for quality of care, the relatively low volumes and de-centralized nature of liver surgery in Australia are resulting in acceptable care by international standards. More work needs to be done to determine oncological performance and long-term survival.

The data collected in this study have revealed that the proportion of major hepatectomy has remained steady over time at approximately 40% (Fig. 1). As has been seen overseas, reduction in this rate through parenchymal preservation would very likely see our mortality rates improve.[7,9] However, the rate found here is only slightly higher than the Memorial Sloan Kettering major hepatectomy rate through a similar era (2007–2012) at 36%.[9]

Hepatectomy in octogenarians has been the subject of three relatively small studies with all showing that resection at this age is safe with good patient selection and recognition of an increased risk.[14–16] Over the 8-year period of this study, there were 648 resections performed on octogenarians with a mortality of 2.3% (15/648). While not statistically significant ($P = 0.075$), the mortality of the octogenarians was less than the 75–79 age group at 3.9% (39/995), possibly reflecting more considered patient selection once the age of 80 was reached.

The good overall results shown here suggest that Australia is performing well by international standards. However, further investigations into the reasons for interstate variability are needed to confirm that this is truly the case in all regions. The difference between the best and worst performing states/territories may be due to case mix and could be a reflection of aggressive versus conservative behaviour. However, population data does not help explain the variability in POMR between regions. The numbers of cases per million population varied by region and there was no relationship between regional caseload and POMR.

Two states, NSW and WA, had relatively high POMR for major hepatic resection in comparison to the other states and territories. For all types of hepatic resection, 53% of the deaths throughout the study period occurred in patients treated in NSW, where 37% of the total population was treated. Increasing age was a significant predictor of poor outcome in NSW overall and patients over 60 years of age undergoing major resection suffered a particularly high mortality rate. The proportion of extended hepatectomy was slightly higher for NSW than the other states suggesting that this state may do more of these more morbid cases. However, this was not statistically significant and it could also be due to variability in coding practices. Four NSW hospitals are participating in the American College of Surgeons National Surgical Quality Improvement Program (NSQIP), the broadening of this participation or another type of national registry may provide more explanation for the interstate variability seen in this study.

The relatively high POMR for major hepatic resection seen in WA is almost entirely accounted for within the 70–79 year age group where nearly two-thirds of their deaths were seen. It is possible that good patient selection in octogenarian patients was the reason for the zero POMR in this age group. However, further investigation is required to determine the reason for the high POMR for patients in their 70s.

The major limitation of this study is the inability to allow for case mix adjustment between states and territories. The lack of detail inherent in using an administrative data set precludes the authors from commenting definitively on the reason for the interstate variability. The difference between the best and worst performing states/territories may be due to case mix and could be a reflection of aggressive versus conservative behaviour. The numbers of cases per million population do not suggest that performance is related to proportion of population treated. Data revealing the relationship between hospital volume and POMR would have been a valuable addition to this study. However, the de-identified nature of the data set did not allow this to be derived.

A further limitation of this study is the inability to derive a 90-day mortality rate from the data set. The quality of hepatic resection lies also in the oncological outcomes which are not recorded at a population level in Australia.

Despite its limitations, the results of this study confirm that POMR for hepatic resection in Australia is similar to that reported internationally. The results should drive further investigation into the quality and variability of hepatic surgery in Australia. The significant variation between regions warrants further investigation. The development of a national registry of hepatic resection data would enable further study and potentially reveal areas where some centres excel and others fail, thereby generating overall improvement. In particular, patient selection, the degree of parenchymal preservation and the use of appropriate rescue where necessary would significantly affect mortality rates and would only be captured well by prospective study or a large-scale registry.

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Conflicts of interest

None declared.

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Publication 2

Peer review of mortality after pancreaticoduodenectomy in Australia

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Name of Principal Author (Candidate)	Claire Stevens		
Contribution to the Paper	Designed the study, performed the literature review, sourced and sorted the data, performed the data analysis and drafted the manuscript.		
Overall percentage (%)	80%		
Certification:	This paper reports on original research I conducted during the period of my Higher Degree by Research candidature and is not subject to any obligations or contractual agreements with a third party that would constrain its inclusion in this thesis. I am the primary author of this paper.		
Signature		Date	06 Dec 19

Co-Author Contributions

By signing the Statement of Authorship, each author certifies that:

i. the candidate's stated contribution to the publication is accurate (as detailed above);
ii. permission is granted for the candidate to include the publication in the thesis; and
iii. the sum of all co-author contributions is equal to 100% less the candidate's stated contribution.

Name of Co-Author	Ms Jessica Reid		
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ORIGINAL ARTICLE

Peer review of mortality after pancreaticoduodenectomy in Australia

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Abstract

Background: The data within the Australian and New Zealand Audit of Surgical Mortality (ANZASM) provides a unique opportunity to consider the contributing factors to perioperative deaths as determined by peer review. Consideration of the factors contributing to mortality after pancreaticoduodenectomy (PD) can provide greater insight into how deaths can be prevented.

Methods: ANZASM data from 1 January 2010 to 30 Jun 2017 was reviewed and all deaths following PD were selected for analysis. Assessor's determination of whether management could have been improved were reviewed and classified into groups of significant clinical events using thematic analysis with a data driven approach.

Results: The study included 87 deaths reported to ANZASM after PD. Forty-two major complications were considered significant clinical events in 29/84 (35%) of patients. The assessor determined that there was a delay in recognising a significant complication in 18/84 (21%) of patients. In 14/84 (17%) of patients, ANZASM assessment questioned the decision to operate.

Conclusion: Multi-disciplinary decision making is strongly recommended when deciding which patients to treat with PD. Late recognition, and therefore delayed action to treat complications, in almost a quarter of deaths is a significant finding that warrants consideration for clinicians involved in the postoperative care of PD patients.

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Introduction

The Australian and New Zealand Audit of Surgical Mortality (ANZASM) is a peer review audit of surgical deaths under the direction of the Royal Australasian College of Surgeons (RACS). The objective of the audit is to improve the quality of surgical practice through information gathering, education and facilitation of change. The audit has been conducted Australia-wide since 2010 and has collected considerable data on surgeon identified avoidable issues contributing to in-hospital surgical deaths. While ANZASM was formed for the purposes of both nation's surgical communities, New Zealand does not currently participate in the ANZASM program. In New Zealand, a Perioperative Mortality Review Committee is responsible for reviewing and reporting mortalities with a view to reducing deaths and enabling continuous quality improvement.

Pancreaticoduodenectomy (PD) is a complex procedure with a perioperative mortality rate of around 3% in Australia.[1,2] For PD, Australian hospitals have morbidity and mortality results comparable to those reported internationally, despite relatively low volumes.[3,4] There have been multiple studies worldwide reporting the benefits of centralisation, with the reasons given for the improved results seen in larger centres being related to the management of major postoperative complications.[5,6] However, additional factors such as multidisciplinary approaches to care including preoperative planning and decision making, and the availability of pooled competence, capacity and peer support in patient care are likely to contribute to better patient outcomes.

☆ No previous communication to society or meeting.

The ANZASM provides a unique opportunity to investigate the events leading to the in-hospital mortality post-PD in Australian hospitals over recent years. This audit enables examination of the preoperative, intraoperative and postoperative events leading to each investigated death. The objective of this study was to determine the reasons for deaths post-PD in Australia as considered by the reviewers.

Methods

ANZASM data and peer review process

The function, governance and objectives of the ANZASM have been thoroughly described elsewhere.[7] However, a synopsis of the audit process is described here.

Independently of the treating surgeon, ANZASM is notified of in-hospital surgical deaths (whether there was a surgical procedure or not) by medical records departments. The hospital data includes designation of the admission as emergency or elective, which is determined by whether the admission was due to a planned procedure listed on a waiting list. Clinical details are collected via a standardised form completed by the treating surgeon either online or in paper format. (The ANZASM patient report form is available at https://www.surgeons.org/media/25780653/example_racs_generic_scf_non-trauma.pdf).

ANZASM data is stored in an encrypted database that enables a complete audit trail. The de-identified patient details are sent for first-line assessment to a surgeon of the same specialty and from a different hospital. In most cases, conclusions may be reached about the patient's care at this point and further investigation is deemed unnecessary. Alternatively, if further consideration of the patient's care is required, a second-line assessment is conducted by a different surgeon. The second-line assessor reviews the involved hospital's patient notes. Second-line assessment has been undertaken in 12–13% of all patients referred to ANZASM for the time period examined in this study.[8]

As a part of the audit process, ANZASM assessors determine whether there was an aspect of the patient's management that could have been better, and feedback is provided to the treating surgeon. The ANZASM data is held under qualified privilege which protects the confidentiality of identifying information for both practitioner and patient.[9] This protection enables surgeons to freely divulge information with confidence that the information gathered will be used exclusively for the purposes of professional development. Since 2012, 100% of public hospitals, up to 92% of private hospitals and over 98% of surgeons participate.[8,10]

Data analysis

Prospectively collected ANZASM data from 1 January 2010 to 30 Jun 2017 was retrospectively reviewed and deaths following PD were selected for analysis. Demographics, clinical and treatment details were gathered from the information submitted by Australian hospitals and treating surgeons. Assessor's determination of whether management could have been improved in the areas of decision to operate, intraoperative and technical management of surgery and postoperative care were analysed.

As a part of the audit process, assessors determine significant clinical events relevant to the patient's care and classify these into a level of seriousness. The process is similar for first and second-line assessment. Where a second-line or patient note assessment was performed, this was used in the analysis and the first line assessment disregarded. For all other patients, the first line assessment findings were included. Assessors annotate whether each of the clinical events were firstly, a contributing factor in the death of the patient and secondly, preventable or not. The determination of preventability, while relevant to each individual patient, was not considered further here. Preventable and non-preventable clinical events leading to mortality were all included in this study as they are useful in the determination of causes for mortality as an outcome of PD.

Assessor's clinical issue descriptions were reviewed and classified into groups of significant clinical events using thematic analysis with a data driven approach.[11] Methods described by Braun and Clarke were used to develop themes.[12] Two researchers (CS and JR) then independently classified the assessor's clinical issue descriptions into the relevant themes. Differences were discussed, and consensus achieved.

Results

From January 2010 to June 2017 there were 87 deaths reported to the ANZASM after PD. Medicare Australia data (which includes all patients, private and public) recorded 2330 PDs during this period.[13] The cohort of patients represented in the ANZASM represent 3.7% of this number.

