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Surgical Complications in Rural Centres

Title: Rural centres do not have a higher prevalence of post-operative complications than urban centres; a retrospective analysis of a mortality audit.

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ABSTRACT

Background

The trend towards centralisation of surgical care from rural to high-volume centres is based on studies showing better outcomes for patients requiring complex surgical procedures. However, evidence that this also applies to less complex procedures is lacking. This study therefore aimed to determine whether there was a relationship between geographic location (rural vs urban) of surgical procedures of varying complexity, and post-operative complications.

Methods

This was a retrospective cohort study examining all in-hospital deaths reported to the Australian and New Zealand Audit of Surgical Mortality (ANZASM) between 2009-2016. Multivariable logistic regression was used to ascertain interactive effects of location and complexity of surgical procedures on post-operative complications, adjusted for potential confounders.

Results

There was no interactive effect of hospital location and operation complexity on the occurrence of post-operative complications. Post-operative complications were reported in 2,160/6,963 (31%) of patients who died post-surgery. Patients operated on in rural centres had lower risk profiles: younger, with lower ASA grades and less likely to present with injury and circulatory diseases. Nonetheless, risk of post-

operative complications did not differ between procedures performed in rural compared with urban hospitals.

Conclusion

Results of this study suggest that a wide range of procedures may be safely performed in rural centres. Further prospective studies of unfiltered cohorts are warranted to validate these findings.

Surgical Complications in Rural Centres

INTRODUCTION

Residents of rural Australia experience greater all-cause mortality than their urban counterparts, and have worse health risk-factor profiles: they are on average older, poorer, more likely to smoke, drink alcohol, be overweight and more often experience physical injury^(1,2). An important contributor to this gap is the limitation in timely access to health services⁽¹⁾. Access to Medicare funded services provided in inner regional areas diminishes from 74% of those provided in large urban centres to 30% in very remote areas⁽³⁾.

The discrepancy is particularly large for surgery⁽²⁾. One third of Australia's population lives in regional or rural areas, in towns of less than 5,000 inhabitants⁽⁴⁾. This results in significantly restricted access to specialist surgeons, who require an estimated 20,000 inhabitants for professional/financial viability⁽⁵⁾. Rural patients frequently travel long distances to urban centres to seek surgical treatment, with significant associated costs, loss of income, and poorer continuity of care^(5,6). Therefore, they are more likely to present late and to require emergency surgery^(1,7). Unmet surgical needs are not unique to Australia⁽⁸⁾. In the United States, there are similar trends towards fewer surgeons in regional areas, with a decline from 6.36 to 5.02 surgeons per 100,000 persons from 1981 to 2005⁽⁹⁾. The situation is even more dire in middle and low-income countries due to the lack of infrastructure, and where health services are seldom publicly-funded⁽¹⁰⁾.

Whether procedures performed in rural centres harbour a higher mortality risk

remains debatable⁽²⁾. In high-income countries, decades past have been characterised by an increasing geographic centralization of surgical care to urban centres^(2,11-13). The rationale is that there is an inverse relationship between mortality, morbidity and case-volume^(11,14). Evidence supporting this for complex operations is substantial, with lower mortality rates in urban centres performing high volumes of complex procedures (e.g. oesophagectomies)^(2,6,12,13).

However, the question of whether surgical interventions, other than highly complex procedures can be safely performed in rural centres thus remains unanswered^(2,15,16). Furthermore, use of case-volume as a quality-of-care indicator in rural surgery has limitations, because rural surgeons typically perform a large variety of low-volume cases^(6,12,14,17). Other patient outcomes such as post-operative complications should therefore also be considered. This study aimed to determine whether there is an interactive effect of location for rural versus urban sites of operations and complexity of operations on post-operative complications in patients who died following surgery. We hypothesized that patients undergoing procedures of minor complexity in rural hospitals would experience occurrence of post-operative complications equivalent to urban hospitals, while patients undergoing procedures of major complexity in rural hospitals would be more likely to experience post-operative complications than in urban hospitals.

METHODS

Study design and population

This is a retrospective cohort study examining all in-hospital deaths reported to the Australia and New Zealand Audit of Surgical Mortality (ANZASM) between 2009-2016, of surgical patients who had not been transferred from another hospital, and who underwent only one elective or emergency operation in Australian public and private hospitals, classified as rural or urban.

In 2010, the Royal Australasian College of Surgeons (RACS) mandated treating surgeons to complete a standard surgical case form for all in-hospital deaths of patients under the care of a surgeon or where a surgeon was significantly involved, whether an operation occurred or not. Deaths are notified to the audit directly by hospitals, and since 2011, 100% of hospitals participate (except New South Wales). All de-identified cases undergo a first-line review by a surgeon from the same specialty from a different hospital, and approximately 12% of these have a detailed second line review where a different surgeon has access to the original hospital records⁽¹⁸⁾. Feedback is then provided to the treating surgeon with the aim of education and improving patient care.

There are numerous definitions of 'rurality' and 'remoteness', varying between countries and outcomes of interest⁽¹⁹⁾. To classify hospitals into 'rural' or 'urban', ANZASM matches hospital location to the Rural, Remote and Metropolitan areas (RRMA) classification, an index of remoteness developed by the Australian Bureau of Statistics (ABS) according to population size (Table S1 and Figure S1)⁽²⁰⁾. The location of procedure for patients were independent of their residential RRMA classification. For instance, a patient from a rural or regional location admitted to an

urban centre would be classified as having undergone a procedure at an urban hospital.

