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Reduction of Surgical Mortality and Morbidity in Diabetic Patients undergoing Cardiac Surgery with a Combined Intravenous and Subcutaneous Insulin Glucose Management Strategy

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Running Title: Glycemic Control and Cardiothoracic Surgery Outcomes

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Abstract

Objective: To determine if glucose management in post-cardiothoracic (CT) surgery patients with a combined intravenous (IV) and subcutaneous (SC) insulin regimen reduces mortality and morbidity in patients with diabetes and stress-induced hyperglycemia.

Research Design and Methods: Retrospective review of 614 consecutive patients who underwent CT surgery in 2005 was performed to evaluate the incidence and treatment of postoperative hyperglycemia and operative morbidity and mortality. Hyperglycemic patients (glucose >6.05mmol/L) were treated with IV insulin in the ICU followed by SC insulin (outside ICU). Subgroup analysis was performed on 159 coronary artery bypass graft (CABG) -only patients.

Results: Among all CT surgeries, patients with a preoperative diagnosis of diabetes had higher rates of postoperative mortality (7.3% vs. 3.3%; $p=0.03$) and pulmonary complications (19.5%vs. 11.6%; $p=0.02$), but had similar rates of infections and cardiac, renal and neurologic complications on univariate analysis. However, on multivariate analysis a preoperative diagnosis of diabetes was not a significant factor in postoperative mortality or pulmonary complications. In CABG-only patients, no significant differences were seen in outcomes between diabetic and non-diabetic patients. Independent of diabetic status, glucose $\geq$ 11 mmol/L on ICU admission was predictive of higher rates of mortality and renal, pulmonary, and cardiac postoperative complications.

Conclusions: A combination of IV insulin (in the ICU) and SC insulin (outside the ICU), a less costly and less nursing-intensive therapy than 3 days of IV insulin postoperatively, results in a reduction of the increased surgical morbidity and mortality in diabetic patients following cardiothoracic surgery.

Introduction

The leading cause of death among individuals with diabetes is cardiovascular disease and the prevalence of diabetes among patients undergoing coronary artery bypass grafting (CABG) has been reported as high as 34% (1). Historically, diabetic patients have had worse surgical outcomes when compared to those without diabetes, specifically higher perioperative mortality (2), deep sternal wound infections (3), postoperative strokes, and longer length of hospital stays (4). Surgical outcomes have been associated with the presence and degree of hyperglycemia in the post-operative period independent of a prior diagnosis of diabetes (5).

Following cardiac surgery, most patients are sent to the intensive care unit (ICU) and even a modest degree of hyperglycemia occurring after ICU admission is associated with a substantial increase in hospital mortality (5). Glucose control via continuous intravenous (IV) insulin infusions for three days postoperatively has been shown to eliminate the incremental increase in in-hospital mortality and deep sternal wound infection rates after coronary artery bypass grafting associated with diabetes (3,6).

Practically, however, continuous insulin infusions are extremely labor-intensive and costly so that it would be ideal to determine whether similar glycemic control using a subcutaneous (SC) insulin protocol can achieve similar benefits. A protocol has been established at Northwestern Memorial Hospital (NMH) that is designed to achieve normoglycemia (4.4-6.05 mmol/L) using IV insulin for the immediate post-operative period with transition to a SC insulin regimen upon resolution of critical illness, initiation of oral intake, and transfer out of the ICU (7).

The primary objectives of this study were to determine if glucose management in post-cardiothoracic (CT) surgery patients with a combined IV and SC insulin regimen reduces mortality and morbidity in diabetic patients and, in those diabetic patients undergoing CABG only, compare surgical outcomes with studies in which patients receive 3 days of continuous intravenous insulin.

Research Design and Methods

A retrospective review of 622 consecutive patients who underwent cardiothoracic (CT) surgery between 1/1/2005 and 12/31/2005 at NMH, a 776-bed tertiary care center in Chicago, Illinois was performed to evaluate the incidence and treatment of postoperative hyperglycemia and operative morbidity and mortality. Out of 622 patients, eight cases were excluded: five died during the initial procedure, one had a sternal wire removed and was not admitted to the hospital post-operatively, one had a cardiac laceration with hemopericardium and was not under the primary care of cardiac surgeons postoperatively, and one was a duplicate entry into the surgical database. After exclusions, the study population consisted of 614 patients. A predefined subgroup analysis was also performed on 159 consecutive patients who underwent CABG only.