Patient characteristics retrieved from the ANZASM patient reports are summarised in Table 1. The median age of the patients was 72 years (49–87 years). Clinically significant infection was reported in 28/87 (32%) patients. Return to theatre was reported in 50/87 (58%) patients and included formal radiological intervention such as embolisation.

ANZASM first-line peer review assessment was conducted in 84/87 (97%) of the reported deaths, while 22/84 (26%) went on to have second-line assessment with full review of the patient's hospital documentation. Seventy-two clinically significant events were described by the assessors in 50 patients, with 22 patients having two or more events described. Tables documenting patient outcomes have each patient labelled with an individual number 1–50 for purposes of tracking. In the remaining 34 patients, there were no assessors' comments on clinically significant events leading to the patient's mortality. For these 34 patients and the three patients who had no ANZASM assessment, the data submitted by the treating surgeon was reviewed by the authors and a summary of that record of events is included as Supplementary Table 2a (patients 51–84) and 2b (patients

Table 1 Summary of patients

	Number of patients (%)
American Society of Anaesthesiologists (ASA) score	
ASA 1	3 (3)
ASA 2	34 (39)
ASA 3	44 (51)
ASA 4	4 (5)
Not recorded	3 (3)
Hospital type	
Major public referral	52 (60)
Other public	15(17)
Private	20 (23)
Urgency of admission	
Elective	66 (76)
Emergency	20 (23)
Not recorded	1 (1)
Expected pathology	
Malignant	79 (91)
Benign	7 (8)
Not recorded	1 (1)

85–87) respectively. The treating surgeon noted that there had been an adverse event in 14/37 (38%) of these patients.

The clinically significant events as determined by the ANZASM assessors were grouped into the following themes by two of the authors:

A. Preoperative
   1. decision to operate
B. Intraoperative
   1. decision to proceed
   2. vascular injury
C. Postoperative
   1. delay in recognising complication
   2. postoperative haemorrhage
   3. anastomotic leak
   4. other complications

Operative decision making

The ANZASM assessment of 'decision to operate' as a significant clinical event was recorded in 14/84 (17%). A summary of the ANZASM findings for these patients is reported as Table 2.

The 'decision to proceed' with the operation after unexpected interoperative findings or events was considered to be a factor in

Table 2 Patients in whom ANZASM Assessor's determined a flawed decision to operate

Decision to operate, *n* = 14/84, 17%					
Patient number	Age	Admission	Presumed malignancy	Additional significant event	ANZASM assessor's comment
1	78	Emergency	Yes	No	Transfer to larger hospital for ERCP should have been considered instead of PD
2	71	Elective	Yes	No	Inadequate pre-operative assessment of vascular involvement
3	81	Elective	Yes	No	Multiple comorbidities
4	57	Elective	Yes	Post-operative bleed	Pancreatitis at time of PD
5	52	Elective	Yes	Delay in recognising complication	Multiple comorbidities
6	75	Emergency	Yes	Post-operative bleed	Portal vein reconstruction in elderly patient with multiple comorbidities
7	63	Elective	Yes	Vascular injury	Insufficient pre-operative assessment
8	71	Elective	Yes	No	Tumour involved hepatic artery
9	73	Elective	Yes	No	Hepatic cirrhosis
10	85	Emergency	Yes	No	ERCP/PTC and stent should have been considered instead of PD
11	70	Elective	Yes	Delay in recognising complication	Comorbidities: obesity and immune deficiency
12	80	Elective	No	No	Likely benign cyst in older patient
13	55	Emergency	Yes	No	ERCP and stent should have been considered instead of PD
14	52	Elective	No	Post-operative bleed	Pancreatitis at time of PD, no suspicion of malignancy

ERCP, endoscopic retrograde cholangiopantography; PTC, percutaneous transhepatic cholangiogram.

five (6%) deaths. A summary of the ANZASM findings for these patients is shown in Table 3. Two of these patients had a significant vascular injury and a further two patients had locally advanced disease, which would have made complete excision highly improbable. In three of the six descriptions, the surgeon completing the patient report had already determined that in hindsight she/he would not have attempted to continue with the resection. There was no overlap of patients who had an assessment of a poor decision to operate or proceed (intraoperative decision to continue).

Major complications

Forty-two complications were considered significant clinical events in 29/84 (35%) patients. These complications were categorised by the authors as 'postoperative haemorrhage' (Table 4), 'vascular injury' (Table 5) and 'other complication' (Supplementary Table 7). All but two of the twelve anastomotic leaks were from the pancreatic anastomosis and were associated with postoperative haemorrhage. Two of the patients whose complications were considered to be recognised late suffered a leak from the hepaticojejunostomy. The assessor determined that there was a delay in recognising a significant complication in 18/84 (21%) of patient deaths. These complications are summarised in Table 6.

Vascular injury was determined by the ANZASM assessors to be a significant intraoperative clinical event in eight (10%) patients. Three patients were noted to have aberrant anatomy. One vascular injury was discovered postoperatively; this was a pseudoaneurysm of the hepatic artery discovered on day two. All injuries identified intraoperatively resulted in the primary surgeon requesting and receiving assistance from either another hepatobiliary surgeon or vascular surgeon. ANZASM assessors questioned the decision to proceed after the injury in two patients and the decision to operate in another. The most common course to death after vascular injury was successful initial control of bleeding, followed by delayed ischemia of either the bowel or liver resulting in multi-organ failure.

Discussion

This study sought to quantify and thematically describe the significant clinical issues around peer-reviewed audited deaths post-PD in Australia. The ANZASM assessment process was completed in 97% of patients who died in hospital after PD across the study period. This cohort of patients represents a crude mortality rate of 3.7%, which is consistent with the 3% reported in a recent Australian study inpatient deaths after PD.[1]

The frequency of second-line assessment seen in the patients who died after PD is double the average second-line assessment rate in ANZASM, and likely reflects the complex and specialised nature of PD and its complications. ANZASM concordance analysis has shown agreement between first and second-line assessment in around 70% of patient care reviews.[14] When looking at the documentation of each patient death, it is evident that the process encourages thorough review of events by the treating surgeon and ANZASM assessors. This reflection of practice and the feedback provided by the assessors is likely to be beneficial to the treating team and is also seen as an educational opportunity for assessors. Assessors collect continuing professional development points in recognition of their voluntary participation.

Preoperative decision making is crucial both to prevent unhelpful surgery and to provide the best care to those that are resectable. While the benefit of hindsight may be a confounding factor, assessors were of the opinion that the decision to operate was flawed in 17% of patient deaths. Retrospective examination of the individual patient reports revealed significant comorbidities overlooked, insufficient radiological imaging or proceeding despite radiologically identified vascular involvement or known metastatic disease. While the actual number of deaths is low, the relative incidence of the finding of a poor decision to operate did not improve through the study period and there were four such events in the 2016–2017 financial year. There is considerable evidence in the literature for routine preoperative multidisciplinary team (MDT) discussion for optimal decision making prior to PD.[3,15,16] The ANZASM data is not sufficient to

Table 3 Patients in whom ANZASM Assessor's determined a flawed decision to proceed with the PD

Decision to proceed, *n* = 5/84, 6%					
Patient number	**Age**	**Admission**	**Presumed malignancy**	**Additional significant event**	**ANZASM assessor's comment**
15	74	Elective	Yes	No	Intraoperative finding of metastatic and locally advanced disease
16	68	Elective	Yes	Delay in recognising complication	Combined with hepatic resection. Intraoperative finding of mesenteric vein involvement more than expected
17	65	Elective	Yes	No	Intraoperative finding of locally advanced disease
18	61	Elective	Yes	Vascular injury	Injury to hepatic artery, very long operative time
19	69	Elective	Yes	Vascular injury	Intraoperative injury to coeliac trunk when releasing media arcuate ligament

Table 4 Patients who suffered a postoperative haemorrhage

Post-operative haemorrhage, *n* = 17/84, 20%				
Patient number	**Age**	**Additional significant event/s**	**Nature of bleed**	**ANZASM assessor's comment**
4	57	Decision to operate	Elective PD for malignancy in setting of pancreatitis and death from post-operative haemorrhage less than 24 h later	The decision to attempt a pancreatic resection on this patient was a mistake due to peri-operative pancreatitis.
6	75	Decision to operate	POPF and secondary haemorrhage requiring re-operation. Patient was accidentally fully anticoagulated	Aggressive operation with portal vein reconstruction in elderly patient with advanced disease. Unsatisfactory medical management.
14	52	Post-operative bleed	Catastrophic secondary haemorrhage on POD9 post discharge from hospital	Pancreatitis at time of PD, no suspicion of malignancy
20	72	Anastomotic leak	POPF and secondary haemorrhage POD8 with GDA stump bleed seen at laparotomy. Post second operation, small bowel and hepatic ischemia	POPF and secondary haemorrhage
21	79	Delay in recognising complication anastomotic leak	POPF and bleed from GDA pseudoaneurysm POD6. Failed embolisation. Proceed to laparotomy where portal vein was injured.	Late recognition of POPF and secondary haemorrhage. Questioned management of bleeding post-embolisation
22	76	Anastomotic leak	Transferred from another hospital after failed re-operation to control post-operative haemorrhage. Underwent embolisation and further re-operation to revise anastomoses	Referral hospital unsuccessful in management of pancreatic fistula
23	64	Anastomotic leak	Laparotomy for bleeding on POD1. Portal vein branches actively bleeding and oversewn. POD6 and POD7 laparotomy for bleeding. GDA stump bleed found and oversewn. Further bleeding. No interventional radiology available at hospital	Post-operative bleeding
24	73	Anastomotic leak	Contrast imaging showed bleeding from GDA in setting of POPF. Laparotomy confirmed bleeding from GDA and SMA with ischemic bowel.	POPF and secondary haemorrhage
25	59	Other complication	Returned to theatre POD6 for debridement of abscess in anterior abdominal wall. Intra-abdominal haemorrhage and laparotomy on the following day revealed GDA stump bleed	Bleed from gastro-duodenal artery
26	62	Delay in recognising complication anastomotic leak	POPF and secondary haemorrhage. Investigated and unsuccessfully treated with gastroscopy and laparotomy. Source not seen radiologically. Eventual catastrophic haemorrhage	Delayed recognition of POPF. Surgeon operating without sub-specialist training
27	55	No	Catastrophic haemorrhage post-operative day (POD) 8. At emergency laparotomy, right gastric artery ligated	Questioned method used to secure right gastric artery at PD; technical cause of delayed haemorrhage (method not noted in comment)
28	77	Vascular injury	Right hepatic artery accidentally divided and repaired during PD. Emergency laparotomy POD10 revealed bleeding behind the hepatico-jejunostomy and an ischemic right colon. Subsequent hepatic ischemia.	Poor management of the deteriorating patient and documentation of events.
29	67	Anastomotic leak	Known POPF and secondary haemorrhage POD6. At emergency laparotomy, bleeding from branch of SMA	POPF and secondary haemorrhage
30	69	Delay in recognising complication anastomotic leak	Delayed gastric emptying and CT evidence of POPF for a week prior to massive haematemesis.	Delay in investigating the patient with delayed gastric emptying and evidence of POPF
31	70	Delay in recognising complication	Laparoscopic PD complicated by port site hernia and POPF. Laparotomy POD9 found bleeding from GDA stump. Portal vein narrowed on subsequent scans.	Post-operative care in managing POPF was unsatisfactory