Exclusion criteria included patients who had (Figure S2):

- American Society of Anaesthesiologists (ASA) grade 6, as these are “*declared brain dead patients whose organs are being removed for donor purposes*”⁽²¹⁾.
- Undergone >1 operation, as recorded complications could refer to any of the operations performed during the admission.
- Been transferred to and/or from any hospital, to ensure that the recorded location of hospital accurately reflected location of both surgery and death, rather than location of death only.
- Undergone an operation under the specialties of cardiothoracic, neurosurgery and plastics, as no operations (only one operation in plastics) were conducted in a rural setting.

Data extraction

Data on age, sex, risk factors for death such as obesity, ASA grade (surgeon assigned), payment status (private/public), surgical specialty, admission type (emergency/elective), operation timing, operating surgeon experience, procedure complexity (Supplementary Figure 3) surgical diagnosis, and cause of death were extracted.

Experience of the operating surgeon was classified as: 1) senior, which included consultants or fellows and 2) trainee, which included house officers within a surgical

unit who may or may not have been selected into a surgical training program, and who operated under the supervision of a consultant or fellow ⁽²²⁾. The primary outcome was the occurrence of post-operative surgical complications such as anastomotic leaks, and general complications such as pneumonia.

Statistical methods

Multivariable logistic regression was conducted to examine the interactive effect between location (rural/urban) and operation complexity on the occurrence of post-operative complications. The decision to proceed with surgery in a rural centre rather than transferring patients to a larger centre is not random; hence it is possible that procedures undertaken in rural hospitals may differ from those in larger urban ones. The literature suggests that rural surgeons perform more operations overall, including more minor, endoscopic, general, gynaecological and orthopaedic procedures^(23,24). Additionally, surgical patients tend to be younger, with fewer co-morbidities in rural areas, and more frequently undergo non-elective operations^(2,19). We therefore used univariate logistic regression to investigate the relationship between factors that may influence where the operations were performed (age, sex, risk factors for death, ASA grade, hospital and admission status, case specialty, operation timing, operation complexity, operator experience, length of stay) and surgery location. Variables significantly associated ($p < 0.05$) with location of surgery in the univariate analyses were included in the multivariable model as potential confounders. In addition, variables that were significantly associated with operation complexity were also

included as potential confounders. Surgical diagnoses and causes of death were not included in the multivariable model, as a substantial proportion of patients had >1 diagnosis and cause of death, and these did not provide any additional information on the procedure complexity or patient health status that were not already included. Cases with missing data for any of the variables included in the multivariable model were excluded. Statistical analyses were performed using Stata Version 12⁽²⁵⁾. Model goodness-of-fit was assessed using Hosmer-Lemeshow goodness-of-fit test, while discriminative ability of the model was assessed by the area under the receiver operating characteristic (ROC) curve⁽²⁶⁾.

The Monash University Human Research Ethics Committee (MUHREC) granted approval for this study on 18th August 2017 (10729).

RESULTS

Population

Of 32,008 deaths reported to the ANZASM between 2009-2016, 7,969 met inclusion criteria (Figure S2), and 6,718 with known data for all variables, were included in the

multivariable regression model. Adjusting for potential confounders, analysis showed no significant interactive effect of location and operation complexity on post-operative complications for patients who died after surgery (p-value for interaction term=0.533).

Table 1 presents demographic and clinical characteristics of patients in urban and rural locations. Majority of patients were aged 76 years and above (5,416;68.57%), almost half presented with an ASA grade 4 (3,707;46.94%), representing severe systemic disease posing a constant threat to life, and most had one or more risk factors for mortality, most commonly cardiovascular and respiratory disease. Most patients underwent emergency admissions (6,545;82.87%) (Table 1).

Notably, univariate logistic regression showed significant differences between patients operated on in urban centres (UC) compared to patients operated on in rural centres (RC), with the latter having overall a lower risk profile. RC were more often younger with a significantly higher proportion aged between 46 and 85 years compared to UC. Yet, a significantly smaller proportion of RC were very young (0-15 years). RC were significantly less likely to have higher ASA grades of 3-5. Likelihood of presenting with neoplasm and gastrointestinal diagnoses were 21% (OR 1.21;95% CI 1.06-1.39) and 32% higher (OR 1.32;95% CI 1.17-1.49), respectively, whilst the likelihood of presenting with injury or circulatory diseases were 20% lower (OR 0.80;95% CI 0.70-0.90) and 45% lower (OR 0.55;95% CI 0.44-0.68) respectively. There was no difference in types of admission and timing of operation (elective/emergency) between UC and RC.

RC were less likely to be admitted to private and co-located (public and private) hospitals, and were more likely to be operated on as general surgical cases than other specialties. Their odds of undergoing a major/complex operation was 32% lower (OR 0.68;95% CI 0.60-0.77) than operations for UC, while odds of an operation by trainees were 28% lower (OR 0.72;95% CI 0.62-0.84) than UC (Table 1).

Overall, common surgical diagnoses were reported at similar frequencies between urban and rural areas. Exceptions were abdominal and inguinal hernias in general surgery, which were almost twice as prevalent in rural centres (3.4% vs 1.8%), and peripheral vascular disease and embolism/thrombosis in vascular surgery which were almost triple or double the prevalence in urban locations (3.1% vs 1.1% and 0.78% vs 0.33%) (Table S2).

Table S3 presents demographic and clinical characteristics of patients who underwent operations of minor and major complexity. Patients who underwent operations of major complexity were more likely to be female and aged over 85 years, with risk factors for mortality including: age, cardiovascular disease, neurological disease and respiratory disease. In contrast, they were less likely to have advanced malignancy, diabetes, obesity, renal disease, hepatic disease and other mortality risk factors. Surgical diagnosis of patients who underwent major operations was more likely to be injury and circulatory related; similarly, case specialty was more likely to be orthopaedics and vascular. Post-operative complications were more likely after major operations than minor operations, and trainees conducted proportionally more major operations than senior surgeons.

