

Katherine Tse

The establishment of a tertiary level upper gastrointestinal/Hepatopancreatobiliary (UGI/HPB) surgical unit



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Sponsor: The Surgical Research Trust

The Wellington Hospital Upper GI/HPB Surgical unit was set up in 2006. The large multidisciplinary team has performed various major UGI/HPB operations such as Oesophagogastrectomy, Whipple's Procedure, Liver Resection and Distal Pancreatectomy. UGI/HPB surgeries involve high risks which can be complicated by serious pathologies such as invasive carcinoma.

The process of Surgical Admissions requires much expertise and comprehensive recovery care. From diagnosis, to procedure to recovery, the process is dependent on clinical input, cohesiveness and interaction between different specialities.

With 184 elective major UGI/HPB operative cases from 2006-2011 the unit has had a high success rate. The unit aims to provide and maintain this quality care with the morbidity and mortality incidence rates postulated to be 35% and 5% respectively.

This retrospective clinical audit evaluates the outcomes of all the major UGI/HPB surgeries conducted by this team. An overall morbidity of 21.7% was found, with a higher rate of 36.4% morbidity in Pancreatic Procedures (33 cases) and 31.1% in Oesophagogastric Procedures (45 cases). A low morbidity rate of 19.1% was demonstrated in the Liver Procedures (47 cases).

An overall mortality of 1.1% was found. These two cases were both in the ≥ 71 age group. Both patients had gastric lesions, one having adenocarcinoma and the other having a neuroendocrine tumour of the lesser omentum.

As a Tertiary Level UGI/HPB unit in Wellington Hospital, an overall low morbidity and mortality rate exhibits the cohesiveness of Surgeons, Nurses, Anaesthetists, Radiologists, ICU Specialists and auxiliary disciplines in high quality UGI/HPB care.

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SCIENTIFIC REPORT

THE ESTABLISHMENT OF A TERTIARY LEVEL UPPER GASTROINTESTINAL/ HEPATOPANCREATOBILIARY (UGI/HPB) SURGICAL UNIT

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Sponsored by The Surgical Research Trust

•Introduction

The Wellington Upper Gastrointestinal/Hepatopancreatobiliary (UGI/HPB) Surgical Unit was established in June 2006. It was set up as a specialist Multi-Disciplinary-Team (MDT) to select, perform, support and evaluate eligible cases for surgical intervention in Wellington Hospital. This team is headed by two consultant Upper Gastrointestinal/Hepatopancreatobiliary Surgeons and performs regular peer review, radiology review and morbidity and mortality meetings with other surgical teams to assess and evaluate their performance.

Case selection for elective surgery is based on initial assessment by the specialist staff, followed by formal discussion at a multidisciplinary team meeting with input from other disciplines such as Radiology, Oncology, Gastroenterology and Pathology. Preoperative assessment is undertaken at dedicated pre-assessment anaesthetic clinics whereby surgical and anaesthetic teams optimise risk management. The cases involved are predominately from the Wellington region, with some transfers or elective referrals from surrounding regions such as Whanganui, Blenheim and Nelson. Following case selection, appropriate patients undergo a staging laparoscopy and/or relevant minor procedures (such as port-a-cath insertion) where it is determined whether the lesion is operable or if there are concomitant pathologies that may alter the care plan.

During the time of operation a team of Surgeons, Anaesthetists, Intensive Care Unit (ICU) specialists, Haematologists, Physiotherapists, Radiologists and respective Nurses are involved in procedure and recovery. This includes pre-operative assessment and ward assessment prior to surgery, post-anaesthetic care and ward support following theatre. The majority of patients are admitted to the High Dependency Unit (HDU) for the first 24 hours after surgery.

Once discharged, follow up in the Outpatient clinic are provided by the Surgical Team and further assessment and management is provided until the patient is deemed independent of any further medical assistance.