Table 4 (*continued*)

Post-operative haemorrhage, *n* = 17/84, 20%				
Patient number	**Age**	**Additional significant event/s**	**Nature of bleed**	**ANZASM assessor's comment**
32	69	Anastomotic leak	POPF and secondary haemorrhage from pseudoaneurysm of the common hepatic artery. This was embolised with subsequent hepatic ischemia.	Haemorrhage secondary to POPF
33	77	Delay in recognising complication anastomotic leak	POPF and secondary haemorrhage POD18. Required transfusion on the three days prior with normal CT angiogram. Subsequent formal angiogram showed bleeding pseudoaneurysm that was embolised.	Suggested earlier consideration of interventional angiography (agreed with surgeon's self-assessment)

POD, postoperative day; GDA, gastroduodenal artery; POPF, post-operative pancreatic fistula.

determine whether preoperative MDT discussions took place. However, logic would suggest that a group discussion could have prevented at least a proportion of the deaths considered as subsequent to a poor decision to operate. In addition, predictive algorithms such as the ACS-NSQIP 'Pancreatectomy Risk Calculator'[17] may assist in quantifying risk when making the decision to operate.

The most common cause of death after vascular injury was ischemia of either the bowel or liver resulting in multi-organ failure. Ischemic complications are important considerations after PD and can be due to pre-existing arterial stenoses or inadvertent arterial injury.[18] While meticulous dissection can minimise complications, peripancreatic inflammation or invasion may obliterate dissection planes and distort anatomy.[19] It is crucial that aberrant arterial anatomy is identified prior to surgery to ensure unusual anatomy under difficult circumstances is anticipated. Porto-mesenteric venous resection with the aim of achieving an R0 resection has not been shown to worsen perioperative outcome[20] and did not present as an issue with this cohort of patients.

Late recognition and therefore delayed action to treat complications in almost a quarter of deaths is a significant finding that warrants consideration for clinicians involved in the postoperative care of PD patients. The concept of failure to rescue (FTR) is defined as the death of a patient due to a major postoperative complication.[21] Nationwide studies from the United States, Germany and the Dutch Pancreatic Cancer Audit (DPCA) into PD outcomes have suggested that varying mortality rates can be explained by variations in FTR rather than major complication rates.[5,6,22] FTR rates in the DPCA were calculated as the number of deaths after major complication divided by the number of major complications and found to be 14%.[5] While an FTR rate cannot be calculated from the ANZASM figures, the earlier recognition of complications would go further to reducing FTR and subsequent inpatient mortality in Australia.

Participation in the ANZASM peer review and feedback process has increased nationwide across the duration of this study and over this time a decrease in the overall surgical postoperative mortality rate (POMR) has been well documented.[7] Relevant to PD was the centralisation of the procedure in Western Australia

Table 5 Patients who suffered an intraoperative vascular injury

Vascular injury, *n* = 8/84, 10%					
Patient number	**Age**	**Admission**	**Presumed malignancy**	**Additional significant event**	**Nature of injury**
7	63	Elective	Yes	Decision to operate	Portal vein injury with massive intra-operative haemorrhage
18	61	Elective	Yes	Decision to proceed	Hepatic artery injury in setting of aberrant anatomy
19	69	Elective	Yes	Decision to proceed	Intraoperative injury to coeliac trunk when releasing media arcuate ligament
28	77	Elective	Yes	Post-operative haemorrhage	Right hepatic artery accidentally divided. Aberrant anatomy.
34	65	Elective	Yes	No	Division of superior mesenteric artery
35	75	Elective	Yes	No	Portal vein injury with massive intra-operative haemorrhage
36	67	Elective	Yes	No	Division of superior mesenteric artery
37	63	Elective	Yes	No	Portal vein injury with massive intra-operative haemorrhage

Table 6 Patients who had a complication where there was a delay in its recognition, and subsequent rescue was unsuccessful as a result

Delay in recognising complication, n = 18/87, 21%					
Patient number	**Age**	**Admission**	**Presumed malignancy**	**Additional significant event**	**ANZASM assessor's comment**
5	52	Elective	Yes	Decision to operate	Multiple comorbidities
11	70	Elective	Yes	Decision to operate	Transfer to a larger hospital should have occurred before complication became too difficult to manage
16	68	Elective	Yes	Decision to proceed	Combined with hepatic resection. Intraoperative finding of mesenteric vein involvement more than expected
21	79	Elective	Yes	Post-operative haemorrhage	Late recognition of POPF and secondary haemorrhage. Questioned management of bleeding post-embolisation
26	62	Emergency	Yes	Post-operative haemorrhage	Delayed recognition of POPF. Surgeon operating without sub-specialist training
30	69	Elective	Yes	Post-operative haemorrhage	Delay in investigating the patient with delayed gastric emptying and evidence of POPF
31	70	Elective	Yes	Post-operative haemorrhage	Post-operative care in managing POPF was unsatisfactory
33	77	Elective	Yes	Post-operative haemorrhage	POPF and secondary haemorrhage. Suggested earlier consideration of interventional angiography
39	74	Elective	Yes	Other complication	SMV thrombosis and ischemic small bowel
42	73	Emergency	Yes	No	Delay in recognising POPF. Clinical changes on POD4/5 could have been considered more seriously
43	77	Elective	Yes	No	Delayed gastric emptying without nasogastric decompression that resulted in aspiration. Unsatisfactory analgesia
44	70	Emergency	Yes	No	Failure to aggressively investigate haematemasis and hypotension when patient re-presented to hospital on POD17
45	65	Elective	Yes	No	Delay in relook laparotomy with findings of POPF and colonic ischemia
46	83	Elective	Yes	No	Delayed gastric emptying without nasogastric decompression that resulted in aspiration
47	79	Emergency	Yes	No	Admission to ICU with intra-abdominal sepsis and multi-organ failure without mention of any action taken to treat
48	73	Elective	Yes	POPF	Leak from hepatico-jejunostomy that was recognised late
49	66	Elective	Yes	No	Nasogastric tube not in place despite vomiting
50	81	Elective	Yes	POPF	Leak from hepatico-jejunostomy and POPF

POPF, post-operative pancreatic fistula; POD, postoperative day.

after a review using ANZASM data.[23] A more recent review of nationwide data shown a reduction in PD POMR since participation in ANZASM has increased.[1] While there will likely always be a significant risk of mortality as a result of a complex procedure such as PD, the ANZASM formalises the reflection that surgeons and their teams undertake after each death and provides objective feedback. It can be seen from the data presented here, that the reasons for mortality post-PD have not changed significantly. While an individual death is likely to be well considered within the relevant surgical unit, review of a large number of PD mortalities has not been available. This paper is unique in its examination of the clinical events leading to mortality for PD and is the first to examine the ANZASM assessors' findings of the significant clinical events prior to mortality for a specific procedure.

The limitations of this study include consideration of a high majority (97% of hospital reported deaths), but not every death post-PD in Australia. Aside from the patients that went to second line assessment (with full patient note review), the details surrounding each patient's death are those provided by the treating surgeon themselves. The assessors make an individual and subjective assessment of the events leading to each patient's death and consistency across assessments cannot be assured. The ANZASM does not include procedural volume and therefore little can be said about the POMR from this data. While this could be crudely extrapolated by combining ANZASM data with national Medicare data, POMR has been more comprehensively analysed elsewhere.[1] ANZASM assessors did not describe a significant adverse event in a some patient deaths where there were issues with post-operative care. To maintain consistency, these patients were not included in the reported results. However, these patient reports were re-examined by the authors and the details included as supplementary data.

The factors under a surgeon's control that can impact the success, or otherwise, of an operative intervention include the decision to operate in the first place, the quality of the operation performed and the postoperative care. For PD, a highly complex procedure with significant morbidity, these factors become magnified. This study has sought to summarise the significant clinical events leading to mortality after PD in Australia. The large proportion of patients where the decision to operate or proceed was questioned by assessors was a concerning feature. In addition, the finding of nearly a quarter of deaths being assessed to be associated with late recognition of complications warrants consideration for Australian surgeons involved in PD.

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Conflicts of interest

None declared.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.hpb.2019.03.356.