Major operations were less likely to occur in rural hospitals compared to urban hospitals, and less likely in private hospitals compared to public hospitals. The admission was more likely to be emergency than elective, as was operation timing.

Post-operative complications

Overall, post-operative complications were reported in 2,178 patients (27.3%). Complications included anastomotic leakage, bleeding, tissue ischemia, endoscopic perforation and infection (Table S4). There was no difference in non-adjusted risk of post-operative complications between those who died after surgical treatment at rural and urban centres (Table 1). Multivariable logistic regression, controlling for all of the factors included in Table 2, found no significant interactive effect of location and operation complexity on post-operative complications ($p=0.533$). That is, the effect of operation complexity on post-operative complications did not differ by location of hospital. The interaction between location and operation complexity was therefore removed from the multivariable model to aid interpretation (Table 2). There was no association between hospital location and the odds of post-operative complications ($OR=0.99$; 95% DI 0.85-1.15). Major operations were significantly more likely to have post-operative complications than minor operations ($OR=1.56$, 95% CI 1.33-1.82), regardless of hospital location.

Adults aged 16-65 years had approximately 38% lower odds of post-operative complications than those aged above 85 years, and there was no significant association between gender and the occurrence of post-operative complications

Patients with diabetes as a risk factor for mortality were significantly less likely to have post-operative complications (OR=0.84; 95% CI 0.72-0.98), while obese patients (OR=1.60; 95% CI 1.31-1.97) and those with neurological disease (OR=1.18; 95% CI 1.02-1.36) were significantly more likely to have post-operative complications. Furthermore, other risk factors such as cognitive impairment, alcoholism and anticoagulation (Table S5) increased the odds of post-operative complication by 33% (OR 1.33;95% CI 1.16-1.51). Risk factors for mortality were not significantly associated with post-operative complications in the multivariable model comprised: hepatic disease, renal disease, cardiovascular disease, advanced malignancy, respiratory disease or age.

Relative to general surgery, the odds of post-operative complications were significantly lower in all surgical specialties, with the exception of vascular surgery (OR 1.23;95% CI 1.02-1.48), for which there was a significant increase in odds of post-operative complications.

The odds of post-operative complications were 25% lower in private hospitals compared to public hospitals (OR=0.75; 95% CI 0.64-0.88), and 56% lower in emergency admissions compared to elective admissions (OR=0.44; 95% CI 0.35-0.56). Operations that were performed less than two hours after admission had 44% lower odds of post-operative complications than elective operations (OR=0.56; 95% CI 0.42-0.76). There was no significant association between operator experience (senior or trainee) and odds of post-operative complications (Table 2).

The Hosmer-Lemeshow goodness-of-fit test was not statistically significant ($p=0.42$), indicating that the model was correctly specified, no relevant variables were omitted and model fit was good. The area under the ROC curve was 0.68.

DISCUSSION

In contrast with our hypothesis, there was no interactive effect of hospital location and operation complexity on the occurrence of post-operative complications. While the risk of complication was higher in major procedures than minor procedures, it was not further increased in major surgery performed in RC compared with UC. Patients operated on in rural hospitals and died after surgery did not experience a higher complication rate following operations of minor or major complexity, relative to those in urban hospitals. This could be attributed to judicious selection by surgeons of cases with lower risk profiles. There were notable differences between patients in RC and UC, albeit these were incorporated in the multivariable model to estimate risk of complications. RC were less likely to be very old (>85 years) or very young (<15 years old), or to have deranged physiology on admission. Further, types of operations in rural hospitals differed from that of urban hospitals, with greater prevalence of general surgery cases and minor operations. This observation has been previously reported, suggesting that in the context of limited access to specialist surgeons, rural surgeons select cases appropriate to a resource-limited setting⁽²⁷⁾. Finally, operations

in rural hospitals were less likely to be performed by trainees than senior operators, although those performed by trainees were not associated with an increased risk of complications. Although these factors were controlled for in our multivariate model, it is possible that other factors related to case selection in rural and urban settings may contribute to observed complication rates.

Strengths and limitations

To our knowledge, this is the first study to examine the effect of the hospital location and level of complexity of surgical procedures, on post-operative complications across all surgical specialties and at a population level. Other strengths include a large nationwide population, reliable and accurate clinical data derived from first accounts of the peri-operative events, and having demonstrated external validity⁽²⁸⁾.

An important caveat is the lack of information on the nature of operations classified as major and/or complex, severity of complications, and the case-mix, being largely unknown. Exclusion of 15.7% of cases due to missing data for variables included in the multivariable model may have introduced exclusion bias. Although several regional centres have grown to sizes comparable to peripheral urban centres, the range of services they offer has not followed this trend ⁽³⁾. Therefore despite the RRMA classification system of location used based on 1991 census data being somewhat dated, it remains accurate. Additionally, there may be some heterogeneity in hospitals classified as urban, which may range from high-volume tertiary centres to lower volume suburban district hospitals. Mandatory reporting of surgical deaths was only implemented in 2010, therefore there is potential for incomplete data collection

between 2010 and 2011. Operations not followed by death are not included owing to the nature of the data source, and follow-up time was limited as only in-hospital deaths were recorded.

Certain factors known to affect patient outcomes, such as hospital and surgeon case volume, and surgeon specialty, were not known^(11,14,29-31). Therefore, the next step to ascertain the relationship between location of surgery and post-operative outcomes, including mortality, may entail a prospective cohort study measuring surgeon and hospital case-volume, and an analysis of specific surgical diagnoses and procedures, to better evaluate the effect of operation complexity.