Given the small population of New Zealand, compared to other units worldwide this is a low volume unit, however within New Zealand, this unit has a high flow of UGI/HPB procedures. Comparisons between high and low volume centres such as those in the UK are often used to strengthen the movement for centralisation of tertiary specialties(1). However, there is debate over the volume-outcome relationship, ie the causation between hospital flow and morbidity and mortality (2). Some studies have found that

there is a statistically significant association between high hospital volume and lower mortality risk with certain types of surgery such as oesophagectomy and pancreatic resection(1)(3). Both these studies have the converse relationship for gastrectomy or hepatectomy.

•Aim & Hypothesis

To evaluate the morbidity and mortality complications of major upper gastrointestinal and hepatopancreatobiliary surgeries performed by this unit. It is postulated that this unit has a morbidity rate of 35% and mortality of 5% and is in keeping with other units internationally.

•Design

This is a retrospective clinical audit looking at the major UGI/HPB surgeries conducted by this unit in Wellington Hospital. Theatre lists recorded by official hospital databases were obtained plus associated laparoscopic, exploratory, biopsy and aborted procedures. Each case underwent inclusion/exclusion criteria. Major UGI/HPB surgeries were those involving resection and/or anastomotic formation, repair of giant hiatus hernia, achalasia or gastroesophageal reflux disease (GORD).

Each case was investigated with the use of theatre information, ICU databases, MAP recording systems. Additional information such as indications, co-morbidities, return to ICU, re-operations, hospital stay, intraoperative details, post operative morbidity and mortality and blood transfusions were also recorded.

If any disparities were found there was discussion with the surgeons and physical patient notes were obtained.

The outcome of measure was major morbidity complications and mortality which were classified using the Clavien-Dindo classification of surgical complications(4)(see appendix 1). Complications were graded according to intervention required to treat morbidity. Outliers were compared to the examples provided by the Clavien-Dindo recommendations(4) (see appendix 2). Patients with multiple complications of differing severity were classified according to the morbidity with most intervention, thus the type of complications were recorded as events rather than the main event per patient to highlight the prevalence of complications following major surgery.

Crude case numbers were stratified into sex, age, ASA, operation, complication type and co-morbidities. Age stratification was selected from the options <61, 61-70, >70years, which was adopted from the P-POSSUM scoring system(5) - a tool for measuring physiological and operative severity score of morbidity and mortality. The full P-POSSUM assessment was not used in the study as the parameters required for the POSSUM calculation were not consistently available in retrospective data collection.

•Rationale

The purpose of this clinical audit is to evaluate the performance of this unit established in 2006. No formal, collaborative audit assessing the five year performance has previously been conducted. This audit is to provide a report of the major morbidities and mortalities experienced by patients undergoing major UGI/HPB surgeries.

•Results

A total of 184 elective cases were included in this clinical audit. 52.2% were male and 47.8% were female with the average age of 57 years. Excluded from this audit were 16 aborted cases and 12 unplanned re-operations that followed major UGI/HPB surgery.

Major morbidity was defined as a Clavien-Dindo complication score of Grade 3 or higher. In total, 45.1% of patients experience no morbidity, 33.2% of patients experience mild morbidity which had little effect on recovery, and 21.7% of patients experienced major morbidity, and two cases progressed to mortality (1.1%)

Clavien-Dindo Surgical Complication Grading		
Grading	No	Percentage
0	83	No Morbidity = 45.1%
1	26	Minor Morbidity = 33.2%
2	35	
3a	22	Major Morbidity = 21.7%
3b	11	
4a	4	
4b	1	
5	2	

Major morbidity rates were variable between different operations. The most common surgery in the 2006-2011 timeframe were liver procedures (laparoscopic and open)- 46 resections and one deroofing of cyst, followed

