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ORIGINAL SCIENTIFIC REPORT

An Acute General Surgical Unit (AGSU) Negates the Impact of the Tokyo Guidelines 2018 (TG18) Diagnostic Criteria for the Treatment of Acute Cholecystitis

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Abstract

Purpose The Tokyo Guidelines 2018 (TG18) were developed to aid diagnosis and treatment for acute cholecystitis. The benefits of being treated in an acute general surgical unit (AGSU) include earlier diagnosis and treatment. This study aims to define the usefulness of TG18 before and after the introduction of AGSU.

Methodology Patients who underwent cholecystectomy at Northern Health were audited retrospectively and assessed for TG18 diagnostic criteria and outcomes between 1 February 2012 and 1 February 2014 (one-year pre- and post-AGSU).

Results Five hundred and eighty-seven patients underwent emergency cholecystectomy with 203 (34.6%) patients having a suspected diagnosis, and 234 (39.9%) patients with a definitive diagnosis of acute cholecystitis using TG18 diagnostic criteria. After the introduction of AGSU, time from imaging to operation improved from 2.5 to 1.7 days ($p = 0.012$). There were more operations occurring during in-hours following AGSU implementation (75.8% vs. 62.7%, $p < 0.001$). Maximum pre-operative CRP of >26.6 mg/L had a higher likelihood of Clavien–Dindo complication grade 3 or 4 (OR 3.86, 95%CI 1.18–12.63, $p = 0.027$) compared with TG18 definitive diagnosis criteria (OR 1.50, 95%CI 0.46–4.91, $p = 0.501$). Surprisingly, there was a trend towards higher complications and readmissions for patients operated within 24 h, although this trend was not significant.

Conclusion Patients with suspected acute cholecystitis should be stratified clinically and with CRP in an AGSU with TG18 adding little value in a busy metropolitan unit.

Abbreviations

TG 18	Tokyo Guidelines 2018
AGSU	Acute General Surgery Unit
WCC	White cell count
CRP	C-reactive protein
ASA	American Society of Anesthesiologists Score
OR	Odds ratio

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Introduction

Cholecystitis is one of the common surgical pathologies seen in hospitals [1]. Acute cholecystitis prompts urgent treatment, usually by emergency cholecystectomy, as its complications can cause significant clinical consequences if left untreated [2]. Common complications include gangrenous or emphysematous gallbladder, perforation, sepsis and cholecystoenteric fistula [3–6]. In severe cases,

perforation of gallbladder may cause peritonitis, sepsis, multiple organ failure and death. Therefore, accurate diagnosis and timely treatment are very important in managing these patients [7].

The Tokyo Guidelines were developed to assist with the diagnosis and treatment of patients with suspected cholecystitis (Table 1) [8]. In 2018, the Tokyo Guidelines (TG18) were reassessed and demonstrated a sensitivity of 91.2% and specificity of 96.9% for diagnostic purposes [8]. Several studies have now used TG18 for determining management of patients with suspected cholecystitis with varying results. One study has shown that TG18 demonstrated promising predictive value for length of stay, morbidity, mortality, conversion to open surgery approach, operative duration and readmission for their patients [9]. However, another study found that TG18 may have a tendency to underestimate the extent of inflammation in patients with grade I severity, whereas overestimate the difficulty of surgical dissection in grade II [10]. Two other studies argued that early cholecystectomy was still safe and feasible in moderate and severe cholecystitis by TG18 severity grading system [11, 12].

In this study, we aim to determine the role of the diagnosis of cholecystitis using TG18 and potential benefits to patients who are treated more rapidly in an AGSU. Northern Health (Melbourne, Australia) developed an AGSU that commenced in 2013, and this study compares patients who underwent emergency cholecystectomy for suspected cholecystitis in the 12 months prior to the 12 months following AGSU implementation for differences in operating times, length of stay and complication rates.