Rural hospitals play a vital role in providing surgical care in the Australian health system. This study suggests that they may do so safely for a wide range of procedures. Insofar as the disparity between rural and urban areas in accessing surgical care is projected to grow in many countries, rural surgeons and hospitals must be supported in their efforts to continue to provide high-standards of surgical care.

DISCLOSURE STATEMENT

There is no financial support or relationship that may pose conflict of interest

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Table LEGENDS

Table 1. Demographic and clinical characteristics of patients in urban and rural locations (univariate logistic regression)

Legend: $p < 0.05$ indicated in bold type

¹ Endocrine, metabolic, haematological, respiratory, neurological, dermatological, symptom, unspecified

² ENT, Paediatrics, Obstetrics/Gynaecology, Maxillo-facial, Ophthalmology

*Missing row comprises the number of cases that were excluded or missing from the main data set. This has been recorded as an integer and percentage of total (N) cases.

Table 2. Adjusted and unadjusted associations with post-operative complications

Legend: $p < 0.05$ indicated in bold type

¹ ENT, Paediatrics, Obstetrics/Gynaecology, Maxillo-facial, Ophthalmology

* Multivariable model including all variables in Table 2

APPENDIX/SUPPORTING INFORMATION

Figure S1: Map of RRMA Categories by Geography²⁰

Figure S2: Patient selection flowchart

Figure S3: Assignment of operation complexity

Operation type was classified according to the level of complexity based on recommendations from the RACS procedure list, developed for the purpose of training and assessment⁽³²⁾. Operations that could not be classified by this method were matched against Pasternak and colleagues' criteria, and categorised as minor/intermediate for level 1-3 complexity, or major/complex for level 4-5⁽³³⁾.

Table S1: Rural, Remote and Metropolitan Areas (RRMA) Classification categorises geographic areas into an index of remoteness according to population size.

Table S2: Frequencies of operation types conducted in rural versus urban hospitals

Table S3: Demographic and clinical characteristics of patients who underwent minor and major operations (univariate logistic regression)

Legend: $p < 0.05$ indicated in bold type

¹ Endocrine, metabolic, haematological, respiratory, neurological, dermatological, symptom, unspecified

² ENT, Paediatrics, Obstetrics/Gynaecology, Maxillo-facial, Ophthalmology

*Missing row comprises the number of cases that were excluded or missing from the main data set. This has been recorded as an integer and percentage of total (N) cases.

Table S4: Frequency of Post-Operative Complications

Table S5: Frequencies of 'other' risk factors

Table 1. Demographic and clinical characteristics of patients in urban and rural locations

Characteristics - n (%)	Urban (N = 6396)	Rural (N = 1502)	Odds ratio (95% CI)	p-value
Age Group (years)				
0-15	49 (0.77)	2 (0.13)	0.21 (0.05-0.84)	0.027
16-45	206 (3.22)	32 (2.13)	0.77 (0.53-1.14)	0.189
46-65	718 (11.23)	187 (12.45)	1.30 (1.07-1.56)	0.007
66-75	1021 (15.96)	267 (17.78)	1.30 (1.10-1.54)	0.002
76-85	2025 (31.66)	536 (35.69)	1.32 (1.15-1.51)	<0.0005
>85	2377 (37.16)	478 (31.82)	1	
Missing	1 (0.02)	0 (0)		
Gender				
Female	3021 (47.23)	702 (46.74)	1	
Male	3374 (52.75)	799 (53.20)	1.02 (0.91-1.14)	0.746
Missing	1 (0.02)	1 (0.07)		
Risk Factors for Mortality				
Any	6036 (94.36)	1426 (94.94)	1.06 (0.82-1.37)	0.659
None	332 (5.19)	74 (4.93)	1	
Missing	29 (0.45)	2 (0.13)		
Age - Yes	3823 (59.76)	902 (60.05)	1.00 (0.90-1.13)	0.944
No	2545 (39.78)	598 (39.81)	1	
Advanced malignancy - Yes	1126 (17.60)	281 (18.71)	1.07 (0.93-1.24)	0.339
No	5242 (81.94)	1219 (81.16)	1	
Cardiovascular disease - Yes	4210 (65.81)	992 (66.05)	1.00 (0.89-1.13)	0.987
No	2158 (33.73)	508 (33.82)	1	
Diabetes - Yes	1162 (18.16)	281 (18.71)	1.03 (0.89-1.19)	0.662
No	5206 (81.38)	1219 (81.16)	1	
Obesity - Yes	510 (7.97)	133 (8.85)	1.12 (0.92-1.36)	0.275
No	5858 (91.57)	1367 (91.01)	1	
Renal disease - Yes	1891 (29.56)	427 (28.43)	0.94 (0.83-1.07)	0.348
No	4477 (69.99)	1073 (71.44)	1	
Hepatic disease - Yes	448 (7.00)	133 (8.85)	1.29 (1.05-1.57)	0.015
No	5920 (92.54)	1367 (91.01)	1	
Neurological disease - Yes	1340 (20.95)	315 (20.97)	1.00 (0.87-1.15)	0.971
No	5028 (78.60)	1185 (78.89)	1	
Respiratory disease - Yes	2438 (38.11)	582 (38.75)	1.02 (0.91-1.15)	0.712
No	3930 (61.44)	918 (61.12)	1	
Other - Yes	1437 (22.46)	404 (26.90)	1.26 (1.11-1.44)	<0.0005
No	4931 (77.08)	1096 (72.97)	1	
ASA Grade				
1	57 (0.89)	26 (1.73)	1	
2	374 (5.85)	104 (6.92)	0.61 (0.37-1.02)	0.058