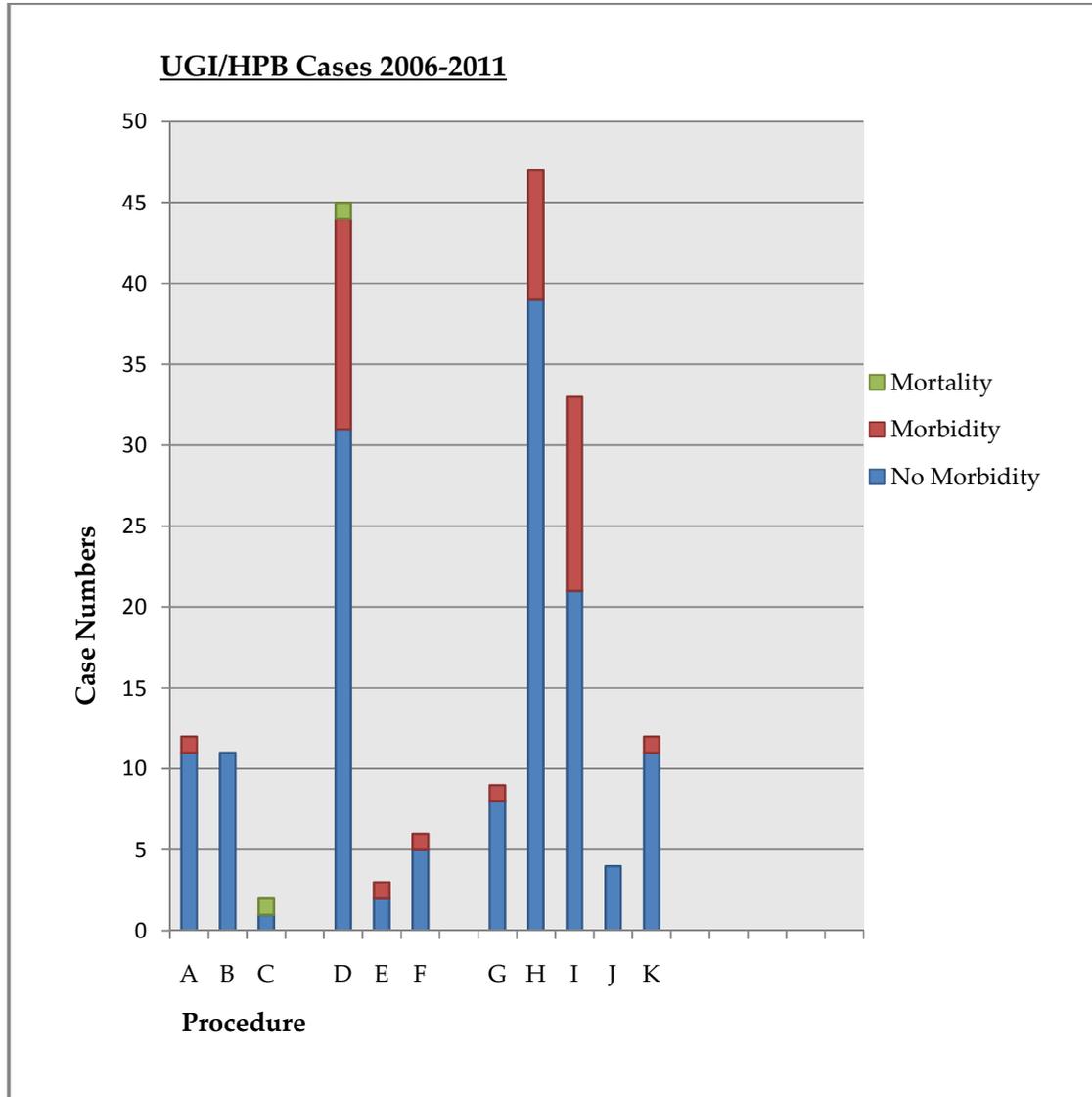
by oesophagogastric procedures-subtotal gastrectomy, total gastrectomy, oesophagogastrectomy (45 cases). Both operations are high risk and lengthy procedures with a median operation time of 5:16 and 7:41 hours respectively.

The highest major morbidity rates were associated with Pancreatic Procedures (Whipples, Distal Pancreatectomy, Enucleation) at 36.4%.