Method

Patients

This study was performed at a single centre, Northern Health, Melbourne, Australia. Patients who underwent emergency cholecystectomy between the 1 February 2012 and the 1 February 2014 were retrospectively audited for demographic, pre-operative, operative and post-operative details. Patients who underwent cholecystectomy as part of a non-gallstone-related cause (e.g. combined with liver resection) were excluded from the study. Pre-operative details included time of triage, time of diagnostic imaging (ultrasound or computed tomography), pre-operative white cell count (WCC)/C-reactive protein (CRP) values and other diagnostic factors that make up TG18 (Table 1). Operative details included the time surgery commenced, length of operation, surgical technique approach and ASA. Post-operative details included histology, length of stay during the index admission and readmission, complications, readmissions and death. This study was approved by the local research and ethics committee (HREC ALR 04.2017).

acute general surgical unit (AGSU)

Prior to the implementation of AGSU in Northern Health, approximately 12 surgeons were on a regular 24-h on-call roster with their unit registrar as well as their other unit duties during the day and evening. There was one dedicated unaccredited night registrar. In the mornings, some surgeons might have had elective lists and theoretically could sometimes add emergency cases even though this was not a common phenomenon. Some surgeons had emergency theatre access which might translate into either access to operating theatre or competitive access with the

Table 1 TG18 diagnostic criteria

Category A (local signs of inflammation)	Murphy's sign
	Right upper quadrant tenderness/pain/mass
Category B (systemic signs of inflammation)	Fever
	Elevated C-reactive protein (CRP)
	Elevated white blood cell count (WBC)
Category C (imaging findings characteristic of acute cholecystitis)	Sonographic Murphy's sign
	Gallbladder wall thickening (greater than 4 mm)
	Pericholecystic fluid/oedema
	CT findings of gallbladder wall thickening and oedema, pericholecystic stranding and fluid
TG18 suspected diagnosis	One item in A plus one item in B, none in C
TG18 definitive diagnosis	One item in A plus one item in B plus one item in C

other specialized surgical teams. Patients who were admitted but not operated on during that 24-h period stayed under the care of the surgeon who then was required to find time to perform the operation over the following days. By mutual agreement, the patient's care was sometimes transferred to another surgeon who agreed with the decision to operate and had greater time capacity and access to theatre.

The AGSU at Northern Health, when commenced on the 1 February 2013, comprised 14 consultant surgeons who were remunerated to be on-site between 0730 and 1830 and on call after those hours to a total of 24 h. Some elective lists and some emergency lists were converted to dedicated AGSU lists, comprising either a full day list or an afternoon list. There were dedicated junior staffs attached to AGSU comprising an accredited registrar and 2–3 interns. Patients who were admitted and treated operatively or did not require an operation were transferred to the surgeon's usual unit the following day. Patients who required operative management but had not yet had surgery were kept on AGSU and were then managed by the incoming on-call surgeon.

Operation

Laparoscopic cholecystectomy was performed according to standard four-port technique with the surgeon standing on the left of the patient. Intraoperative cholangiogram was performed routinely at the discretion of the operating surgeon. Pre-operative antibiotics were given routinely. Post-operative orders were at the discretion of the operating surgeon and varied according to patients' requirements.

Statistical analysis

Descriptive analysis was undertaken to provide a comparative profile of patients within each of the TG18 categories: definitive diagnosis, suspected diagnosis and no diagnosis of cholecystitis and for the pre- and post-AGSU periods. Results were presented as mean and standard deviation for normally distributed variables and medians and interquartile ranges (IQR) for those variables which were non-normally distributed. Categorical variables were presented as counts and frequencies or percentages. To test for statistically significant differences between groups, Student's *t* test and the Mann–Whitney (rank-sum) test were utilized for continuous normal and non-normally distributed variables, respectively. For categorical variables, the Chi-squared test was performed, with Fisher's exact tests used on occasions when frequencies were <5 for any combination.

Multinomial logistic regression analysis was conducted to test for the association between pre-/post-AGSU period and the outcome of Clavien–Dindo grades 3 or 4, when compared to patients with no Clavien–Dindo outcome. Variables included in the multivariable analysis were selected if the p values were <0.2 on univariate analysis. Manual backwards step-wise regression techniques were employed to obtain the final multivariable models.

Stata version 15.1 (Stata Corp, College Station, Texas, USA) was used to conduct the statistical analysis, with all tests two-sided and a p value of <0.05 considered to indicate statistical significance.