3	2389 (37.35)	551 (36.68)	0.51 (0.32-0.81)	0.005
4	3007 (47.01)	700 (46.60)	0.51 (0.32-0.82)	0.005
5	570 (8.91)	121 (8.06)	0.47 (0.28-0.77)	0.003
Missing	-	-		
Surgical Diagnosis				
Infection - Yes	148 (2.31)	40 (2.66)	1.15 (0.81-1.64)	0.424
No	6248 (97.69)	1462 (97.34)	1	
Neoplasm - Yes	1170 (18.29)	321 (21.37)	1.21 (1.06-1.39)	0.006
No	5226 (81.71)	1181 (78.63)	1	
Injury - Yes	2311 (36.13)	466 (31.03)	0.80 (0.70-0.90)	<0.0005
No	4085 (63.87)	1036 (68.97)	1	
Gastrointestinal - Yes	1672 (26.14)	479 (31.89)	1.32 (1.17-1.49)	<0.0005
No	4724 (73.86)	1023 (68.11)	1	
Musculoskeletal - Yes	221 (3.45)	67 (4.46)	1.30 (0.99-1.72)	0.062
No	6175 (96.54)	1435 (95.54)	1	
Circulatory - Yes	688 (10.76)	93 (6.19)	0.55 (0.44-0.68)	<0.0005
No	5708 (89.24)	1409 (93.81)	1	
Genitourinary - Yes	204 (3.19)	48 (3.20)	1.00 (0.73-1.38)	0.989
No	6192 (96.81)	1454 (96.80)	1	
Pre/perinatal - Yes	48 (0.75)	9 (0.60)	0.80 (0.39-1.63)	0.534
No	6349 (99.25)	1493 (99.40)	1	
Other ¹ - Yes	394 (6.16)	103 (6.86)	1.12 (0.90-1.40)	0.316
No	6003 (93.84)	1399 (93.14)	1	
Hospital status				
Public	4906 (76.69)	1330 (88.55)	1	
Private	1318 (20.60)	153 (10.19)	0.43 (0.36-0.51)	<0.0005
Co-location	103 (1.61)	7 (0.47)	0.25 (0.12-0.54)	<0.0005
Missing	70 (1.09)	12 (0.80)		
Admission				
Elective	1044 (16.32)	237 (15.78)	1	
Emergency	5295 (82.77)	1251 (83.29)	1.04 (0.89-1.21)	0.611
Missing	58 (0.91)	17 (1.13)		
Timing of operation				
Elective	1211 (18.93)	276 (18.38)	1	
< 2 hours	755 (11.80)	174 (11.58)	1.01 (0.82-1.25)	0.917
2-24 hours	2169 (35.97)	548 (39.21)	1.11 (0.94-1.30)	0.209
>24 hours	2130 (33.30)	463 (30.83)	0.95 (0.81-1.12)	0.574
Missing	132 (2.06)-	41 (2.73)-		
Case Specialty				
General	2765 (43.22)	928 (61.78)	1	
Orthopaedics	2297 (35.91)	443 (29.49)	0.57 (0.51-0.65)	<0.0005
Urology	344 (5.38)	71 (4.73)	0.61 (0.47-0.80)	<0.0005
Vascular	796 (12.44)	42 (2.80)	0.16 (0.11-0.22)	<0.0005
Other ²	195 (3.05)	18 (1.20)	0.28 (0.17-0.45)	<0.0005

Missing	-	-		
Operation Complexity				
Minor/Intermediate	1279 (20.00)	402 (26.76)	1	
Major/Complex	5050 (78.94)	1080 (71.90)	0.68 (0.60-0.77)	<0.0005
Missing	68 (1.06)	20 (1.33)		
Most Senior Operator				
Senior	4354 (68.07)	1046 (69.64)	1	
Trainee	1431 (25.80)	249 (17.44)	0.72 (0.62-0.84)	<0.0005
Missing	612 (6.12)	207 (12.92)		
Post-operative complications				
Yes	1750 (27.36)	410 (27.30)	1 (0.88-1.13)	0.984
No	4591 (71.77)	1077 (71.70)	1	
Missing	56 (0.88)	15 (1.00)		

Legend: p<0.05 indicated in bold type

¹ Endocrine, metabolic, haematological, respiratory, neurological, dermatological, symptom, unspecified

² ENT, Paediatrics, Obstetrics/Gynaecology, Maxillo-facial, Ophthalmology

*Missing row comprises the number of cases that were excluded or missing from the main data set. This has been recorded as an integer and percentage of total (N) cases.

Table 2. Adjusted and unadjusted associations between risk factors and post-operative complications

Characteristics – n (%)	Post-op Complications (N=2178)	No post-op Complications (N=5719)	Unadjusted OR (95% CI)	Adjusted OR (95% CI)*	p-value
Location					
Urban	1750 (80.35)	4591 (80.28)	1	1	0.874
Rural	410 (18.82)	1077 (18.83)	1.00 (0.88-1.13)	0.99 (0.85-1.15)	
Missing	18 (0.83)	51 (0.89)			
Operation complexity					
Minor/Intermediate	379 (17.40%)	1295 (22.64)	1	1	<0.0005
Major/Complex	1774 (81.45%)	4363 (76.29%)	1.39 (1.22-1.58)	1.56 (1.33-1.82)	
Missing	25 (1.15%)	61 (1.07%)			
Age Group (years)					
0-15	9 (0.41)	43 (0.75)	0.61 (0.30-1.27)	0.76 (0.32-1.78)	0.522
16-45	34 (1.56)	204 (3.57)	0.49 (0.34-0.71)	0.61 (0.39-0.95)	0.029
46-65	218 (10.01)	680 (11.89)	0.94 (0.79-1.12)	0.62 (0.48-0.80)	<0.0005
66-75	422 (19.38)	861 (15.06)	1.44 (1.25-1.66)	1.01 (0.82-1.23)	0.961
76-85	768 (35.26)	1794 (31.37)	1.26 (1.12-1.42)	0.98 (0.85-1.13)	0.800
>85	727 (33.38)	2136 (37.36)	1	1	
Missing	0 (0)	1 (0.02)			
Gender					
Female	994 (45.64%)	2725 (47.65%)	1	1	0.749
Male	1183 (54.32%)	2993 (52.33%)	1.08 (0.98-1.19)	0.98 (0.87-1.10)	
Missing	1 (0.05%)	1 (0.02%)			
ASA Grade					