Procedures with low morbidity were laparoscopic procedures Hellers Myotomy (0%) – 11 cases, and Nissen Funduplications+Giant Hiatus Hernia repair (8.3%) – 12 cases.

“Other Laparotomy Procedures” included Gastrojejunostomy and Oversew of Aorto-Duodenal fistula.

<u>Laparoscopic</u>	Grade 3+ Morbidity	Mortality	Median Hosp Stay
A.Nissen Fundoplication+Gastropexy/Fundopexy+Giant Hiatus Hernia Repair(12)	1(8.3%)	0	2(2-12)
B.Hellers Myotomy(11)	0	0	3(2-10)
C.Other Laparoscopic Procedures(2)	1(50%)	1(50%)	4(3-4)
<u>UGI</u>			
D.Oesophagogastric Procedures(45)	14(31.1%)	1(2.2%)	16(5-97)
E.Bypass Procedures(3)	1(33.3%)	0	30(16- 42)
F.Other Laparotomy Procedures(6)	1(16.7%)	0	40(9-87)
<u>HPB</u>			
G.Liver – Biliary(9)	1(11.1%)	0	10(7-24)
H.Liver – Resection/Cyst(47)	8(19.1%)	0	9(2-45)
I.Pancreatic Procedure(33)	12(36.4%)	0	17(7- 171)
J.Pancreatic Cystogastrostomy(4)	0	0	12(9-14)
K.Splenectomy(12)	1(8.3%)	0	6(2-10)
TOTAL(184)	40(21.7%)	2(1.1%)	



Demographically, 62.5% of major morbidity was experienced by male patients. Patients in the age bracket ≥ 71 years were 1.38 times as likely to have a major complication compared to those aged ≤ 70 . The two cases of mortality were all in the ≥ 71 age demographic.

Patient Demographics						
Age	Total	%	+Grade3/+ Complic.	%	+ Mortality	%
≤60	94	51.1	16	8.7	0	0
61-70	58	32.0	15	8.2	0	0
≥71	32	17.4	9	4.9	2	1.1
Total	184		40	20.7	2	1.1

Patient physiological state prior to surgery described by the ASA score covered a range of 1-4. Most surgeries were performed on patients with ASA of 2 – patient having mild systemic disease (55.4%)(5). 36.4% of cases were ASA 3 and 0.5% of cases were ASA 4.

ASA 3 morbidity rate was 20.9% and ASA 2 was 23.5%. ASA 2 patients were 1.12 times as likely to have major complications compared to ASA 3 patients, and 1.64 times as likely to have major complications compared to ASA 1 patients.

Two mortalities occurred in ASA 2 patients. One mortality occurred in a patient who had an initial procedure of total gastrectomy then three days later required an emergency ASA 4E laparotomy. A second patient died of non-GI causes after discharge.

ASA	Number	%	+Morbidity	%total	Mortality	%total
1	14	7.6	2	1.1	0	0
2	102	55.4	24	13.0	2	1.1
3	67	36.4	14	7.6	0	0
4	1	0.5	0	0	0	0

Co-morbidities were concomitant in many cases of complication. Both patient's who died had multiple co-morbidities. Complication was prevalent in 29.7% of patients recorded as being a current or former smoker.

COMORBIDITIES	Total	%	+ Grade3/+ Complication		+ Mortality %	
Cardiovascular Disease	58	31.5%	16	8.7%	1	0.5%
Pulmonary Disease	20	10.9	2	1.1	0	0
Renal Disease	7	3.8	3	1.6	0	0
Diabetes Mellitus	25	13.6	6	3.3	0	0
Smoker – current or ex	37	20.1	11	6.0	0	0
Neurological	9	4.9	3	1.6	0	0

The specific complications according to the Clavien-Dindo classification were calculated as events due to patients often having multiple complications throughout their hospital stay. Grade 2 events have been included in the following table to examine minor morbidity closely.

Rate of complication was calculated by number of events divided by number of those at risk of that complication. For example, only 54 patients were at risk of having an anastomotic leak – 45 oesophagogastric patients, 3 bypass and 6 other laparotomy.