Results

Over the study period, 587 patients underwent emergency cholecystectomy based on a clinical diagnosis of cholecystitis by the treating surgeon. Patients were retrospectively classified according to TG18 (Table 1), with 150, 203 and 234 classified as ''clinical diagnosis only'', ''suspected diagnosis'' and ''definitive diagnosis'', respectively. Compared with "clinical diagnosis only" and "suspected diagnosis", "definitive diagnosis" patients were older and more gender balanced with ages at admission of 46.9, 44.5 and 50.7, respectively ($p = 0.002$), and 55.1% females compared with 72.0% and 71.4% in "clinical diagnosis only" and "suspected diagnosis" groups, respectively (Table 2). There was a significant difference in the admission and maximum pre-operative CRPs and WCCs between all three groups (Table 2). There was no significant difference in complications between all three groups (Table 3). Interestingly, there was no difference in length of stay between the groups and this is probably a reflection of the lack of difference in complication rate.

When comparing histological diagnosis of acute and acute on chronic cholecystitis to TG18 diagnosis, there was a successful rate of diagnosis of 33.5% when it was a "suspected diagnosis" and 61.5% when it was a "definitive diagnosis" (Table 3). Of the "clinical diagnosis only" patients, 21.3% had a missed diagnosis of either acute or acute on chronic cholecystitis. Thus, TG18 is useful in stratifying risk of acute or acute on chronic cholecystitis in our cohort, but given the high rate of false negatives, it does not replace clinical judgement.

There were 282 patients treated with emergency cholecystectomy in the 12-month pre-AGSU compared with 305 patients in the 12-month post-AGSU (Table 4). There were no significant differences in the age or gender of patients. Using ASA as a surrogate for patient comorbidities, there was no significant difference in the overall underlying health of patients before and after AGSU implementation. There was an increase in the number of histological diagnosis of acute and acute on chronic cholecystitis with 107

Table 2 Patient characteristics based on the diagnostic criteria of TG18

Factor	Clinical diagnosis only	Suspected diagnosis	Definitive diagnosis	*p* value
N	150	203	234	
Age at admission (years), mean (SD)	46.9 (19.3)	44.5 (17.9)	50.7 (17.7)	0.002
Gender				
Female	108 (72.0%)	145 (71.4%)	129 (55.1%)	<0.001
Male	42 (28.0%)	58 (28.6%)	105 (44.9%)	
Murphy's sign	24 (16.9%)	97 (48.0%)	122 (52.8%)	<0.001
RUQ tender/mass	59 (41.5%)	199 (98.5%)	233 (99.6%)	<0.001
CRP on admission, median (IQR)	3 (1, 13.3)	11.2 (4.15, 33.15)	12.6 (5.4, 46.3)	<0.001
Maximum CRP pre-op, median (IQR)	3.4 (1.4, 69.4)	18 (7.15, 81.6)	39.6 (11.1, 156.1)	<0.001
WCC on admission, median (IQR)	9.3 (7.4, 12)	11.05 (8.6, 13.6)	11.6 (9.5, 15)	<0.001
Maximum WCC pre-op, median (IQR)	9.4 (7.5, 12.9)	11.5 (9.3, 14.2)	12.5 (10, 15.8)	<0.001
Operating time (min), median (IQR)	85 (62, 110)	86 (65, 120)	95 (75, 120)	0.031
Lap/open				
Lap	145 (96.7%)	197 (97.0%)	224 (95.7%)	0.60
Open	3 (2.0%)	2 (1.0%)	2 (0.9%)	
Lap conv. open	2 (1.3%)	4 (2.0%)	8 (3.4%)	
LoS, median (IQR)	3 (2, 5)	4 (2, 5)	3 (2, 5)	0.55
90-day unplanned readmission	7 (4.7%)	7 (3.4%)	7 (3.0%)	0.68