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Publication 3

Peer review of mortality after hepatectomy in Australia

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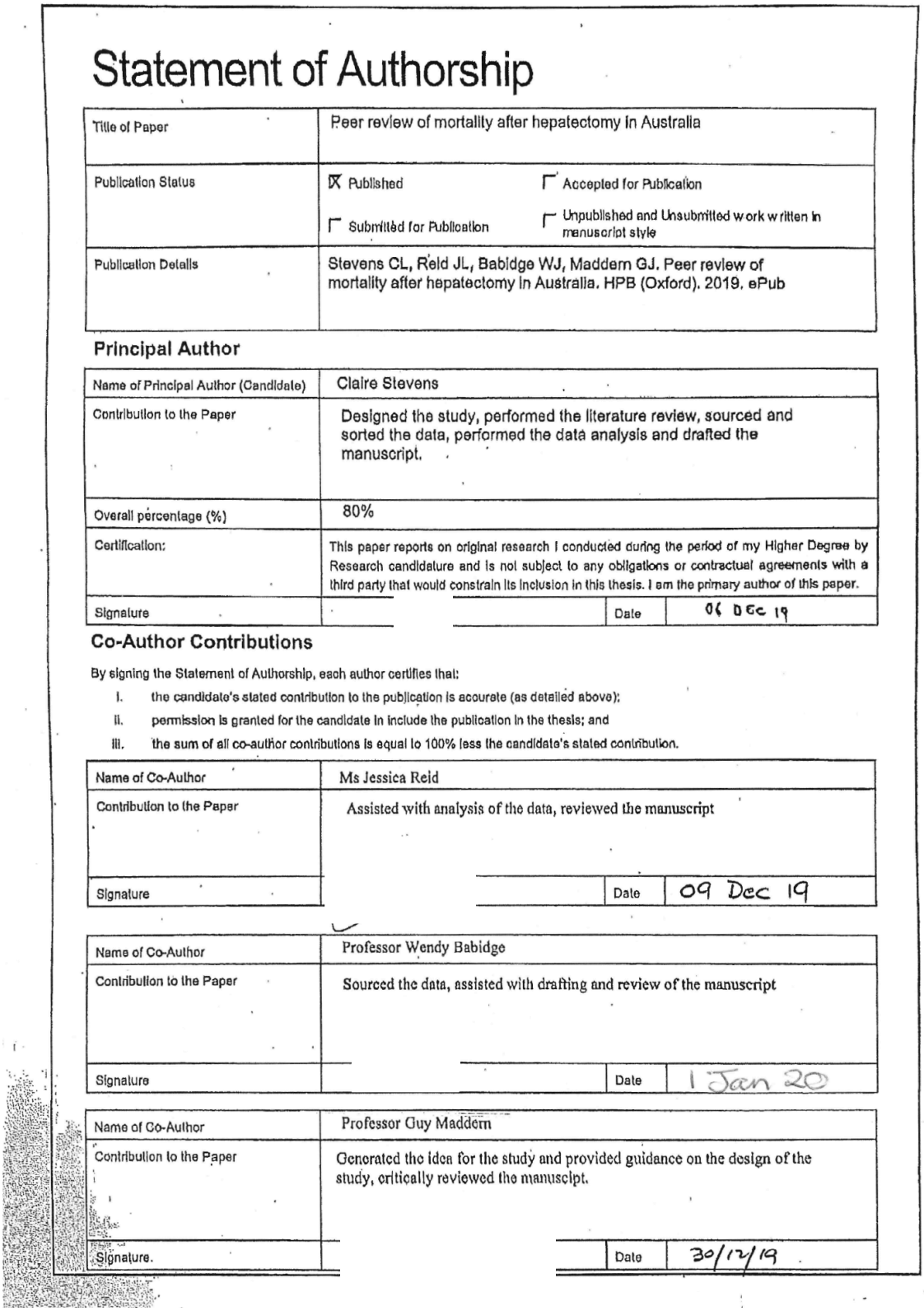

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Principal Author

Name of Principal Author (Candidate)	Claire Stevens		
Contribution to the Paper	Designed the study, performed the literature review, sourced and sorted the data, performed the data analysis and drafted the manuscript.		
Overall percentage (%)	80%		
Certification:	This paper reports on original research I conducted during the period of my Higher Degree by Research candidature and is not subject to any obligations or contractual agreements with a third party that would constrain its inclusion in this thesis. I am the primary author of this paper.		
Signature		Date	06 Dec 19

Co-Author Contributions

By signing the Statement of Authorship, each author certifies that:

i. the candidate's stated contribution to the publication is accurate (as detailed above);
ii. permission is granted for the candidate to include the publication in the thesis; and
iii. the sum of all co-author contributions is equal to 100% less the candidate's stated contribution.

Name of Co-Author	Ms Jessica Reid		
Contribution to the Paper	Assisted with analysis of the data, reviewed the manuscript		
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Name of Co-Author	Professor Guy Maddern		
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ORIGINAL ARTICLE

Peer review of mortality after hepatectomy in Australia

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Abstract

Background: The data within the Australian and New Zealand Audit of Surgical Mortality (ANZASM) provides a unique opportunity to consider the contributing factors to perioperative deaths as determined by peer review. Consideration of the factors contributing to mortality after hepatectomy can provide greater insight into how deaths can be prevented. The objective of this study was to determine the reasons for patient deaths post-hepatectomy in Australia.

Methods: ANZASM data from 1 January 2010 to 30 Jun 2017 was reviewed and all deaths following hepatectomy were selected for analysis. Assessors determinations of whether management could have been improved were reviewed, and then classified into groups of significant clinical events using thematic analysis with a data driven approach.

Results: The study included 88 deaths reported to ANZASM after hepatectomy. The assessors questioned the decision to operate in 23/88 (25%) patients with a further nine (10%) patients insufficiently investigated prior to resection. ANZASM assessors determined that there was a delay in recognising a significant complication in 16/88 (18%) patients.

Conclusion: Multi-disciplinary decision making is strongly recommended when deciding which patients to treat with hepatic resection. Optimal care post-hepatectomy includes early recognition of complications and enactment of an adequate rescue plan.

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Introduction

The Australian and New Zealand Audit of Surgical Mortality (ANZASM) is a peer review audit of surgical deaths under the direction of the Royal Australasian College of Surgeons (RACS). The objective of the audit is to improve the quality of surgical practice through information gathering and feedback, education and facilitation of change. The audit has been conducted Australia-wide since 2010 and has collected considerable data on surgeon identified avoidable issues contributing to in-hospital surgical deaths. While ANZASM was formed to serve both nations, New Zealand does not currently participate in the ANZASM program. In New Zealand, a Perioperative Mortality Review Committee is responsible for reviewing and reporting mortalities, with a view to reducing deaths and enabling continuous quality improvement.

In Australian hospitals, hepatic resection (hepatectomy) has a perioperative mortality rate of 1.6%.[1] Despite being conducted in relatively low volume centres, morbidity and mortality rates for patients undergoing hepatectomy performed in Australia are comparable to those seen internationally.[1] International studies have shown improved perioperative outcomes over time due to better patient selection, improved anaesthetic and perioperative management of patients, and higher proportions of parenchymal sparing segmental resections.[2,3] The hospital and surgeon volume effect on outcomes has been extensively investigated with recommendations such as threshold volumes,[4,5] the presence of organised multidisciplinary teams and optimisation of hospital resources for complex surgical procedures.[6,7] The ability to "rescue" a patient after a major complication directly affects mortality rates, which has been linked to both hospital resources[8] and patient selection prior to surgery.[9] Consideration of all these factors are likely to lead to improved outcomes post-

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hepatectomy. However, debate continues as to which aspects of patient care are most likely to have the most impact on perioperative mortality.

The ANZASM provides a unique opportunity to investigate the events leading to mortality post-hepatectomy in Australian hospitals over recent years. This audit enables examination of the preoperative, intraoperative and postoperative events leading to each investigated death. The objective of this study was to determine the reasons for patient deaths post-hepatectomy in Australia.

Methods

ANZASM data and peer review process

The function, governance and objectives of the ANZASM have been thoroughly described elsewhere.[10] However, a synopsis of the audit process is described here.

Independent of the treating surgeon, ANZASM is notified of in-hospital surgical deaths (whether there was a surgical procedure or not) by medical records departments. The hospital data includes designation of the admission as emergency or elective, which is determined by whether the admission was due to a planned procedure on a waiting list. Clinical details are collected via a standardised form completed by the treating surgeon either online or in paper format. (The ANZASM surgical case form is available at https://www.surgeons.org/research-audit/surgical-mortality-audits/requests-for-anzasm-data). ANZASM data is stored in an encrypted database that enables a complete audit trail. The de-identified patient details are sent for first-line assessment to a surgeon of the same speciality from a different hospital. In most cases, conclusions may be reached about the patient's care at this point and further investigation is deemed unnecessary. However, if further consideration of the patient's care is required, a second-line assessment is conducted by a different surgeon. The second-line assessor reviews the involved hospital's patient notes. Second-line assessment was undertaken in approximately 12% of all patients referred to ANZASM during the study period.[11]

As a part of the audit process, ANZASM assessors determine whether there was an aspect of the patient's management that could have been better, and feedback is provided to the treating surgeon. The ANZASM data is held under qualified privilege which protects the confidentiality of identifying information for both practitioner and patient.[12] This protection enables surgeons to freely divulge information with confidence that the information gathered will be used exclusively for the purposes of quality assurance and professional development. Since 2012, 100% of public hospitals, up to 92% of private hospitals and over 98% of surgeons participate.[11,13]

Data analysis

Prospectively collected ANZASM data from 1 January 2010 to 30 Jun 2017 was retrospectively reviewed and deaths following hepatectomy were selected for analysis. Deaths included are inpatient deaths including those re-admitted after initial discharge after hepatectomy. The authors excluded patients with procedures of additional complexity outside of normal practice or in an emergency setting for trauma or haemorrhage. Demographics, clinical and treatment details including the documentation of post-hepatectomy liver failure (PHLF) were gathered from the information submitted by Australian hospitals and treating surgeons. For each patient, the assessor's determination of whether management could have been improved in the areas of decision to operate, intraoperative and technical management of surgery and postoperative care were analysed.

As a part of the audit process, assessors determine significant clinical events relevant to the patient's care. The process is similar for first and second-line assessment. Where a second-line or patient note assessment was performed, this was used in the analysis and the first line assessment disregarded. For all other patients, the first line assessment findings were included. Assessors annotate whether each of the clinical events were firstly, a contributing factor in the death of the patient and secondly, preventable or not. The determination of preventability, while relevant to each individual patient, was not considered further here. Preventable and non-preventable clinical events leading to mortality were all included in this study as they are useful in the determination of causes for mortality as an outcome of hepatectomy.

Assessor's clinical issue descriptions were reviewed and classified into groups of significant clinical events using thematic analysis with a data driven approach.[14] Methods described by Braun and Clarke were used to develop themes.[15] Two researchers (CS and JR) then independently classified the assessor's clinical issue descriptions into the relevant themes. Differences were discussed, and consensus achieved.

Results

From January 2010 to June 2017 there were 98 deaths reported to the ANZASM after elective hepatectomy. Medicare Australia data (which includes all patients, private and public) recorded 8587 HRs during this period.[16] This cohort of patients from ANZASM represent 1.1% of all hepatic resections. Ten (1.0%) patients were excluded from the study due to procedures of emergent nature or complexity of outside of normal practice. Three patients who had combined pancreaticoduodenectomy and a further three patients who had caval resection and/or veno-venous bypass were included in this number.

Patient characteristics retrieved from the ANZASM patient reports are summarised for 88 patients in Table 1. The median age of the patients was 71 years (45–89 years). Clinically significant infection was reported in 34/88 (39%) patients. Return to theatre was reported in 35/88 (40%) patients. Postoperative hepatic liver failure was documented as a complicating factor in 56/88 (64%) of patients.