Expectedly, the lower grades of complication have higher frequency of occurrence. 19 transfusions were required, of note 6 of these patients underwent oesophagogastric operations, 5 underwent liver surgery and four had a splenectomy. Pulmonary issues such as pneumonia requiring antibiotic treatment and physiotherapy were common minor complications.

The most common grade 3a complications were pancreatic leaks that did not require GA rather surgical drainage and close observation.

Lymphatic Leaks occurred in 5 cases, three requiring re-operative repair thus graded 3b, the other two were minor and effectively managed conservatively.

Readmissions to the ward following hospital discharge are those requiring surgical care considered imperative to recovery. Examples include JJ feeding tube detachment.

COMPLICATION EVENTS	No.	%
Grade 2 – Pharmacological Treatment (184)		
Pulmonary	15	8.2
Renal	1	0.5
GI	4	2.2
Wound Infxn	9	3.3
Surgical Site Infxn	1	0.5
Blood Transfusions	19	10.3
SVT	1	0.5
MI	2	1.1
PE	1	0.5
Grade 3a – requiring further intervention not under GA		(according to procedure)
Wound Dehiscence/Vac dressing (184)	2	1.9%
Anastomotic Leak (54)	3	5.6
Pancreatic Leak (33)	4	12.1
Biliary Leak(9)	1	11.1
Lymphatic Leak(184)	2	1.1
DVT(184)	1	0.5
ERCP + Stenting (9)	1	11.1
Site Abscess requiring CT guided drainage(184)	1	0.5
Unplanned return to ICU(184)	3	1.6
Readmission to Ward following D/C(184)	3	1.6
Grade 3b – requiring further intervention under GA		
Unplanned Laparotomy for leak + ICU (184)	4	2.2%
Unplanned Laparotomy for bleed + ICU(184)	3	1.6
Unplanned Laparotomy for Ischaemic bowel(184)	2	1.1
Unplanned Laparoscopy (184)	1	0.5
Iatrogenic requiring additional surgical care(184)	2	1.1
Grade 4a – Life Threatening Complication(184)		
Respiratory Failure	3	1.6
Pancreatitis	1	0.5
CardioVascular	1	0.5
Grade 4b		
Multi organ dysfunction	1	0.5
Grade 5 - Mortality		
	2	1.1

There were 12 re-operations under general anaesthetic (Grade 3b), two of which were on the same patient who had a Whipples procedure. The most common cause for re-surgery was for leaks of lymphatic nature. It should be noted when crude numbers for reoperation are compared to those at risk from that procedure, return to theatre rates are relatively low.

Of the 184 cases, there were 2 deaths – a 1.1% mortality rate. These cases both had ASA 2 immediately prior to theatre and were 71 years or older.

The first mortality was a 76 year old male who initially underwent a total gastrectomy for adenocarcinoma of the stomach with an ASA 2 and comorbidities of hypertension and recent chemotherapy. Following a 21 hour routine stay in ICU he was admitted to the ward where he developed oliguria, vomiting, oxygen desaturations, small bowel ischemia and severe metabolic acidosis. The patient was returned to theatre three days later for resection of ischaemic small bowel with an ASA 4E. Recovery in ICU following the reoperation was poor, oxygen saturation was not maintained and renal function declined further despite maximal fluids, dialysis and inotropic support. The patient died in ICU 29 hours later from aspiration pneumonitis secondary to ileus and ischaemic bowel resulting from total gastrectomy.

The second death was a 71 year old man with a neuroendocrine tumour of the lesser omentum. A gastroscopy 3 month prior revealed a small sliding hiatus hernia, otherwise he had minimal medical history. He had an ASA of 2 and underwent a laparoscopic resection of the gastric tumour. Post-operatively he had discomfort with breathing and was given chest physiotherapy and occupational therapy. On day two post-operatively he was well and discharged home. Day three post-operatively the patient died at home, a post mortem revealed cause of death was a myocardial infarction.