Table 3 Patient outcomes based on the diagnostic criteria of TG18

Factor	Clinical diagnosis only	Suspected diagnosis	Definitive diagnosis	*p* value
N	150	203	234	
Clavien–Dindo grade				
None	132 (88.0%)	185 (91.1%)	201 (85.9%)	0.28
Grade 1 or 2	14 (9.3%)	14 (6.9%)	20 (8.5%)	
Grade 3 or 4	4 (2.7%)	4 (2.0%)	13 (5.6%)	
Death	3 (2.0%)	1 (0.49%)	1 (0.4%)	0.57
Histology				
Normal	1 (0.7%)	4 (2.0%)	2 (0.9%)	<0.001
Cholelithiasis, normal GB	19 (12.7%)	22 (10.8%)	6 (2.6%)	
Acute cholecystitis	16 (10.7%)	26 (12.8%)	77 (32.9%)	
Acute on chronic	16 (10.7%)	42 (20.7%)	67 (28.6%)	
Chronic cholecystitis	96 (64.0%)	106 (52.2%)	80 (34.2%)	
GB cancer	0 (0.0%)	1 (0.5%)	1 (0.4%)	
Other	1 (0.7%)	0 (0.0%)	1 (0.4%)	
N/A	1 (0.7%)	2 (1.0%)	0 (0.0%)	
Acute and acute on chronic cholecystitis	32 (21.3%)	68 (33.5%)	144 (61.5%)	<0.001
Any cholecystitis	128 (85.3%)	174 (85.7%)	224(95.7%)	<0.001

cases before and 137 cases (37.9% vs. 44.9%, $p = 0.087$) after AGSU implementation. This may account for the observed increase in operating time after AGSU implementation which increased from a median of 85 to 93 min ($p = 0.009$). There was a trend towards a shorter hospital stay (a decrease from a median 4 to 3 days, $p = 0.16$), of which the major contribution was a decrease in the time from diagnostic imaging to operation (median 2.5 vs.

Table 4 Comparing pre-AGSU and post-AGSU periods

Factor	Pre-AGSU	Post-AGSU	*p* value
N	282	305	
Age at admission (years), mean (SD)	47.1 (18.9)	48.1 (17.9)	0.51
Gender			
Female	191 (67.7%)	191 (62.6%)	0.19
Male	91 (32.3%)	114 (37.4%)	
Imaging to operation (days), median (IQR)	2.5 (1.4, 4.4) (n = 262)	1.7 (1.5, 3.5) (n = 289)	0.012
Time of operation			
8:00–17:00	173 (62.7%)	229 (75.8%)	<0.001
17:00–22:00	64 (23.2%)	27 (8.9%)	
22:00–8:00	39 (14.1%)	46 (15.2%)	
Operating time (min), median (IQR)	85 (60, 115)	93 (70, 121)	0.009
ASA			
1	54 (28.0%)	49 (26.3%)	0.33
2	100 (51.8%)	97 (52.2%)	
3	29 (15.0%)	36 (19.4%)	
4	10 (5.2%)	4 (2.2%)	
Histology			
Cholelithiasis and/or normal GB	30 (10.6%)	24 (7.9%)	0.246
Acute and acute on chronic cholecystitis	107 (37.9%)	137 (44.9%)	0.087
Chronic cholecystitis	142 (50.4%)	140 (45.9%)	0.28
Any cholecystitis	249 (88.3%)	277(90.8%)	0.32
LoS, median (IQR)	4 (2, 5)	3 (2, 5)	0.16
90-day unplanned readmission	11 (3.9%)	10 (3.3%)	0.69
Clavien–Dindo grade			
None	249 (88.3%)	269 (88.2%)	0.57
Grade 1 or 2	25 (8.9%)	23 (7.5%)	
Grade 3 or 4	8 (2.8%)	13 (4.3%)	
Death	5 (1.8%)	0 (0%)	0.020

1.7 days, $p = 0.012$). Additionally, there was a significant shift of operating to in-hours theatre time (62.7% vs. 75.8%) from evening operating (23.2% vs. 8.9%) ($p < 0.001$), with overnight operating between 2200 and 0800 unaffected.

Interestingly, by performing a multivariate analysis in predicting Clavien–Dindo grade 3 or 4 complications, there was no statistical correlation between TG18 diagnosis or period (pre-AGSU or post-AGSU) and Clavien–Dindo grade 3 or 4 complications (Table 5). Age was a significant predictor of Clavien–Dindo grade 3 or 4 complications ($p = 0.035$). A maximum CRP pre-operative value of 26.6 mg/L maximized the prediction performance of CRP in predicting Clavien–Dindo grade 3 or 4 (odds ratio 3.86, $p = 0.026$). Thus, in our cohort, a CRP > 26.6 mg/L was more important than TG18 diagnosis in predicting major complications after emergency cholecystectomy.