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Table 1 Summary of patients

	Number of patients (%)
American Society of Anaesthesiologists (ASA) Score	
ASA 1	3 (3)
ASA 2	35 (40)
ASA 3	43 (49)
ASA 4	5 (6)
Not recorded	2 (2)
Hospital type	
Public	76 (86)
Private	12 (14)
Expected pathology	
Colorectal metastases	28 (32)
Hepatocellular carcinoma	25 (28)
Cholangiocarcinoma	25 (28)
Gall bladder cancer	2 (2)
Bile duct stricture of uncertain aetiology	2 (2)
Polycystic liver disease	1 (1)
Other metastatic disease	5 (6)

Other metastatic disease: Melanoma, gastric adenocarcinoma, renal cell carcinoma, neuroendocrine tumour, squamous cell carcinoma.

ANZASM first-line peer review assessment was conducted in all 88 of the reported deaths. Second-line assessment with full review of the patient's hospital documentation was conducted for 25% (22/88) of these patients. Sixty-nine clinically significant adverse events were described by the assessors in 58 patients, with 11 patients having two adverse events described. Tables documenting patient outcomes by the themes identified by the assessors are shown in Tables 2–6 and Supplementary Table 1. Each patient is labelled with an individual number (patients 1–58) for purposes of tracking across the themes. In the remaining 30 patients, there were no assessors' comments on clinically significant adverse events leading to the patient's mortality. For these 30 patients, the data submitted by the treating surgeon was reviewed by the authors and a summary of that record of events is included as Supplementary Table 2 (patients 59–88). The treating surgeon noted that there had been an adverse event in three of these patients.

Discussion

This study sought to quantify and thematically describe the significant clinical issues around peer-reviewed audited deaths post-hepatectomy in Australia. The ANZASM assessment process was completed in all of the patients who died in hospital after hepatectomy across the study period. This cohort of patients represents a crude mortality rate of 1.1%, which is consistent with the 1.6% reported in a recent Australian study examining inpatient deaths after hepatectomy.[1]

The frequency of second-line assessment seen in the patients who died after hepatectomy is double the average second-line assessment rate in ANZASM. This is similar to the findings of a study examining ANZASM assessment of mortality after pancreaticoduodenectomy.[17] The use of second line assessment likely reflects the complex nature of care post hepatobiliary surgery and its associated complications. When looking at the documentation of each patient death, it is evident that the process encourages thorough review of events by the treating surgeon and ANZASM assessors. This reflection of practice and the feedback provided by the assessors is likely to be beneficial to the treating team and is also seen as an educational opportunity for assessors. Assessors collect continuing professional development points in recognition of their voluntary participation.

Preoperative decision making for hepatectomy is complex and requires consideration of multiple factors including overall patient health, tumour burden, functional volume (including chemotherapy effects and/or the presence of cirrhosis), and inflow and outflow preservation. Assessors were of the opinion that the decision to operate was flawed in 25% of patient deaths after hepatectomy. While the benefit of hindsight may be a confounding factor in this assessment, the high proportion of patient deaths that this represents is concerning. When the decision to operate was questioned by the assessors, explanatory comments commonly referred to the patient's age and comorbidities. Increased mortality risk for older patients has been well documented. However, hepatectomy is considered a reasonable operation in the well selected octogenarian[18,19] and a recent Australian study has reported excellent results in age group.[20] A study using date from the American College of Surgeons National Surgical Quality Improvement Database,[9] has reported a significantly higher mortality risk for borderline operative patients irrespective of the tumour resected. By their definition, a combination of factors rendered an individual patient a borderline operative candidate for hepatectomy including age >75 years, pulmonary disease, cardiovascular disease, weight loss, steroid use and or perioperative sepsis. These comorbid patients were found to be more susceptible to postoperative adverse events that were subsequently unable to be rescued. Thorough preoperative patient assessment, medical optimisation of borderline operative patients and the choice of appropriate magnitude operations can improve surgical outcomes.[9]

Assessors' explanatory comments for questioning the decision to operate included instances where technical aspects of the type of surgery were thought to need more careful consideration. Alternatives to liver resection such as liver transplantation, ablative techniques and other locoregional therapies may be a more appropriate choice for some patients. International consensus statements warn against combined major colon and major liver resection[21] and any combined surgery requires careful consideration of risks to the patient. There is evidence in the literature for routine preoperative multidisciplinary team (MDT) discussion to consider these issues and optimise each patient's treatment

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Table 2 Patients in whom ANZASM assessor's determined a flawed decision to operate

Decision to operate n = 23/88, 26%						
Patient Number	**Age**	**Pathology**	**Type of Resection**	**Liver failure**	**Additional Significant Event**	**ANZASM Assessor's Comment**
1	81	Colorectal metastasis	Right hemi-hepatectomy and sub-segmental resection	yes	Delay in recognising complication	Post chemotherapy liver, age and multiple comorbidities with a major resection
2	70	Colorectal metastasis	Right hemi-hepatectomy	no	Decision to proceed	Critical number of comorbidities including Parkinson's disease, stroke and prior ICU admission requiring tracheostomy and slow wean. MDM not mentioned. Tumour adhered to IVC and diaphragm - inoperable (injury to both). Never recovered from ICU stay.
3	54	Colorectal metastasis	Multiple sub-segmental resections and colostomy reversal	yes	Inadequate preoperative assessment	Decision to perform multiple resections with the reversal of a colostomy
4	76	Colorectal metastasis	Right hemi-hepatectomy and ultra-low anterior resection of colon	yes	Inadequate preoperative assessment	Combining major colonic with major liver resection not recommended especially in elderly patient
5	66	Colorectal metastasis	sub-segmental resection	no	Decision to proceed	Insufficient discussion at MDM after chemotherapy interrupted (plan was to consider surgery if good result from chemotherapy). Second liver surgery for colorectal metastases and in the setting of known cirrhosis.
6	80	Colorectal metastasis	Right hemi-hepatectomy and sub-segmental resection	yes	no	Major resection post-chemotherapy given age and comorbidities including ischemic heart disease, respiratory disease
7	58	Colorectal metastasis	Right hemi-hepatectomy and partial peritonectomy	no	no	Should not have resected liver metastases in the setting of known peritoneal disease (died of viral pneumonia)
8	75	Colorectal metastasis	Extended right hepatectomy	yes	no	Major resection in chemotherapy affected liver
9	80	Colorectal metastasis	Right hemi-hepatectomy	yes	no	Large resection of post -chemotherapy liver in 80 year old
10	76	Hepatocellular carcinoma	Extended right hepatectomy	yes	Other adverse event	decision to operate - large HCC in cirrhotic 76
11	59	Hepatocellular carcinoma	Right hemi-hepatectomy	no	Delay in recognising complication	decision to operate - large HCC involving diaphragm
12	77	Hepatocellular carcinoma	Parenchymal transection and portal vein ligation (intended staged procedure)	yes	no	Large tumour, small remnant, previous liver surgery and comorbidities
13	78	Hepatocellular carcinoma	Right hemi-hepatectomy	yes	no	2 cm HCC in elderly patient. Ablative options or doing nothing should have been considered instead
14	63	Hepatocellular carcinoma	sub-segmental resection	yes	no	Preoperative ASA score of 4. Predictable cardiac event and subsequent MODS

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Table 2 (*continued*)

Decision to operate n = 23/88, 26%						
Patient Number	**Age**	**Pathology**	**Type of Resection**	**Liver failure**	**Additional Significant Event**	**ANZASM Assessor's Comment**
15	73	Hepatocellular carcinoma	sub-segmental resection	yes	no	2 cm hepatocellular carcinoma in patient who had had previous resection
16	77	Hepatocellular carcinoma	Extended right hepatectomy	yes	no	Patient had portal vein thrombus and therefore incurable disease
17	80	Hepatocellular carcinoma	Sub-segmental resection	no	no	Extensive comorbidities including age
18	74	Cholangio-carcinoma	Extended right hepatectomy with bile duct excision	yes	no	Patient had biloma from PTC, fatty liver and small remnant liver
19	73	Cholangio-carcinoma	Extended right hepatectomy including caudate with bile duct excision	yes	no	Highly morbid operation for an older and comorbid patient
20	75	Cholangio-carcinoma	Left hemi-hepatectomy with bile duct excision	yes	no	Known preoperative stenosis of coeliac axis and vascular injury by radiologist when stenting duct. Resection complicated by ischemic hepatitis was probably predicable.
21	75	Cholangio-carcinoma	Extended right hepatectomy and caudate with bile duct excision	yes	no	Inadequate recognition of perioperative risk and functional remnant liver post resection
22	61	Polycystic liver disease	Right hemi-hepatectomy	yes	no	Liver transplant would have been better than resection for this patient
23	75	Melanoma	Right hemi-hepatectomy	yes	no	Major resection in older patient

ICU: Intensive care unit; MDM: Multidisciplinary meeting; IVC: Inferior vena cava; HCC: hepatocellular carcinoma; PTC: percutaneous transhepatic cholangiogram.

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Table 3 Patients in whom ANZASM Assessor's determined that there was inadequate preoperative assessment

Inadequate preoperative assessment n = 9/88, 10%						
Number	**Age**	**Pathology**	**Type of Resection**	**Liver failure**	**Additional Significant Event**	**ANZASM Assessor's Comment**
3	54	Colorectal metastasis	Multiple sub-segmental resections and colostomy reversal	yes	Decision to operate	Inadequate preoperative imaging given bi-lobar involvement
4	76	Colorectal metastasis	Right hemi-hepatectomy and ultra-low anterior resection of colon	yes	Decision to operate	Inadequate preoperative imaging: no MRI and multiple additional metastases found on intraoperative ultrasound
24	81	Gall bladder adenocarcinoma	Segmental with bile duct excision	no	Delay in recognising complication	Insufficient imaging prior to planned resection - tumour not likely to be resectable
25	64	Cholangio-carcinoma	Extended right hepatectomy with bile duct excision and portal vein resection	no	no	Inadequate assessment of imaging findings prior to surgery
26	66	Cholangio-carcinoma	Left hemi-hepatectomy including caudate with bile duct excision and portal vein resection	yes	no	Inadequate preoperative assessment of respiratory disease
27	65	Hepatocellular carcinoma	sub-segmental resection	no	no	Degree of portal hypertension grossly underestimated
28	78	Cholangio-carcinoma	Right hemi-hepatectomy and bile duct excision and portal vein resection	no	no	Use of unnecessary pre-operative PTC (no evidence of preoperative biliary obstruction) with biliary drain that remained post operatively leading to sepsis
29	63	Squamous cell carcinoma	Right posterior sectionectomy and segmental resection	yes	no	Preoperative remnant liver volume assessment inadequate
30	45	Hepatocellular carcinoma	Right hemi-hepatectomy	yes	no	Degree of cirrhosis and portal hypertension underestimated

PTC: percutaneous transhepatic cholangiogram.