Surgical Complications in Rural Centres

1	17 (0.78)	64 (1.12)	1	1	
2	179 (8.22)	297 (5.19)	2.27 (1.29-4.00)	1.03 (0.54-1.94)	0.936
3	984 (45.18)	1953 (34.15)	1.90 (1.11-3.26)	1.04 (0.57-1.92)	0.895
4	894 (41.05)	2817 (49.26)	1.19 (0.70-2.05)	0.78 (0.42-1.45)	0.436
5	104 (4.78)	588 (10.28)	0.67 (0.37-1.18)	0.43 (0.22-0.81)	0.010
Missing	0 (0)	0 (0)			
Mortality risk factors					
Obesity					
No	1934 (88.80)	5289 (92.48)	1	1	
Yes	241 (11.07)	402 (7.03)	1.64 (1.39-1.94)	1.60 (1.31-1.97)	<0.0005
Missing	3 (0.14)	28 (0.49)			
Neurological					
No	1728 (79.34)	4484 (78.41)	1	1	
Yes	447 (20.52)	1207 (21.11)	0.96 (0.85-1.09)	1.18 (1.02-1.36)	0.021
Missing	3 (0.14)	28 (0.49)			
Advanced malignancy					
No	1782 (81.82)	4681 (81.85)	1	1	
Yes	393 (18.04)	1010 (17.66)	1.02 (0.90-1.16)	1.05 (0.90-1.23)	0.551
Missing	3 (0.14)	28 (0.49)			
Age					
No	852 (39.12)	2275 (39.78)	1	1	
Yes	1323 (60.74)	3416 (59.73)	1.03 (0.93-1.14)	1.05 (0.91-1.22)	0.515
Missing	3 (0.14)	28 (0.49)			
Cardiovascular					
No	727 (33.38)	1930 (33.75)	1	1	

Surgical Complications in Rural Centres

Yes	1448 (66.48)	3761 (66.76)	1.02 (0.92-1.13)	1.02 (0.89-1.17)	0.743
Missing	3 (0.14)	28 (0.49)			
Respiratory					
No	1367 (62.76)	3479 (60.83)	1	1	
Yes	808 (37.10)	2212 (38.68)	0.93 (0.84-1.03)	0.97 (0.86-1.10)	0.669
Missing	3 (0.14)	28 (0.49)			
Renal disease					
No	1578 (72.45)	3965 (69.33)	1	1	
Yes	597 (27.41)	1726 (30.18)	0.87 (0.78-0.97)	0.95 (0.83-1.08)	0.401
Missing	3 (0.14)	28 (0.49)			
Hepatic disease					
No	2049 (94.08)	5238 (91.59)	1	1	
Yes	126 (5.79)	453 (7.92)	0.71 (0.58-0.87)	0.87 (0.68-1.11)	0.254
Missing	3 (0.14)	28 (0.49)			
Diabetes					
No	1779 (81.68)	4642 (81.17)	1	1	
Yes	396 (18.18)	1049 (18.34)	0.99 (0.87-1.12)	0.84 (0.72-0.98)	0.030
Missing	3 (0.14)	28 (0.49)			
Other					
No	1604 (73.65)	4427 (77.41)	1	1	
Yes	571 (26.22)	1264 (22.10)	1.25 (1.12-1.40)	1.33 (1.16-1.51)	<0.0005
Missing	3 (0.14)	28 (0.49)			
Case specialty					
General	1120 (51.42)	2554 (44.66)	1	1	
Orthopaedics	581 (26.68)	2166 (37.87)	0.61 (0.54-0.69)	0.55 (0.47-0.64)	<0.0005

Surgical Complications in Rural Centres

Urology	118 (5.42)	299 (5.23)	0.90 (0.72-1.13)	0.75 (0.57-1.00)	0.047
Vascular	301 (13.82)	543 (9.49)	1.26 (1.08-1.48)	1.23 (1.02-1.48)	0.034
Other ¹	58 (2.66)	157 (2.75)	0.84 (0.62-1.15)	0.68 (0.47-1.00)	0.049
Surgeon experience					
Senior	1577 (80.62)	3832 (74.57)	1	1	
Trainee	379 (19.38)	1307 (25.43)	0.70 (0.62-0.80)	0.88 (0.75-1.02)	0.089
Hospital status					
Public	1698 (77.96)	4537 (79.33)	1	1	
Private	428 (19.65)	1041 (18.20)	1.10 (0.97-1.25)	0.75 (0.64-0.88)	<0.0005
Co-location	26 (1.19)	85 (1.49)	0.82 (0.52-1.27)	0.76 (0.47-1.24)	0.274
Missing	26 (1.19)	56 (0.98)			
Admission type					
Elective	643 (29.73)	634 (11.20)	1	1	
Emergency	1520 (70.27)	5028 (88.80)	0.30 (0.26-0.34)	0.44 (0.35-0.56)	<0.0005
Timing of operation					
Elective	681 (31.27)	802 (14.02)	1	1	
< 2 hour	181 (8.31)	751 (13.13)	0.28 (0.23-0.34)	0.56 (0.42-0.76)	<0.0005
>=2 hours	704 (32.32)	2183 (38.17)	0.38 (0.33-0.43)	0.81 (0.63-1.04)	0.096
>24 hours	612 (28.10)	1983 (34.67)	0.36 (0.32-0.42)	0.82 (0.64-1.05)	0.119