Glucose data was collected from patient medical records. Outcomes data was extracted from the Society of Thoracic Surgeons (STS) Adult Cardiac Surgery Database collected by NMH cardiothoracic surgeons. Approval for this study was granted by the Northwestern University Institutional Review Board.

The primary outcome of this study was postoperative mortality as defined in the STS database. Secondary outcomes included the incidence of deep sternal wound infection, other infections, pulmonary complications, cardiac complications, renal complications, neurological complications, and readmission to the hospital within 30 days of the initial procedure **[Table 1]**. If a patient had ≥1 complication within an outcome category, the category was flagged as a single complication.

Statistical analysis on demographic data was performed with one-way ANOVA (with Tukey test on all statistically significant results) using GraphPad InStat version 3.00 for Windows 95 (GraphPad Software, San Diego, California USA,). A Chi-square test or Fisher's exact test (when sample size was small) was used for univariate analysis to compare the incidence between the groups for the primary and secondary outcomes. Subsequently, multivariate analysis was performed using logistic regression to explore the relationship between statistically significant outcomes and the covariates of interest. The multivariate model included the covariates that were significant at the 0.1 level in the univariate analysis. A stepwise model selection technique was used to build the final model. A p-value ≤ 0.05 was considered statistically significant. The statistical analysis was carried out using SAS software Version 9.1 (SAS Institute Inc., Cary, NC, USA).

Results

The study cohort is described with respect to demographic characteristics, cardiac risk profile, and glycemic profile in **Table 2**, comparing those patients who had a pre-existing diagnosis of diabetes (diabetic patients, N=123, 20%) with those that did not (non-diabetic patients, N=491, 80%). Significant differences between the diabetic and non-diabetic patients were fewer Caucasians, a higher average age, and a significantly higher body mass index in the diabetic group. Traditional cardiac risk factors were significantly more common in the diabetic cohort, specifically hypertension, dyslipidemia, and previous smoking history. Preoperative co-morbid illnesses were also present more commonly in the diabetic cohort, specifically chronic lung disease, renal failure, and history of myocardial infarction. Non-elective cardiac surgery was performed more often in the diabetic cohort. Preoperatively, outpatient antihyperglycemic regimens for the diabetic cohort included insulin (27%), oral hypoglycemic agents (59%), diet only (6%), and no treatment (8%).

Postoperatively, hyperglycemia (glucose level >6.05 mmol/L) was almost universal (98% diabetic vs. 99% non-diabetic patients) in the ICU. Independent of diabetic status, ICU admission glucose ≥11 mmol/L was predictive of higher rates of postoperative mortality (6.1% vs. 2.3%; p=0.04), renal (10.7% vs. 3.9%; p=0.02), pulmonary (21.4% vs. 11.0%; p=0.02), and cardiac (32.1% vs. 21.8; p=0.02) complications.

In diabetic compared to nondiabetic patients, significantly higher values were found for the mean glucose upon ICU admission, the overall mean glucose in the ICU, and the overall mean glucose following transfer out of the ICU **[Table 2]**. The IV insulin protocol was initiated on 95% of the diabetic and 94% of the non-diabetic patients and the SC insulin protocol was subsequently initiated on 94% of the diabetic and 88% of the non-diabetic patients. Among all cardiothoracic surgeries, diabetic patients had higher rates of postoperative mortality (7.3% vs. 3.3%; p=0.03) and pulmonary complications (19.5% vs. 11.6%; p=0.02), but had similar rates of deep sternal wound infections, , other infections, and cardiac, renal and neurologic complications compared to non-diabetic patients on univariate analysis. **[Figure 1]**. However, on multivariate analysis it was found that the presence of diabetes was not a significant factor in either pulmonary complications or mortality. In this multivariate analysis, renal failure, non-elective surgery, and older age were positively associated with pulmonary complications and renal failure, non-elective surgery, and female gender were positively associated with postoperative mortality independently of the patient’s diabetic status.