Table 4 Patients in whom ANZASM Assessor's determined a flawed decision to proceed with the hepatectomy

Decision to proceed n = 5/88, 6%						
Number	**age**	**Pathology**	**Type of Resection**	**Liver failure**	**Additional Significant Event**	**ANZASM Assessor's Comment**
31	51	Cholangio-carcinoma	Extended left hepatectomy and caudate	yes	Other complication	Involvement of second order portal venous branches
32	66	Cholangio-carcinoma	Extended right hemi-hepatectomy with bile duct excision	no	Other complication	Incurable disease seen at laparotomy
33	64	Cholangio-carcinoma	Extended right hepatectomy with bile duct excision	yes		Abnormal liver (steatotic) and extensive resection planned
34	54	Cholangio-carcinoma	Extended left hepatectomy with bile duct excision	no		Incurable disease seen at laparotomy
35	68	Hepatocellular carcinoma	Subsegmental	yes		Unexpected severity of cirrhosis should have reconsidered resection

Table 5 Patients in whom ANZASM Assessor's determined that a technical complication affected the outcome

Technical complication n = 5/88, 6%						
Patient Number	**Age**	**Pathology**	**Type of Resection**	**Liver failure**	**Additional Significant Event**	**ANZASM Assessor's Comment**
36	73	Colorectal metastasis	Extended right hepatectomy with bile duct excision	no	no	Left hepatic vein injury - ongoing bleeding post-op requiring return to theatre.
37	72	Colorectal metastasis	Extended left hepatectomy	no	no	Right posterior duct injured when dividing left pedicle. Required re-operation complicated by bleeding
38	75	Hepatocellular carcinoma	Extended left hepatectomy	yes	no	Stapler failure at hepatic veins. Massive transfusion. Recovery complicated by liver failure
39	62	Hepatocellular carcinoma	Right hemi-hepatectomy	yes	no	Massive intraoperative haemorrhage from collateral portal circulation.
40	68	Cholangio-carcinoma	Left hemi-hepatectomy with bile duct excision	yes	no	Prolonged operation due to intraoperative bleeding, including from hepatic vein; Perioperative cardiac event likely related to intraoperative hypotension

Table 6 Patients in whom ANZASM Assessor's determined that a delay in recognising a significant complication affected the outcome

Delay in recognising complication n = 16/88, 18%						
Patient Number	**Age**	**Pathology**	**Type of Resection**	**Liver failure**	**Additional Significant Event**	**ANZASM Assessor's Comment**
1	81	Colorectal metastasis	Right hemi-hepatectomy and sub-segmental resection	yes	Decision to operate	Postoperative collection and sepsis - delay to drainage.
11	59	Hepatocellular carcinoma	Right hemi-hepatectomy	no	Decision to operate	Postoperative collection and sepsis - delay to drainage.
24	81	Gall bladder adenocarcinoma	Segmental with bile duct excision	no	Inadequate preoperative assessment	Postoperative bleed should have been recognised and patient taken to theatre sooner
41	67	Cholangio-carcinoma	Right hemi-hepatectomy with bile duct excision	no	Other adverse event	Inadequate imaging at time of collection. Undiagnosed pseudoaneurysm subsequently ruptured resulting in death
47	59	Colorectal metastasis	Extended right hepatectomy	yes	no	Required earlier ERCP to address biliary obstruction (left hepatic duct stricture) and subsequent sepsis
48	55	Colorectal metastasis	Right hemi-hepatectomy	no	no	Sub-phrenic abscess unsuccessful radiological drainage, late decision to re-operate, never overcame sepsis
49	66	Renal cell carcinoma	Right hemi-hepatectomy and sub-segmental resections	no	no	Bile leak. Earlier ERCP likely to have improved outcome
50	57	Hepatocellular carcinoma	Segmental resection	yes	no	Postoperative collection and sepsis - delay to drainage. Lead to decompensated liver failure
51	63	Cholangio-carcinoma	Extended right hepatectomy	no	no	Late recognition of small bowel perforation and bile leak in immunocompromised patient
52	61	Colorectal metastasis	sub-segmental resection	no	no	Postoperative collection and sepsis - delay to drainage of collection and empyema.
53	64	Colorectal metastasis	Right hemi-hepatectomy	no	no	Ongoing feeding and no nasogastric decompression in setting of gastroparesis lead to aspiration
54	70	Cholangio-carcinoma	Right hemi-hepatectomy with bile duct excision	no	no	Postoperative bleed. Delayed return to theatre.

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Table 6 (continued)

Delay in recognising complication n = 16/88, 18%						
Patient Number	Age	Pathology	Type of Resection	Liver failure	Additional Significant Event	ANZASM Assessor's Comment
55	79	Colorectal metastasis	Segmental	no	no	No nasogastric decompression in setting of ileus lead to aspiration
56	77	Hepatocellular carcinoma	Laparoscopic Right hemi-hepatectomy	no	no	Postoperative gastrointestinal bleed without endoscopic investigation until shocked
57	74	Colorectal metastasis	Sub-segmental resections	no	no	No nasogastric decompression in setting of ileus lead to aspiration
58	74	Hepatocellular carcinoma	Left hemi-hepatectomy and caudate with bile duct excision and portal vein resection	no	no	Postoperative bleed should have been recognised and acted on earlier

ERCP: endoscopic retrograde cholangiopantography.

plan.[5,7,22] ANZASM data is not sufficient to determine whether preoperative MDT discussions took place. However, specialist group discussion could likely have prevented at least a proportion of the deaths considered as subsequent to a poor decision to operate. The patients that had insufficient pre-operative assessment would likely all have benefited from such a discussion.

Post-hepatectomy liver failure (PHLF) is the most serious complication of hepatectomy, which has been shown to contribute significantly to mortality. Of the patients in this study, 64% were documented as suffering this complication. This is consistent with the 40–60% rate of PHLF reported elsewhere in patients who died in the 90 days post-hepatectomy.[23,24] However, there was no consistent definition used by assessors or surgeons in making this determination in patients' audit documents. Risk factors for PHLF are similar to those reported for overall mortality,[25] and include age >70 years, preoperative chemotherapy, steatosis, major resection, vascular reconstruction and intra-operative blood loss.[23,26,27] The application of a surgeon's understanding of these risk factors is vital to appropriate selection and optimisation of patients for surgery and in the decision to proceed when faced with unexpected intraoperative events.

The management of complications is an important determinant of mortality[4,28] and the surgical procedure itself is only a part of the care model for patients undergoing hepatectomy. ANZASM assessors concluded that late recognition, and therefore delayed action to treat complications, occurred in almost a fifth of patient deaths. The concept of failure to rescue (FTR) is defined as the death of a patient due to a major postoperative complication.[29] FTR has been linked to a relative lack of specialised hospital resources,[6] the analysis of which is beyond the scope of this paper. The significant number of patients seen here to have been subject to FTR warrants further investigation, particularly in Australia where resources available in hospitals performing hepatectomy vary, and hospital and surgeon volumes are relatively low. The second influencing factor on the ability to rescue after major complication is the comorbid state of the patient.[9] The need for careful patient selection has already been discussed. Late recognition of complications can only be magnified in a more fragile patient. The earlier recognition of complications would go further to reducing FTR and subsequent inpatient mortality.

Participation in the ANZASM peer review and feedback process has increased nationwide across the duration of this study and over this time a decrease in the overall surgical postoperative mortality rate (POMR) has been well documented.[10] However, a recent review of nationwide data did not show a reduction in hepatectomy POMR over time.[1] That study concluded that more work needed to be done to determine the reasons for regional variability and the lack of improvement over time. Examining the data presented here reveals no significant change in the reasons for mortality post-hepatectomy over time. However, it does highlight the need for improved decision making prior to surgery and careful attention to perioperative care.

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While there will likely always be a significant risk of mortality as a result of a complex procedure such as hepatectomy, the ANZASM formalises the reflection that surgeons and their teams undertake after each death and provides objective feedback. This paper is unique in its nationwide examination of the clinical events leading to mortality post-hepatectomy.

The limitations of this study include firstly that hepatic resection is a variable procedure for different pathologies being performed on an organ that may be diseased due to preoperative treatment or cirrhosis. Aside from the patients that went to second line assessment (with full patient note review), the details surrounding each patient's death are those provided by the treating surgeon themselves. The assessors make an individual and subjective assessment of the events leading to each patient's death and consistency across assessments cannot be assured. The ANZASM does not include procedural volume and therefore little can be said about the POMR from this data. While this could be crudely extrapolated by combining ANZASM data with national Medicare data, POMR has been more comprehensively analysed elsewhere.[1] ANZASM assessors did not describe a significant adverse event in a some patient deaths where there were issues with postoperative care. To maintain consistency, these patients were not included in the reported results. However, these patient reports were re-examined by the authors and the details included as supplementary data.

The factors under a surgeon's control that can impact the success, or otherwise, of an operative intervention include the initial decision to operate, preoperative preparation of the patient and their liver, the quality of the operation performed and the postoperative care. For hepatectomy, a complex procedure with significant risk of morbidity, these factors become magnified.

This study has sought to summarise the significant clinical events leading to mortality after hepatectomy in Australia. The large proportion of patients where the decision to operate was questioned by assessors was a concerning feature of this study's result. In addition, the finding of a nearly a fifth of deaths being associated with late recognition of complications warrants consideration for Australian surgeons involved in hepatectomy. The authors recommend participation in multidisciplinary discussion prior to hepatectomy, particularly in the case of major resections on comorbid patients. Perioperative care is as important as the operative procedure itself and warrants careful attention to detail, such that complications are detected early and the patient can be appropriately rescued.

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Conflict of interest

None declared.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.hpb.2019.09.001.

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Publication 4

The short-term outcomes of pancreaticoduodenectomy in the state of Victoria – Hospital resources are more important than volume.