•Discussion

Overall the results of this clinical audit imply that the complication rate of major upper GI/HPB surgeries performed by this unit is 20.7% major morbidity and 1.1% mortality.

Comparisons to other units who have undertaken similar audits using the Clavien-Dindo classification scheme can be made.

A paper on surgical complications following procedures for oesophageal and gastroesophageal cancer written by Lerut and Moons has a 34.7% major morbidity and 1.4% mortality (138 cases)(6). A similar study by Montenovo and Chambers has a major morbidity rate of 6.0% and mortality of 1.4% (37

cases). When closely analysed, this paper had reported 13 anastomotic leaks which were classified as Grade 1 complications. These were resolved with bedside opening of the wound and packing or drainage(7), this is a serious and potentially life-threatening complication and should have been graded higher, thus increasing their morbidity rate. (7). Lee and Park's study showed Open Distal Gastrectomy had a 5.4% major complication rate and 0.8% mortality in 629 patients(8). For oesophagogastric procedures this unit demonstrates a 31.1% morbidity and 2.2% mortality (45 cases) thus performing between these two studies.

Breitenstein and DeOliveira's study on Liver Resection on 615 patients showed 26% major morbidity and 3% mortality. These were performed at the Swiss HPB Centre, University Hospital in Zurich(9). This unit performed well with 19.1% morbidity and 0% mortality in 47 cases.

Braga and Capretti's study on Pancreaticoduodenectomy had 700 cases, a 16.7% major morbidity and 3.9% mortality(10). Casadei and Ricci's study on 61 distal pancreatectomy patients had a 11.4% morbidity and 0% mortality(11). This unit had 36.4% morbidity and 0% mortality in 33 cases, performing lower than the mentioned studies.

Cocieru and Saldinger's audit of pancreatic, liver and biliary surgical cases in a small volume HPB centre (140 patients) had a major morbidity rate of 2.7% and 0.7% death(12). This unit had a collective HPB morbidity of 23.6% (21/89) and 0% death.

It should be noted that case numbers in this audit are small compared to worldwide surgical units, thus in time as a bigger sample size is available results will have a higher statistical significance.

The retrospective design of this clinical audit meant that information provided was reliant on the accuracy of recording methods. There were occasional disparities between sources of information, thus the original documents were sourced plus reviewed by the surgeons. Contextual parameters such as smoking and past medical history were included in information collection as they were recorded ie. if they were not mentioned in information sources it was assumed to be nil. Although this assumption would change the accuracy of results it was not viable to investigate such information for all cases.

The Clavien-Dindo classification was used as an objective and comparable means of reporting surgical complications. Many reports using the Clavien-

Dindo classification for Upper GI or HPB surgeries considered major or severe complications as Grade 3a or higher(11)(8). A Clavien-Dindo self – evaluation eluded to the variability in threshold for ‘major complication’, with one paper considering grade 3a as moderate, and 3b or higher as major complications(13).

The clear classification method proved applicable to this unit’s surgical outcomes and the example table assisted in determining grading of questionable morbidities.

As a Tertiary Level UGI/HPB unit an overall low morbidity of 21.7%, and mortality rate of 1.1% exhibits the cohesiveness and success of the multidisciplinary teams involved in these types of surgeries.

Compared to international units the Wellington Hospital UGI/HPB unit has performed well and this can be attributed to expertise of Surgeons, Radiologists, Nurses, ICU specialists, Anaesthetists and auxiliary disciplines who have produced high quality UGI/HPB care.

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•Acknowledgments

Thank You to

Mr Susrutha K. Wickremesekera

Mr Simon Bann

Dr Peter Hicks

Dr Dorothy Dinesh

Ankh Spice

Tina Uiese

James Norman

Gloria Ashton

Ari Pfeiffenberger

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Appendix

1.