Legend: p<0.05 indicated in bold type

¹ ENT, Paediatrics, Obstetrics/Gynaecology, Maxillo-facial, Ophthalmology

* Multivariable model including all variables in Table 2

Response to Reviewer Comments: Rural centres do not have a higher prevalence of post-operative complications than urban centres; a retrospective analysis of a mortality audit
ANZJS – ANS – 2018 - 00570

Reviewer Comments and Author Amendments – ANZJS

Reviewer #	Reviewer Comment	Author Comment	Location of Edit
1	I would like to thank you and congratulate you for choosing this very important subject and for delivering this excellent work. I am sure your paper will be the 'kick-off' for a very interesting and fruitful discussion and will be the start for further research in this field. Well done.	Acknowledged with thanks. No changes requested	-
Summary Comments			
2	Objectives: The stated objective of the study is to determine if procedures of varying length and complexity have complication rates that are different in urban or rural centres. The unstated objective is revealed in the conclusions: whether surgery can be performed safely in rural centres.	Accept. Although our research team would have liked to evaluate whether surgery can be performed safely in rural centres, the data limitations did not allow for a comprehensive evaluation of this question. As such, in order to feasibly answer a research question the manuscript's objectives needed to align with the data available from the ANZASM database. Introduction/objectives amended. Sentence added: <i>"However, the question of whether surgical interventions, other than highly complex procedures, can be safely performed in rural centres thus remains unanswered."</i>	Page 6. Lines 28-29.
	Study Design: Retrospective review of complications recorded on the nation wide mortality audit. Thus a large and comprehensive study of a highly select group. The "urban centres" group is heterogeneous, varying from high volume centres of excellence to smaller suburban district hospital. I believe this should be pointed out.	Accept. Strengths and Limitations amended. Sentence added: <i>"Additionally, there may be some heterogeneity in hospitals classified as urban, which may range from high-volume tertiary centres to lower volume suburban district hospitals."</i>	Page 15. Lines 272-274.

Potential Contribution: Large. Any information that could help direct policy regarding the provision of rural surgical services is important.	Acknowledged. We thank the reviewer, and hope too that the findings of this study will make a substantial contribution to highlighting the very important issue of surgical access for our rural population and improving the provision of rural surgical services. No changes requested.	-
Strengths: Large, nationwide, well documented. Weaknesses: The study looks at the number of complications, not the severity. I feel it is debatable as to whether ignoring the ultimate complication, death, can be valid. At least it should be discussed.	Accept. Please refer to limitations and future directions section(s) where it is discussed that we were not able to investigate and compare mortality rates between urban and rural centres, owing to the nature of the data source. Strengths and limitations amended. Sentence amended: " <i>An important caveat is the lack of information on the nature of operations classified as major and/or complex; severity of complications and the case-mix being largely unknown.</i> "	Page 15. Line 265-267.
Overall: A large, comprehensive study but with an unstated, counter-intuitive assumption at its base.	Acknowledged. No changes requested.	-
Numbered Comments		
Title		
(1.) Title. Clearly states the nature and result of the study	Acknowledged. No changes requested.	-
Abstract		
The background states "Trends towards centralisation of surgical care from rural to urban centres...". The literature is, however, about rural vs high volume centres of excellence that are in urban areas. I think this distinction should be made because this study does not make the same comparison.	Accept. Abstract introduction. Sentence amended: " <i>The trend towards the centralisation of surgical care from rural to high-volume centres in urban areas, is based on studies showing better outcomes for patients requiring complex surgical procedures.</i> "	Abstract – Introduction. Page 3.
The conclusion starts with a statement concerning resource allocation which does not belong here, it belongs in "Discussion".	Accept. Abstract conclusion. Sentence removed: " <i>Rural surgery has vital roles in delivering an effective health system in Australia.</i> "	Page 3.

The conclusion also states that the study "...suggests common and simple surgical procedures..." yet >70% of procedures were classified as "major/complex" (table 1). This contradiction needs to be addressed.	Accept. Abstract conclusion. Sentence amended: <i>"Results of this study suggest that a wide range of procedures may be safely performed in rural centres. Further prospective studies of unfiltered cohorts are warranted to validate these findings."</i>	Abstract – Conclusion. Page 4.
Methods		
Good detail is given as to how the data were collected.	Acknowledged. No changes requested.	-
Results		
The figures supplied document that RC were younger, had lower ASA ratings and were less likely to have a major/complex operation but had the same rate of complications. Would this not suggest that the risk of complications is higher? I feel this should be discussed.	Rebuttal. Factors stated by the reviewer were accounted for as potential confounders given they differed between rural and urban populations. As these variables were likely to be associated with post-operative complications, the regression model was adjusted for age, ASA ratings and operation complexity as well as the other variables differing between urban and rural populations (see Table 2). Location was not associated with post-operative complications in this multivariable model (i.e. didn't predict risk after confounding factors were statistically accounted for). This has been re-iterated in the discussion section. Discussion amended. Sentence added: <i>"There were notable differences between patients in RC and UC, albeit these were incorporated in the multivariate model to determine risk of complications."</i>	Page 14. Lines 245-247.
The validity of ignoring the entry criterion being the ultimate complication needs to be explained.	Acknowledged. We thank the reviewer for highlighting this issue. We also feel that comparing mortality between these two populations would be extremely beneficial. Unfortunately, we were not able to undertake this comparison due to the nature of the dataset. As described in the manuscript, further characterisation of the quality of surgical care provided in UC and RC, would entail a prospective study measure post-operative complications including mortality. There is however, much to learn from mortalities, including from post-operative complications that precede deaths. This was recognized many decades ago by the implementation of morbidity and mortality meetings, to which surgeons across the world partake on a regular basis. Death is indeed the ultimate complication, yet surgical care can be improved by examining the other events that took place prior to a patient's death. No changes made.	-