Table 5 Odds ratio of variables in predicting Clavien–Dindo grade 3 or 4 complications

Factor	OR	95% CI	*p* value
Period			
Pre-AGSU	1	–	–
Post-AGSU	1.38	0.55–3.47	0.498
Cholecystitis diagnosis			
Clinical diagnosis only	1	–	–
Suspected diagnosis	0.69	0.16–2.92	0.612
Definitive diagnosis	1.50	0.46–4.91	0.501
Age at admission (years)	1.03	1.002–1.056	0.035
Maximum CRP pre-op > 26.6	3.86	1.18–12.63	0.026

There were five deaths in the patient cohort, all in the pre-AGSU era. Two patients, an 85-year old and an 83-year old, were transferred from regional centres with

septic shock and multiorgan failure. The 85-year old had a gallbladder empyema at operation, but ongoing multiorgan failure was palliated 7 days post-operatively. The 83-year old had only chronic cholecystitis and had a rapid continuing deterioration post-operatively and was palliated 15 h later. An 85-year old with severe medical comorbidities presented with a gangrenous gallbladder but developed oliguric renal failure post-operatively and eventually succumbed 5 days later with the patient declining intervention. An 83-year old who had an NSTEMI 1 month earlier is presented with septic shock, renal and hepatic failure with acute cholecystitis. Post-operatively the multiorgan failure worsened and was complicated by a post-operative bleed requiring a 3 unit blood transfusion and laparotomy, although no bleeding source was found. The patient died 12 h later from deteriorating multiorgan failure. The fifth patient, an 83-year old, died 43 days post-operatively in a transitional care facility with worsening chronic kidney failure, and heart failure after these diagnoses had deteriorated with cholecystitis and cholangitis that were treated with cholecystectomy and on table ERCP.

Patients with a TG18 "definitive diagnosis" were then analysed according to the time of day and time from admission to operation (Fig. 1). Surprisingly, there was a trend towards higher complications and readmissions for patients operated within 24 h, although this trend was not significant. There was also no association between time from triage to operation, operative time of day and the outcomes of Clavien–Dindo grade and/or 90-day unexpected readmissions in the overall cohort (Fig. 2). Therefore, there was no statistical difference overall in outcome for TG18 "definitive diagnosis" patients; this may be due to these patients getting treated earlier and more intensely during in-hours when consultant surgeons are on-site.

Discussion

Early cholecystectomy for cholecystitis has been shown to improve patient outcomes, reduce patient symptoms, shorten length of stay and reduce hospital cost [13]. Thus, the current issues for a major metropolitan centre with competing interests after the same resources are to identify which patients with suspected cholecystitis are at higher risk of complications if cholecystectomy is delayed, and to also dedicate resources to treat all patients with suspected cholecystitis so that the less urgent patients are not waiting for many days for treatment.

TG18 have been developed to aid with the diagnosis and treatment of cholecystitis [8]. AGSU implementation has been shown to aid with resources and theatre access for patients with suspected cholecystitis [14, 15]. The role of using TG18 within an AGSU has yet to be determined, with potential benefits in prioritizing patients for early cholecystectomy and reduction in complications.

TG18 uses clinical examination signs, blood test results, and imaging features to aid with the diagnosis of acute cholecystitis, and this has been validated in the literature [8]. The guidelines quote very high sensitivity and specificity, whereas our cohort falls well below that when we compare TG18 patients with their histological diagnoses. This may be due to a slight difference in the upper limit of