Grade	Definition
Grade I	Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic, and radiological interventions Allowed therapeutic regimens are: drugs as antiemetics, antipyretics, analgesics, diuretics, electrolytes, and physiotherapy. This grade also includes wound infections opened at the bedside
Grade II	Requiring pharmacological treatment with drugs other than such allowed for grade I complications Blood transfusions and total parenteral nutrition are also included
Grade III	Requiring surgical, endoscopic or radiological intervention
Grade IIIa	Intervention not under general anesthesia
Grade IIIb	Intervention under general anesthesia
Grade IV	Life-threatening complication (including CNS complications)* requiring IC/ICU management
Grade IVa	Single organ dysfunction (including dialysis)
Grade IVb	Multiorgan dysfunction
Grade V	Death of a patient
Suffix "d"	If the patient suffers from a complication at the time of discharge (see examples in Table 2), the suffix "d" (for "disability") is added to the respective grade of complication. This label indicates the need for a follow-up to fully evaluate the complication.

*Brain hemorrhage, ischemic stroke, subarachnoid bleeding, but excluding transient ischemic attacks.
CNS, central nervous system; IC, intermediate care; ICU, intensive care unit.

2.

Grades	Organ System	Examples
Grade I	Cardiac	Atrial fibrillation converting after correction of K ⁺ -level
	Respiratory	Atelectasis requiring physiotherapy
	Neurological	Transient confusion not requiring therapy
	Gastrointestinal	Noninfectious diarrhea
	Renal	Transient elevation of serum creatinine
Grade II	Other	Wound infection treated by opening of the wound at the bedside
	Cardiac	Tachyarrhythmia requiring β-receptor antagonists for heart rate control
	Respiratory	Pneumonia treated with antibiotics on the ward
	Neurological	TIA requiring treatment with anticoagulants
	Gastrointestinal	Infectious diarrhea requiring antibiotics
Grade IIIa	Renal	Urinary tract infection requiring antibiotics
	Other	Same as for I but followed by treatment with antibiotics because of additional phlegmonous infection
	Cardiac	Bradycardia requiring pacemaker implantation in local anesthesia
	Neurological	See grade IV
	Gastrointestinal	Biloma after liver resection requiring percutaneous drainage
Grade IIIb	Renal	Stenosis of the ureter after kidney transplantation treated by stenting
	Other	Closure of dehiscence noninfected wound in the OR under local anesthesia
	Cardiac	Cardiac tamponade after thoracic surgery requiring fenestration
	Respiratory	Bronchopleural fistulas after thoracic surgery requiring surgical closure
	Neurological	See grade IV
Grade IVa	Gastrointestinal	Anastomotic leakage after descenderectostomy requiring relaparotomy
	Renal	Stenosis of the ureter after kidney transplantation treated by surgery
	Other	Wound infection leading to eventration of small bowel
	Cardiac	Heart failure leading to low-output syndrome
	Respiratory	Lung failure requiring intubation
Grade IVb	Neurological	Ischemic stroke/brain hemorrhage
	Gastrointestinal	Necrotizing pancreatitis
	Renal	Renal insufficiency requiring dialysis
	Cardiac	Same as for IVa but in combination with renal failure
	Respiratory	Same as for IVa but in combination with renal failure
Suffix "d"	Gastrointestinal	Same as for IVa but in combination with hemodynamic instability
	Neurological	Ischemic stroke/brain hemorrhage with respiratory failure
	Renal	Same as for IVa but in combination with hemodynamic instability
	Cardiac	Cardiac insufficiency after myocardial infarction (IVa-d)
	Respiratory	Dyspnea after pneumonectomy for severe bleeding after chest tube placement (IIIb-d)
Suffix "d"	Gastrointestinal	Residual fecal incontinence after abscess following descenderectostomy with surgical evacuation. (IIIb-d)
	Neurological	Stroke with sensorimotor hemiparesis (IVa-d)
	Renal	Residual renal insufficiency after sepsis with multiorgan dysfunction (IVb-d)
	Other	Hoarseness after thyroid surgery (I-d)

TIA, transient ischemic attack; OR, operating room.