<p>A map showing which areas were in each group (RC vs UC) would be welcome.</p>	<p>Acknowledged Unfortunately a map showing rural vs urban centres is not possible due to Quality Privilege constraints. The ANZASM maintains the confidentiality of surgeons and institutions that partake in the audit.</p> <p>We are however, able to include a generic map of the RRMA classification of Australia so that readers may understand which geographical regions classify as urban or rural/remote.</p> <p>Figure added.</p>	<p>See Supplementary Information Document - <i>Supplementary Figure 1</i></p> <p>Manuscript text has been amended to reflect the addition of a figure.</p> <p>Page 7: Line 67, Line 71</p> <p>Page 8: Line 88</p> <p>Page 10: Line 136</p> <p>Page 21: Line 495, Line 497, Line 499</p>
<p style="text-align: center;">Discussion</p>		
<p>Can the opening statement that "operation complexity had no influence on outcome.." be supported when the RC had fewer major/complex operations?</p>	<p>Rebuttal. Operation complexity did indeed influence the outcome (Table 1, Table 2). Our statement rather refers to no interaction between location and operation complexity on post-operative complications (Page 12. Line 255: "...there was no interactive effect of the location of the hospital and operation complexity on the occurrence of post-operative complications."). I.e. the effect of complexity on post-operative complications did not differ according to location. Furthermore, location was not a variable predicting post-operative complications on its own (univariate model) therefore was dropped from the model (Table 1). We have attempted to clarify the above in the discussion section.</p> <p>Discussion amended. Sentence added: <i>"In other words, the risk of complication was higher in major procedures, yet it was not further increased in major surgery performed in RC compared with UC."</i></p>	<p>Page 14. Lines 240-242.</p>
<p>As mentioned above, it would be pertinent to point out that the UC is heterogeneous because it includes smaller, suburban hospitals as well as large centres of excellence to which referral would be made if deemed necessary.</p>	<p>Accept. Please refer to sentence and amendment above regarding study design.</p>	<p>Page 15. Lines 272-274.</p>

	Otherwise, the discussion is all well considered and relevant. In particular, the influence of surgical selection is noted and the strengths and weaknesses are well discussed. However, given these clear problems, I believe that the second last sentence "This study shows..." should be reworded "This study suggests..."	Accept. Conclusion amended. Sentence amended: <i>"This study suggests that they may do so safely for a wide range of procedures."</i>	Page 16. Line 286.
Major Author Led Changes to Manuscript			
	Data Re-Analysis	<p>Our study's hypotheses related to the interactive effect of location and operation complexity on post-op complications.</p> <p>Potential confounders are therefore anything related to location, operation complexity and post-op complications.</p> <p>Originally, Table 1 showed the univariate relationships between potential confounders and hospital location. During the revision process we noted that operation complexity is also a risk factor that is part of the main hypothesis, therefore we also needed to look at potential confounders of the relationship between operation complexity and post-op complications. This has been added to the manuscript as a new table (Table S3).</p> <p>Table 2 shows the results of the new multivariable analysis that includes all potential confounders.</p> <p>The sentences in the methods, results and discussion sections that changed as a result of this have been amended.</p> <p>There is no real change to the main conclusions of the study in light of the re-analysis, therefore the points made in the discussion section remain relevant. .</p> <p>Amendments: Addition of Table S3: Demographic and clinical characteristics of patients who underwent minor and major operations (univariate logistic regression). Amendment to Table 2: Inclusion of potential confounders</p>	Results Section Table Legends Section Addition of Table S3 Amendments to Table 2
	Length of stay variable	<p>The study population died within 30 days. Length of stay (LOS) in this context could reflect time to leaving hospital or time to death. The length of stay might be lower for major ops because they died earlier. We neither use this in the multivariate analysis nor discuss this variable in the manuscript hence we deemed it irrelevant to include in Table 1.</p> <p>Amendment. LOS row deleted – Table 1</p>	Table 1

Repetition of exclusion criteria	<p>Exclusion of specialties that did not have operations in rural hospitals (e.g. cardiothoracics, orthopaedics) have already been stated in the methods section.</p> <p>Amendment. Sentence deleted: <i>"Patients from the following surgical specialties were excluded as none had an operation in rural hospitals, thus precluding comparison of population and outcomes: cardiothoracic, orthopaedic and plastic surgery"</i></p>	Page 9. Line 118-120.
Re-emphasis of study population characteristics	<p>We wish to re-emphasise that the study population comprised patients who died after surgery.</p> <p>Amendment. Sentence amended: <i>"This study therefore aimed to determine whether there is an interactive effect of location for rural versus urban sites of operations and complexity of operations on post-operative complications in patients who died following surgery"</i></p>	Page 6. Line 35-38.
Amendment of patient selection flow chart	<p>The numbers and layout of Fig 2 were incorrect and did not reflect how we applied the inclusion/exclusion criteria.</p> <p>Amendment. Re-numbering of Supplementary Figure 2</p>	Supplementary Information. Figure 2.

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Title:

Rural centres do not have a higher prevalence of post-operative complications than urban centres: a retrospective analysis of a mortality audit

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