Subgroup analysis was also performed on patients who underwent CABG surgery (N=159; 25.9%) without any other simultaneous surgical procedures. The subgroup consisted of 48 diabetic patients (30.2%) and 111 non-diabetic patients (69.8%). **Table 3** describes the demographics, cardiac risk profile, and co-morbid illnesses of the CABG only subgroup. Similar to the entire cohort, diabetic patients undergoing CABG surgery had higher rates of hypertension, dyslipidemia, pre-existing renal failure, and chronic lung disease. The non-diabetic cohort had a higher percentage of previous smokers.

In the CABG only subgroup, use of both IV and SC insulin protocols were similar among diabetic and non-diabetic patients. Mean glucose levels on ICU admission, in the ICU and outside the ICU were higher in diabetic patients [Table 3]. In the CABG only cohort, no statistically significant differences were seen in primary or secondary outcomes between diabetic and non-diabetic patients using univariate analysis **[FIGURE 2]**. No postoperative deaths occurred in this cohort and there was only one deep sternal wound infection.

The major complication of intensive insulin therapy in the perioperative period is hypoglycemia. Out of 37,626 glucose values reviewed in our study, only 465 (1.2%) were below 3.3 mmol/L. Rates were higher in those with a prior history of diabetes compared to those without such a history in the total group (1.7% vs. 1.1%, $p< 0.0001$) and those undergoing CABG only (1.2% vs. 0.6%, $p=0.012$). None of these episodes were considered severe and none resulted in loss of consciousness or seizure.

Discussion

Hyperglycemia has been shown to be an independent risk factor for poor clinical outcomes in multiple patient populations (8-10). Similarly, we found that a glucose level on ICU admission ≥ 11 mmol/L was predictive of higher rates of mortality and postoperative complications (renal, pulmonary, and cardiac).

Diabetic patients undergoing cardiothoracic surgery have been shown to have higher rates of mortality and postoperative complications compared to non-diabetic patients (11-13). Our study demonstrates that glucose management with a combined IV and SC insulin regimen eliminates this known increased postoperative morbidity and mortality in patients with pre-existing diabetes not only in those undergoing CABG, similar to what has been shown with 3 days of continuous IV insulin infusion (3,6,14,15) but in all cardiothoracic surgeries. It should be noted that the diabetic patients in our study had postoperative morbidity and mortality rates similar to those without a prior diagnosis of diabetes despite having higher age, BMI, traditional cardiac risk factors (hypertension, dyslipidemia, smoking history) and more pre-existing co-morbid illnesses (chronic lung disease, chronic renal insufficiency, previous MI, and previous CVA). Although postoperative pulmonary complications and mortality were statistically significant in the diabetic cohort for all cardiac surgery on univariate analysis, they were found to be unrelated to diabetes status on multivariate analysis. The difference in pulmonary complications between diabetic and non-diabetic patients was attributable to higher rates of prolonged ventilation and need for reintubation and these were positively associated with pre-existing renal failure, non-elective surgery, and older age independently of the presence of diabetes. Postoperative mortality was associated with pre-existing renal failure, non-elective surgery, and female gender. Mean glucose levels in the immediate postoperative period were slightly higher in the diabetic cohort, but this calculated mean is influenced by the higher mean glucose on ICU admission.

Ninety-nine per cent of those individuals not known to have diabetes were found to be hyperglycemic postoperatively in our study, with 94% requiring an IV insulin drip for control. Critical illness causes an impairment of insulin secretion and insulin action, resulting in hyperglycemia even in normal individuals and a worsening of the hyperglycemia in patients with diabetes (10,14-18). Biochemical studies suggest that mortality is reduced with improved glycemic control due to favorable alterations in myocardial and skeletal muscle metabolism, improved cell membrane stability, myocardial contractility, and endothelial cell function, as well as increased nitric oxide and decreased inflammatory mediators, platelet aggregation and thrombosis. (19-21).