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Principal Author

Name of Principal Author (Candidate)	Claire Stevens		
Contribution to the Paper	Designed the study, performed the literature review, sourced and sorted the data, performed the statistical analysis and drafted the manuscript.		
Overall percentage (%)	80%		
Certification:	This paper reports on original research I conducted during the period of my Higher Degree by Research candidature and is not subject to any obligations or contractual agreements with a third party that would constrain its inclusion in this thesis. I am the primary author of this paper.		
Signature		Date	06 Dec 19

Co-Author Contributions

By signing the Statement of Authorship, each author certifies that:

i. the candidate's stated contribution to the publication is accurate (as detailed above);

ii. permission is granted for the candidate in include the publication in the thesis; and

iii. the sum of all co-author contributions is equal to 100% less the candidate's stated contribution.

Name of Co-Author	Professor David Watters		
Contribution to the Paper	Assisted with sourcing the data, critically reviewed manuscript		
Signature		Date	09 December 2019

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Short-term outcomes of pancreaticoduodenectomy in the state of Victoria: hospital resources are more important than volume

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Key words
hepatopancreaticobiliary surgery, outcome, pancreaticoduodenectomy, volume.

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Abstract

Background: Pancreaticoduodenectomy (PD) is a high-risk procedure. Australian hospitals perform a relatively low volume of PD. This study sought to gain an understanding of hospital volume and short-term outcomes of the procedure in the Australian state of Victoria.
Methods: The Dr Foster Quality Investigator tool was used to interrogate the Victorian Admitted Episodes Database for the Australian Classification of Health Intervention code for PD (30584) from July 2010 to June 2016. The data set included patients from a peer group of 14 hospitals that included all the public hospitals performing PD during this period. Patient characteristics, inpatient mortality, 30-day readmission rates and median length of stay were reported for each de-identified hospital.
Results: There were 547 PD conducted over 6 years in 10 public hospitals. The median patient age was 65 years. Inpatient mortality was 2.7%. There was a significant risk adjusted difference in mortality between principal referral and other public hospitals. Annual hospital volume ranged from 3 to 20 PD, and there was no significant relationship between mortality, readmission rates or length of stay and hospital volume.
Conclusion: The inpatient mortality associated with PD in Victorian public hospitals is comparable to that seen in overseas studies. While hospital volume is relatively low, there does not seem to be a relationship between volume and short-term outcomes. Variability between hospital peer groups suggests that resource availability is more important than volume. The development of a procedure specific registry would be useful to test the outcomes of this study and determine long-term PD outcomes.

Introduction

Pancreaticoduodenectomy (PD) is a complex specialized procedure with a significant peri-operative mortality rate. Australian hospitals have morbidity and mortality rates comparable to international reported values, despite relatively low surgeon and hospital volumes.[1–3] A recent study examining Australian Institute of Welfare data found an inpatient mortality of 3.6% following PD in Victoria and 3% Australia-wide, with improvement over time and significant inter-state variability.[4]

The last 10 years has seen centralisation of major pancreatic surgery in the USA, UK and the Netherlands[5–7] with subsequent analyses confirming the positive effect of a concentrated volume. The incidence of pancreatic and periampullary cancers in Australia is comparable with that of the USA and Europe.[8] However, Australia's population is significantly smaller and more widely dispersed. In the state of Victoria, there are 10 public and a smaller number of private hospitals where PD is performed to treat a population of 6.4 million[9] undergoing around 100 PD per year.[10]

Dr Foster Quality Investigator (DFQI) is a quality measurement tool that was in use by the Department of Health in the Australian state of Victoria from 2014 to 2017. The system allows the user to access administrative data to investigate mortality rates and other indicators of quality such as readmission rates and length of stay (LOS). Data can be compared with consideration of influencing factors such as patient demographics and diagnoses. The aim of this study was to determine the inpatient mortality rate, readmission rate and LOS for PD in Victorian public hospitals with assessment of individual hospital variation using the DFQI tool.

Methods

The DFQI tool was used to interrogate the Victorian Admitted Episodes Database for the Australian Classification of Health Intervention code for PD (30584). The data set included patients from of 14 public hospitals that had agreed to participate in a peer group for comparison of outcomes under the framework of the DFQI tool. All the public hospitals performing PD during the financial years 2010/2011 to 2015/2016 were a part of this peer group.

Patient characteristics, inpatient mortality, 30-day readmission rates and average LOS were reported for each de-identified hospital. Demographic information included age, gender and comorbidity burden. Comorbidities were those entered on discharge from hospital and included the relevant 31 Elixhauser comorbidities[11] with the addition of dementia. Mortality was defined as inpatient death. There was no data linkage to enable determination of 30-day mortality and as the data is de-identified, deaths in the community (outside of a Victorian hospital) were not available for inclusion. Readmissions were those to any hospital in Victoria within 30 days from discharge, and they were allocated to the hospital that performed the PD. The DFQI tool is operated under a set of business rules which describe these definitions.[12] Transferred patients were recorded against the hospital in which they had their PD.

Australian hospitals are classified into peer groups for the analysis and interpretation of hospital statistics and performance information. Hospitals that share similar characteristics are grouped together, providing a basis for meaningful comparisons.[13] Of the hospitals included in this study, all are acute public hospitals. Six of the hospitals are principal referral hospitals (PRHs) and the other four are public acute group A (PGA) hospitals. PRHs are public acute hospitals that provide a very broad range of services, have a range of highly specialized service units, and have very large patient volumes. The term 'referral' recognizes that these hospitals have specialist facilities not typically found in smaller hospitals. PGA hospitals are public acute hospitals that provide a wide range of services typically including a 24-h emergency department, intensive care unit, coronary care unit and oncology unit, but do not provide the breadth of services provided by PRH.[13] The difference between the two hospital subgroups includes the level of intensive care facilities, availability of specialty care and the inclusion of bone marrow and/or organ transplant services Inpatient mortality for PD was compared between the two hospital peer groups and between individual hospitals by volume.

For mortality rates, risk adjustment was performed using logistic regression to provide a fair comparison between patient cohorts in the Victorian Admitted Episodes Database. This analysis was made within the DFQI tool. Patient factors used in risk adjustments included age, gender, comorbidity burden, emergency admissions in the previous 12 months, admission source and month of admission. The risk modelling benchmark year was July 2013 to June 2014. Statistical analysis of proportions was performed using chi-squared and Fisher's tests with XLSTAT 2017 (Data Analysis and statistical solution for Microsoft Excel; Addinsoft, Paris, France). *P* values less than 0.05 were considered statistically significant.

This project was endorsed by the Dr Foster Intelligence Focus Group Steering Committee and approved by the Barwon Health Research Ethics, Governance and Integrity Unit.

Results

There were 547 PD over 6 years in 10 hospitals with an inpatient mortality of 2.7% (15/547). The median patient age was 64.8 years (15–85 years). The demographic characteristics of the patients who underwent PD are summarized in Table 1.

The median number of PD per year per hospital was eight (3.2–20.0). The overall volume remained steady over the study period. The same 10 hospitals performed at least one PD in each of the studied years. Figure 1 is a funnel plot of inpatient mortality by hospital volume.

The median LOS was 15 days (12–21 days) and there was no significant variation between hospitals. The cumulative deaths by postoperative day are shown in Figure 2. About 86.7% (13/15) deaths occurred within 30 days; 13.5% (74/547) patients were readmitted to a Victorian hospital at least once within 30 days from discharge. Figure 3 is a funnel plot of number of readmissions per year by annual hospital volume. No readmitted patient died. Readmission rates were similar amongst hospitals.

Table 1 Patient characteristics and mortality for pancreaticoduodenectomy in Victoria, July 2010 to June 2016

	n	Inpatient deaths	Mortality rate (%)	*P*
Number of patients	547	15	2.7	
Age, years				
0–17	2 (0%)	0	0	
18–29	5 (1%)	0	0	
30–49	45 (8%)	0	0	
50–64	198 (36%)	4	2.0	
65–74	192 (35%)	9	4.7	
75–84	104 (19%)	2	1.9	
>85	1 (0%)	0	0	0.442
Sex				
Male	320 (59%)	10	3.1	
Female	227 (41%)	5	2.2	0.603
Admission year				
2010/2011	81 (15%)	3	3.7	
2011/2012	104 (19%)	3	2.9	
2012/2013	89 (16%)	2	2.3	
2013/2014	85 (16%)	3	3.5	
2014/2015	95 (17%)	2	2.1	
2015/2016	93 (17%)	2	2.2	0.974
Pathology (discharge diagnosis)				
Malignant	455 (83%)	15	3.3	
Benign	92 (17%)	0	0	0.051
Comorbidities				
Lung disease	5 (1%)	1	20.0	
Diabetes	98 (18%)	6	6.1	
Renal disease	23 (4%)	2	8.7	0.262
Zero comorbidities	208 (38%)	2	1.0	
>3 comorbidities	281 (51%)	11	3.9	0.050

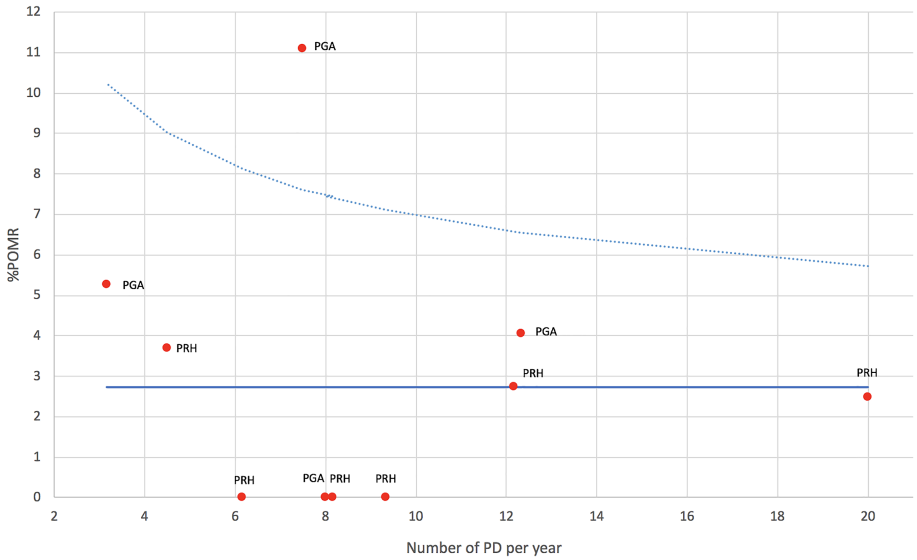

Fig. 1. Funnel plot showing variation in % POMR post-pancreaticoduodenectomy in Victorian public hospitals. (●) %POMR; (——) overall mean mortality; (-----) 95% confidence limit; PRH, principal referral hospital; PGA, public group A hospital.