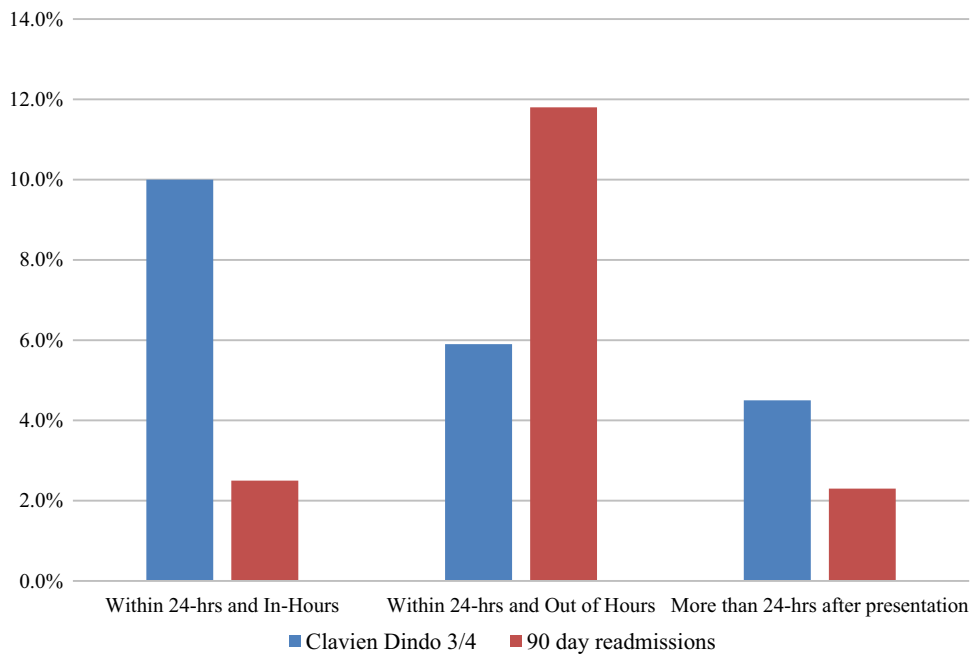

Fig. 1 Clavien–Dindo 3/4, 90-day readmissions of definitive diagnosis of acute cholecystitis by time from triage to operation

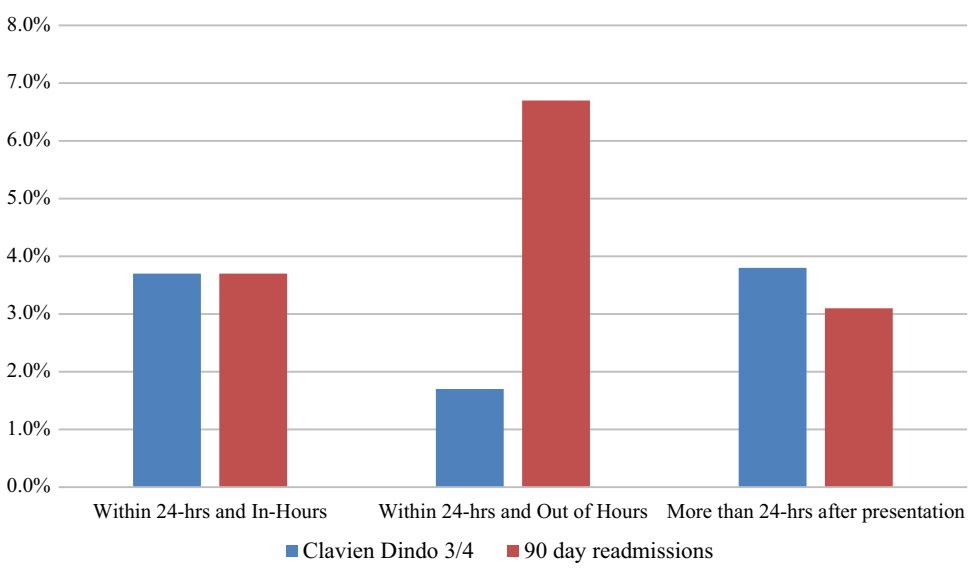

Fig. 2 Clavien–Dindo 3/4 and 90-day readmissions of all emergency cholecystectomy by time from triage to operation

normal range of WCC and CRP. A normal upper limit of WCC is defined as 12×10^9/L (g/L) and that of CRP is 3 g/L. TG18 uses a value above 18,000/mm^3, and therefore a higher threshold for infection and inflammatory markers may contribute to a better sensitivity and specificity of TG18 [8].