Previously, in a prospective, randomized, controlled study, Van den Berghe showed that normalization of elevated glucose levels by intensive insulin therapy in patients in the surgical ICU decreased in-hospital mortality by 34% (10). Post-CABG mortality in diabetic patients undergoing CABG only has been reported to be between 2-4% (22-24) but continuous insulin infusion for 72 hours postoperatively has been shown to reduce this higher risk (6). In a study of 3,554 diabetic patients undergoing isolated CABG surgery, Furnary et al reported a mortality rate of 2.5% in patients treated with a 72-hour postoperative insulin infusion (mean glucose 9.73 ± 1.65 mmol/L) compared to 5.3% of patients treated with subcutaneous insulin therapy (mean glucose 11.71 ± 2.25 mmol/L) (6). Although Furnary did not study the non-diabetic population, he reported an overall CABG mortality rate of 2.8% (N=14,051) at his institution. In comparison, in our study of 159 CABG patients, postoperative mortality was non-existent in both the diabetic and non-diabetic groups.

It is difficult to perform inter-institutional comparison due to differences in surgical experience and techniques. However, we were able to compare our *observed* mortality results of 0% for both patient groups undergoing CABG surgery with those from the national Society of Thoracic Surgery (STS) 2005 database. According to the STS 2005 database, which adjusts for the various risk factors in our patients, the *expected* mortality for the group without a prior diagnosis of diabetes was 1.30% (95% CI - 0, 3.75%), for those with a prior diagnosis of diabetes it was 2.1% (0, 8.24%), and for the entire group of 159 patients undergoing CABG it was 1.50% (0, 2.65%).

Complications of intensive insulin therapy in our patients were very low. Despite over 90% of patients being treated intensively with insulin therapy, hypoglycemia (glucose < 3.3 mmol/L) rates remained low but were higher (1.7% vs. 1.1%, p<0.0001) in those with a prior diagnosis of diabetes. None of the hypoglycemic values was deemed severe and none were associated with loss of consciousness or seizures. Non-diabetic patients were often titrated off SC insulin therapy on postoperative days 4 or 5 due to improvements in postoperative insulin resistance and normalization of blood sugars. The difference in mean glucose levels outside of the ICU can also be explained by the need for continuing to monitor euglycemic, non-diabetic patients after cessation of insulin therapy.

There are limitations to our study. Although it was a prospectively designed protocol, it was not a randomized trial comparing different treatment regimens and there was no control group. We also could not compare surgical complication rates before and after institution of the glycemic protocols because of concomitant changes in the surgeons and changes in a number of aspects of the surgery and perioperative care. Another limitation is the relatively small numbers of patients reported for this single year period. Finally, some of the patients designated as not having diabetes could possibly have had diabetes; it is generally estimated that about 30% of those with diabetes have not been diagnosed. Based on the number of patients in our series with diagnosed diabetes, we can estimate that perhaps an additional 54 (11.0%) patients of the "non-diabetic" group for all CT surgery and an additional 15 (13.5%) patients of "non-diabetic" group undergoing CABG may actually have had diabetes (25).

Conclusions

In this study, diabetic patients had similar rates of postoperative mortality, deep sternal wound infections, other infections, and pulmonary, cardiac, renal and neurologic complications compared to non-diabetic patients following cardiothoracic surgery**.** Thus, for the first time, we have shown that a combination of IV insulin (in the ICU) and SC insulin (outside the ICU), a less costly and less nursing-intensive therapy than 3 days of IV insulin postoperatively, results in a reduction of the increased surgical morbidity and mortality in diabetic patients following cardiothoracic surgery that has been previously described in the literature.

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Conflict of Interest

Mark E. Molitch, M.D. has received research support from Sanofi-Aventis, Genentech, and Amgen Corporations and is a consultant for Abbott and Sanofi-Aventis Pharmaceuticals.

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Table 1. Definition of Primary and Secondary Outcomes (from STS database)