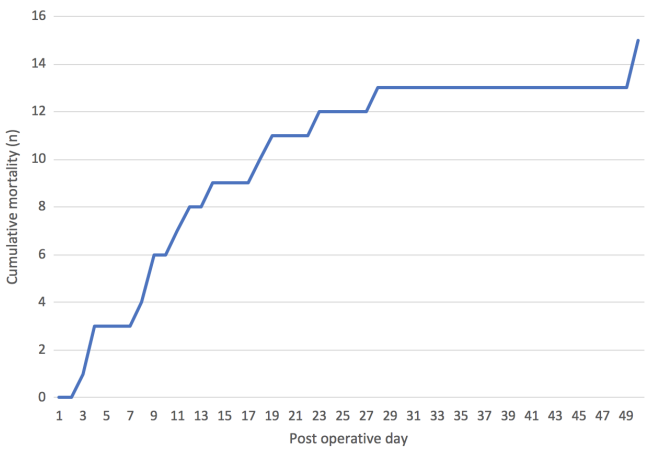

Fig. 2. Cumulative number of deaths post-pancreaticoduodenectomy by postoperative day.

Outcomes for the seven PRHs are compared with the four PGA hospitals in Table 2. The inpatient mortality rate for PRH was 1.7%, significantly lower than that for PGA hospitals at 4.8% (P = 0.039). One of the PGA hospitals was a significant outlier (Fig. 3) and another had a mortality rate of zero. Excluding the poorer performing outlier reduces the inpatient mortality for PGA hospitals to 2.8% and renders the statistical difference between the two hospital groups as insignificant (P = 0.478).

Discussion

This study has examined a state-wide data set that has included all PD performed in public hospitals in the state of Victoria over a 6-year period. The overall crude inpatient mortality rate was 2.7% which compares favourably with that seen internationally with inpatient mortality levels reported as 3–10%.[5,14] While mortality varied between individual hospitals (without statistical significance due to low numbers), there was no relationship between mortality and hospital volume. However, mortality was significantly higher in PGA hospitals than PRH and this was consistent after risk adjustment. A study using Victorian cancer registry data from 2002 to 2003 reported 75 patients treated with PD having a 30-day mortality rate of 5.3%.[15] However, there has been no published examination of state-wide mortality since that study.

The relationship between volume and outcome for PD has been widely discussed in the literature. Guidelines on hospital volume have been put in place in the Netherlands,[5] Canada[16] and Germany[17] and the definition of a high volume hospital continues to evolve.[18] Centralisation and increasing hospital volumes have been shown to improve post-operative and long-term survival for PD.[5,18] However, a suggested explanation is that improvement in mortality could be related to an increased ability to rescue from death after major complications.[6,19,20] The data presented here show a Victorian median public hospital volume of eight PD per year with the highest volume hospital performing 20 PD per year. By most definitions, these are not high volume centres and yet the mortality results are comparable to internationally reported values. Similar to the results seen here, a study into Queensland and New South Wales Cancer Registry data also found no relationship between hospital volume and mortality or survival rates.[21]

The consideration of volume criteria alone can fail to identify high-quality centres as there are other factors that contribute to good outcomes.[22] There is evidence to explain that paradoxically good outcomes for PD in lower volume hospitals may be due to those hospitals having excellent clinical resources.[23] Resource availability can also be a factor in the concept of failure to rescue; defined as the death of a patient due to a major post-operative complication.[24] A recent study into the Australian and New Zealand Audit of Surgical Mortality (ANZASM) findings for patient deaths after PD revealed that there was a delay in the recognition and treatment of complications in almost a quarter of patients.[25] Hospitals with greater resources and more complex institutional experience would likely recognize and rescue the struggling patient earlier than

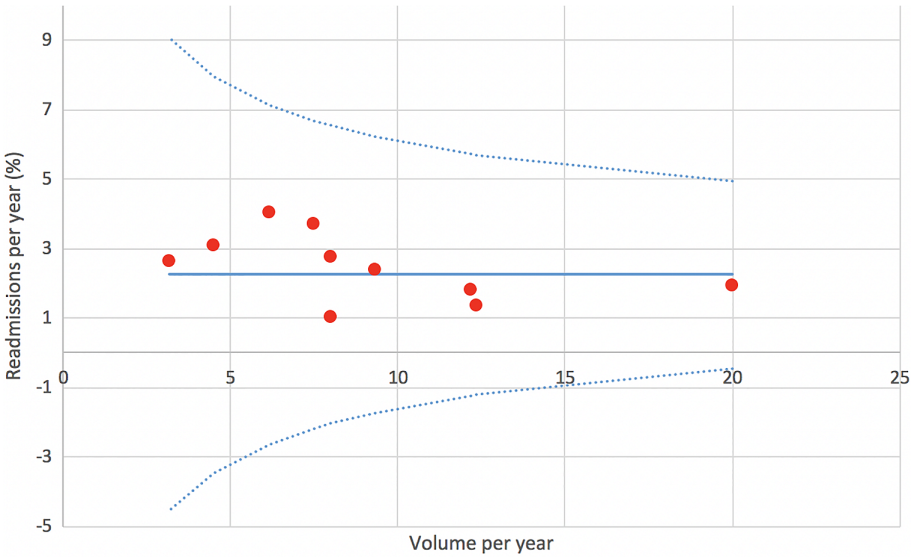

Fig. 3. Funnel plot showing variation in the number of readmissions per year post-pancreaticoduodenectomy in Victorian public hospitals. (●) %readmissions; (——) overall mean readmission rate; (-----) 95% confidence limit.

Table 2 Summary of crude outcomes for pancreaticoduodenectomy by hospital peer group in Victoria, July 2010 to June 2016

	Total	Principle referral hospital	Public acute group A hospital
Number of PD	547	361	186
Mean age (range)	64 (15–85)	64 (15–85)	66 (19–83)
% Male	59	58	60
% Presumed malignancy	83	82	85
Median length of stay (range of medians)	15	15 (12–19)	15 (15–21)
Inpatient deaths* (%)	15 (2.7)	6 (1.7)	9 (4.8)
Relative risk mortality	0.28 (0.15–0.46)	0.17 (0.07–0.41)	0.46 (0.21–0.98)
30-day re-admissions (%)	74 (13.5)	47 (13.0)	27 (14.5)

*$P < 0.05$. PD, pancreaticoduodenectomy.

those used to managing less complex patients with more limited resources. A combination of these factors may account for the significant difference seen in Victorian mortality rates between the PRH and PGA hospitals.

Surgeon volume has been shown to account for a part of the hospital effect in PD.[26–28] A significant proportion of the surgeons who performed the PD in this study's dataset operate in two or more of the hospitals examined. These inter-hospital links commonly extend between a PRH and PGA hospital. In addition, approximately one-third of Australia's PD is undertaken in private hospitals, accounting for additional surgeon volume.[4] It is likely that the difference in mortality between the hospital peer group types is independent of the operating surgeon.

LOS post-PD was similar between hospital peer groups and individual hospitals. The median of 15 days (range 12–21 days) was similar to that reported in other Australian studies[1,2,29] and the 9–21 days reported for high volume hospitals in Germany[19] and the USA.[19,30]

The overall 30-day readmission rate of 13.5% compares favourably with international rates of 15–38%.[30] A recent study by Sutton and colleagues investigating the links between volume and readmission rates after PD for over 9000 patients in the USA found that lower volume hospitals experienced higher readmission rates. They also found that readmitted patients had a longer LOS for their index admission. The relationship between hospital volume and readmission rates was not seen in Victoria.

The data set studied precludes detailed assessment of patient selection and its influence on the findings of inpatient mortality variation between hospital peer groups. However, it should be noted that patient selection has a significant impact on patient outcome on pancreatic surgery. Multi-disciplinary decision making has been strongly recommended by a recent study into Australian patient deaths post PD.[25] Each of the 10 public hospitals examined here coordinate a regular dedicated hepatobiliary and upper gastrointestinal multi-disciplinary meeting at which surgeons and oncologists discuss patients from both public and private practices.

Patients older than 75 years of age made up 19.2% of the statewide public patient cohort. The inpatient mortality of these patients was not significantly different to the younger patients ($P = 0.559$). The low mortality rate in the older age group is suggestive of careful patient selection in this cohort.

The good overall results shown here suggest that the state of Victoria is achieving excellent short-term results for PD by international standards. However, further investigations into the reasons for hospital peer group variability are needed to determine whether improvements to patient outcomes can be made. A recent study into Australia-wide PD mortality including private and public hospitals found significant interstate variability but could not provide risk-adjustment to aid in its explanation.[4] This study has shown using risk adjusted data that within one of the Australian states, hospital peer group and, therefore, resource availability may account for a variation in mortality.

The major limitation of this study has been that it considers only inpatient mortality. The inability to derive a 90-day mortality rate

from the dataset prevents assessment of the full outcomes of such a complex procedure with a long recovery time. An administrative dataset that does not adjust for risks specific to PD such as pathology, extent of resection and operative risk factors such as pancreatic consistency or duct size is limited. The quality of pancreatic resection lies also in the oncological outcomes which are not recorded at a population level in Victoria.

Despite its limitations, the results of this study confirm that inpatient mortality for PD in the Australian state of Victoria is similar to that reported internationally. The significant risk adjusted variation in inpatient mortality between hospital peer groups warrants further investigation. The development of a registry of pancreatic resection data would enable further study and potentially reveal areas where some centres excel and others fail, thereby generating overall improvement. In particular, patient selection, resource availability and the use of appropriate rescue where necessary and would only be captured well by prospective study or a large-scale registry.

Conflicts of interest

None declared.

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Conclusions and Recommendations

The inpatient mortality associated with hepatic resection in Australia is comparable to that seen overseas. However, there is significant variability between states without significant improvement over time.

Contributing factors to death post PD and hepatic resection were seen to be similar. Multi-disciplinary decision making has been strongly recommended in deciding which patients to offer these complex procedures with high rates of complication. Optimal care post PD and hepatectomy includes early recognition of complications and enactment of an adequate rescue plan.

In the Australian state of Victoria, the finding of variability in mortality rates post PD between hospital peer groups and not hospital volume highlights the importance of resource availability in the care of these patients.

The results seen in this group of studies should drive further investigation into the quality and variability of hepatic and pancreatic surgery in Australia. The development of a national registry would enable further investigation into the contributing factors to mortality, its regional variation and the optimal resource allocation strategy to prevent and rescue patients from complications.