The older age group (>65 years) and elevated CRP have been shown to be independent risk factors for acute perforation of gallbladder, and are associated with significantly higher post-operative complications compared to non-perforated cases [16]. CRP/albumin ratio has also been associated with TG18 severity grade II/III acute cholecystitis; however, it did not correlate with post-operative complications [17]. While TG18 uses CRP within its score, there is scant literature comparing CRP alone to TG18. By using the TG18 severity grading system for acute cholecystitis, a recent study conducted in Turkey showed a correlation between CRP levels and the severity grades with a mean value of 18.96 mg/L in patients with grade I severity, 133.51 mg/L in grade II and 237.23 mg/L in grade III [18]. In our cohort, TG18 criteria did not significantly predict complications post-operatively; however, a CRP > 26.6 mg/L was significant on multivariate analysis. This may demonstrate that CRP is a better predictor than TG18 in its entirety, but this may be due to treatment of the sicker patients in our cohort earlier and more intensely which negates the effect of TG18. This is difficult to show retrospectively with ASA a poor marker for critical illness, and future studies will require prospective data collection. It would also suggest that in our institution, clinical acumen to determine the priority of patients may function as well as TG18.

The introduction of an AGSU model of care has been previously studied and demonstrated inconsistent differences between pre- and post-AGSU periods in time to theatre for patients requiring emergency surgery. Two studies show a positive outcome of reduction in median time delay to theatre [15, 19], three studies show no difference in median time to theatre [14, 20, 21], and one study shows a worsening delay to theatre [22]. In our cohort, there was a significantly shorter time duration from imaging to operation from 2.5 to 1.7 days following AGSU implementation, and although there was a trend towards a decreased in length of stay (4–3 days), this was not significant. This may be due to type B error or may simply suggest that more resources and operating availability are required. Our study demonstrates a significant increase in in-hours operating (08:00–17:00) from 62.7 to 75.8% following AGSU implementation. This is in keeping with findings in various studies conducted from hospitals worldwide [20, 21, 23, 24]. We did not demonstrate any difference in complications or readmission rates for cholecystectomy with the introduction of AGSU. This is also similar to other AGSU model studies [15]. Thus, the major benefit of AGSU appears to be efficiency in treating patients with suspected cholecystitis and the underappreciated benefit of surgeon satisfaction in decreasing after hours operating for patients that can be safely treated in protected and dedicated time the following day.

Our data demonstrate an increase in acute and acute on chronic cholecystitis histological diagnoses in the post-AGSU period. Our hypothesis for this is that AGSU allows for greater access to resources and theatre, driving surgeons to perform acute cholecystectomy on sicker and more comorbid patients that might have otherwise been treated conservatively prior to implementation of AGSU. These patients would be expected to have higher complication rates and more acute histology, thus explaining why we do

not see the expected decrease in complication rate in the post-AGSU period. A prospective study would be required to answer this, and this is a future research aim for our institution.

When TG18 criteria and the advances of AGSU (improved access to theatre) were combined (Fig. 1), there were no significant differences in major complications or readmission rates for patients with a "definitive diagnosis". This supports the treatment of these patients in our cohort, as without early surgery, it has been shown that these patients have a higher complication and readmission rate [13]. In fact, with a properly resourced AGSU, it is possible that this negates the useful effect of classifying patients according to TG18, with the benefits of TG18 being restricted to health services with fewer resources. In our institution, it was deemed that the AGSU model was required to maintain the resources and theatre access required for these patients, and thus we support this as a future model of care for major metropolitan centres.

In conclusion, CRP $>$ 26.6 mg/L has been shown a better predictor of moderate-to-severe complications than TG18 in Northern Health patient cohort; however, this may be due to clinical acumen and improved resources for treating critically unwell patients. TG18 definitive diagnosis patients may have similar outcomes to all patients clinically diagnosed with cholecystitis in the setting of a well-resourced AGSU.

Author contributions YL, MM, AY and RH conceived and designed the study. YL, MM and AY collected data. MT performed statistical analysis. YL drafted the manuscript. RH and DB provided senior supervision and contributed to the direction of the project. All authors edited the manuscript and approved the final version for submission.

Compliance with ethical standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical Approval Number HREC ALR 04.2017

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