Primary/Secondary Outcomes	STS Field Definition
Postoperative Mortality	Operative mortality including both (1) all deaths occurring during the hospitalization in which the operation was performed, even if after 30 days; and (2) those deaths occurring after discharge from the hospital, but within 30 days of the procedure unless the cause of death is clearly unrelated to the operation.
Deep Sternal Wound infection	Deep sternal infection involving muscle, bone, and/or mediastinum requiring operative intervention. Must have I&D, +wound culture, and tx with antibiotics
Complications - Other Infections	
Thoracotomy site	Infection involving a thoracotomy or parasternal site. Must have I&D, +wound culture, and tx with antibiotics
Leg vein harvest site	Infection involving a leg vein harvest site. Must have I&D, +wound culture, and tx with antibiotics
Sepsis	Postoperative septicemia with +blood cultures.
Complications - Neurologic	
Permanent Deficit	Central neurologic deficit persisting postoperatively for > 72 hours
Transient Deficit	Postoperative transient neurologic deficit (TIA) recovery within 24 hrs; Reversible ischemic neurologic deficit recovery within 72 hours
Coma	New postoperative coma persisting > 24 hours secondary to anoxic/ischemic and/or metabolic encephalopathy, thromboembolic event or cerebral bleed
Complications - Pulmonary	
Prolonged Ventilation	Pulmonary insufficiency requiring ventilator > 24 hours postoperatively
Need for Reintubation	Patient was reintubated during the hospital stay after the initial extubation.
Pulmonary Embolism	Pulmonary embolus documented by CT scan, V/Q scan, or angiogram
Pneumonia	Pneumonia diagnosed by +culture or sputum, transtracheal fluid, bronchial washings, and/or clinical findings consistent with pneumonia including CXR with pulmonary infiltrates
Complications - Renal	Acute or worsening renal failure resulting in an either a serum creatinine > 2.0 and 2x most recent preoperative creatinine level or a new requirement for dialysis postoperatively
Complications - Cardiac	
Perioperative-MI	Presence of perioperative MI documented by CK-MB > 5x normal (0-24 hrs postop) or ST elevation, new Q waves, new LBBB on EKG, or CK-MB > 3x normal (> 24 hrs)
A-Fib	New onset of Atrial fibrillation requiring treatment. Does not include recurrence of A. fib which had been present preoperatively
Heart-Block	New heart block requiring implantation of a permanent pacemaker prior to discharge
Cardiac-Arrest	Cardiac arrest documented by one of the following: ventricular fibrillation, rapid ventricular tachycardia with hemodynamic instability, asystole
Aortic Dissection	Dissection along any part of the aorta
Readmission within 30 days	Readmission as inpatient within 30 days from the date of initial surgery for ANY reason

Table 2. Diabetes vs. Non-Diabetes (ALL CT SURGERY)

	Diabetes (N=123)	No Diabetes (N=491)	P-value
Male sex	071 (58%)	328 (67%)	0.07
Caucasian	074 (60%)	362 (74%)	0.004
Age (years)	65.6 ± 11.1	62.3 ± 14.1	0.02
BMI (kg/m^2)	30.6 ± 7.7	27.3 ± 5.4	<0.001
Hypertension	085 (69%)	254 (52%)	<0.001
Dyslipidemia	091 (74%)	240 (49%)	<0.001
Smoking history	059 (48%)	183 (37%)	0.04
Chronic Renal Failure	09 (7%)	07 (3%)	0.08
Chronic Lung Disease	017 (14%)	38 (8%)	0.05
Previous Myocardial Infarction	040 (33%)	067 (14%)	<0.001
Previous Stroke	017 (14%)	24 (5%)	0.001
Elective Surgery	070 (57%)	366 (75%)	<0.001
GMS Consult	115 (94%)	437 (89%)	0.18
IV Insulin protocol	117 (95%)	461 (94%)	0.83
SQ Insulin protocol	116 (94%)	434 (88%)	0.07
Mean Glucose on ICU admission (mmol/L)	9.79 ± 3.24	8.74 ± 2.750	0.003
Mean Glucose in ICU (mmol/L)	7.59 ± 1.26	7.15 ± 0.99	< 0.001
Mean Glucose outside ICU (mmol/L)	7.86 ± 1.43	6.54 ± 0.77	< 0.001
Total # Glucose values	9,623	28,003	
# Glucose values < 3.3 mmol/L (%)	164 (1.7%)	308 (1.1%)	<0.0001

Table 3. Diabetes vs. Non-Diabetes (CABG ONLY)

	Diabetes (N=48)	No Diabetes (N=111)	P-value
Male sex	034 (71%)	089 (80%)	0.22
Caucasian	029 (60%)	085 (77%)	0.054
Age (years)	65.2 ± 11.2	65.0 ± 10.3	0.91
BMI (kg/m^2)	31.7 ± 8.6	28.0 ± 4.8	<0.001
Hypertension	035 (73%)	071 (64%)	0.36
Dyslipidemia	039 (81%)	078 (70%)	0.17
Smoking history	019 (40%)	058 (52%)	0.17
Chronic Renal Failure	03 (6%)	02 (2%)	0.16
Chronic Lung Disease	02 (4%)	04 (4%)	1.00
Previous Myocardial Infarction	021 (44%)	033 (30%)	0.10
Previous Stroke	04 (8%)	02 (2%)	0.07
Elective Surgery	028 (58%)	073 (66%)	0.38
GMS Consult	048 (100%)	104 (94%)	0.10
IV Insulin protocol	048 (100%)	105 (95%)	0.18
SQ Insulin protocol	048 (100%)	104 (94%)	0.10
Mean Glucose on ICU admission (mmol/L)	9.79 ± 2.64	8.47 ± 2.09	<0.001
Mean Glucose in ICU (mmol/L)	7.64 ± 1.15	7.20 ± 1.0	0.02
Mean Glucose outside ICU (mmol/L)	8.3 ± 1.7	6.65 ± 0.71	<0.001
Total # Glucose values	2378	3889	
# Glucose values < 3.3 mmol/L (%))	29 (1.2%)	23 (0.6%)	0.012

Figure 1. Postoperative Morbidity and Mortality in Cardiothoracic Surgery Patients with and without Diabetes. Diabetic patients had higher rates of postoperative mortality (P=0.04) and pulmonary complications (P=0.02), but had similar rates of deep sternal wound infections, other infections, cardiac, renal and neurologic complications compared to non-diabetic patients as shown here on univariate analysis. On multivariate analysis it was found that the presence of diabetes was not a significant factor in either pulmonary complications or mortality. (Abbreviations: DSWI – deep sternal wound infections; Neuro – neurologic complications; Pulm – pulmonary complications; Infxn – infection).

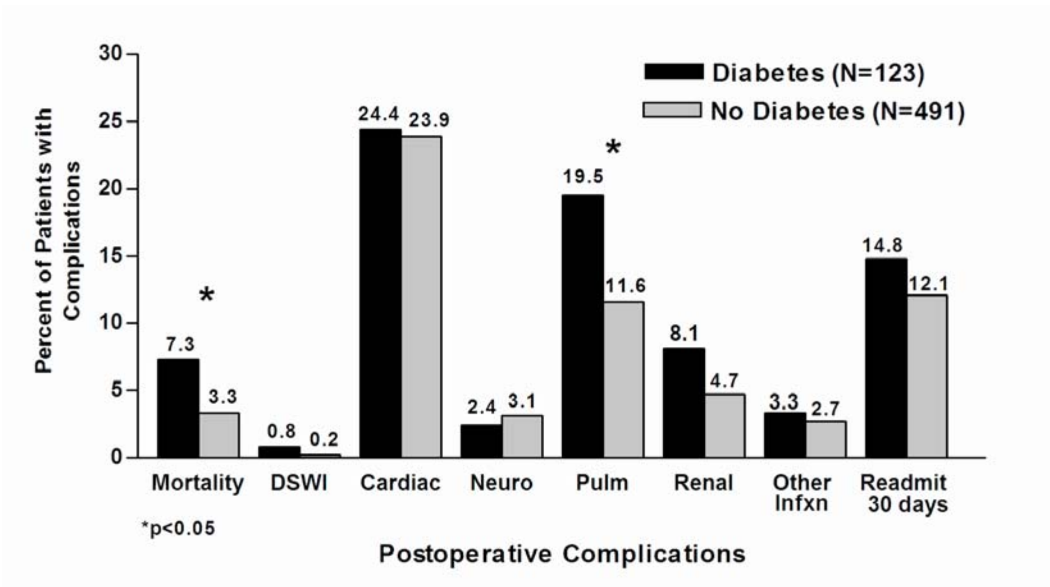

Figure 2. Postoperative Morbidity and Mortality in Patients Undergoing Coronary Artery Bypass Grafting (CABG) with and without Diabetes. There were no statistically significant differences in morbidity and mortality between the groups. (Abbreviations: DSWI – deep sternal wound infections; Neuro – neurologic complications; Pulm – pulmonary complications; Infxn – infection).