**Impact of wait times for cardiac transplantation on outcomes after implantation of left ventricular assist devices (LVAD)**

**Running Title: OHT timing and characteristics after LVAD placement**

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**Abstract (250 – 300 words)**

**Background -** The optimal timing for orthotopic heart transplantation (OHT) after the implantation of left ventricular assist devices (LVAD) is unknown. Some have argued that performing OHT early after LVAD placement poses an increased risk of morbidity and mortality to patients.

**Objectives -** In this study, we describe the impact of timing of post-LVAD OHT on in-hospital mortality and length of stay after OHT.

**Methods -** Using data from the Nationwide Inpatient Sample (NIS) from 1998 to 2011, we identified patients 18 years of age or greater who underwent implantation of a LVAD and for whomthe date of procedure was available. We calculated in-hospital mortality for those patients who underwent OHT during the same hospitalization as a function of time from LVAD to OHT, adjusting for age, sex, race, household income, and number of comorbid diagnoses. Finally, we analyzed the effect of time to OHT after LVAD placement on the length of hospital stay post-transplant.

**Results** - 2200 patients underwent implantation of a LVAD in this cohort. 164 (7.5%) patients also underwent OHT during the same hospitalization, which occurred on average 32 days (IQR 7.75 - 66 days) after LVAD implantation. Of patients who underwent OHT, patients who underwent transplantation within 7 days of LVAD implantation (‘early’) experienced increased in-hospital mortality (26.8% vs. 12.2%, p = 0.0483) compared to patients who underwent transplant after 8 days (‘late’).There was no statistically significant difference in patient demographics between the early and late groups with regards to age, sex, race, household income, or number of comorbid diagnoses. Post-transplant length of stayafter LVAD placement was not significantly different between patients who underwent early OHT and patients who underwent late OHT.

**Conclusions** - In this cohort of patients who received LVADs, the rate of in-hospital mortality after OHT was lower for patients who underwent late OHT (greater than 8 days from LVAD implantation) compared to patients who underwent early post-LVAD OHT.Longer wait times for OHT after LVAD placement did not correlate with longer hospital stays post OHT.

**Key Words –** Mechanical Circulatory Support, Orthotopic Heart Transplant, Bridge to Transplant Left Ventricular Assist Device Outcomes

**Abbreviations** –

LVAD - Left Ventricular Assist Device

OHT - Orthotopic Heart Transplant

**Introduction**

Heart failure (HF) affects an estimated 5.8 million people in the United States and contributes to over 300,000 deaths every year1,2. It is the most common cause of hospital admission and readmission in people aged >65 years, annually accounting for over 2.4 million hospitalizations2,3 and $39 billion in healthcare costs1,4. Although most patients respond favorably to standard medical treatment, a considerable number of patients progress to end-stage heart failure refractory to medical therapy5. Currently, orthotopicheart transplant (OHT) is the gold standard therapy for these patients6,7,8, butthe number of donor hearts available for transplantation isfar fewer than the number of patients on the transplant list. For this reasonleft ventricular assist devices (LVADs) are increasingly being used to bridge patients to cardiac transplantation.5  
 The REMATCH trial in 2001 showed significant mortality reductions in patients placed on a pulsatile-flow LVAD compared to standard medical treatment9. Several subsequent studies since confirmed the survival benefit of both the older pulsatile and newer continuous-flow LVADs10-13. AlthoughLVADs have substantially reduced mortality in end-stage heart failure patients, the absolute mortality rates still remain high. A large portion of this mortality is attributable to complications and other occurrences during the patient’s stay in the hospital15. In-hospital mortality rates as high as 27% have been reported in patients after LVAD surgery15. As the rate of LVAD implantation in the United States increases19-22, effective recommendations on the in-hospital management of LVAD implantation are essential. For example, though patients bridged to OHT with a LVAD achieve similar survival rates as patients who undergo direct heart transplant,14 there is little data to guide clinicians regarding the optimal timing of OHT after LVAD implantation.Some have argued that performing OHT early after LVAD placement poses an increased risk of morbidity and mortality to patients.

Past studies on the appropriate use and outcomes of LVADs have been mostly limited to institutional experience and case series of select populations. While such descriptive investigations are useful, they are often limited by small sample size and variation between institutions and comparison groups. We usedthe National Inpatient Sample, the largest national database of hospitalizations in the United States with data from over 36 million hospitalizations, to assess the optimal timing of OHT after LVAD implantation. To do this, we analyzed a patient cohort who had OHT performed while still hospitalized after LVAD implantation. We hypothesized that early OHT after LVAD placement would exhibit higher mortality than late OHT, and that the hospital length of stay (LOS) after early OHT would be less than LOS after late OHT.

**Methods**

**Data Source**

The Nationwide Inpatient Sample (NIS), from the Healthcare Cost and Utilization Project, Agency for Healthcare Research and Quality, is the largest database of all-payer inpatient discharge information, sampling approximately 20% of all non-federal US hospitals and including approximately 9 million hospital admissions each year. It contains discharge data from over 5000 hospitals located across 45 states, of which approximately 1,200 hospitals are sampled each year to create a stratified sample of United States hospitals. Each NIS entry includes all diagnosis and procedure codes of activity during the patient’s hospitalization at the time of discharge, as well as patient demographics, hospital characteristics, and short-term complications of the hospitalization.

**Study design and Cohorts**

This was a retrospective cross-sectional study using the Nationwide Inpatient Sample (NIS) between 1988 and 2011. We identified all hospitalizations from 1988 to 2011 of patients 18 years of age or greater that underwent placement of a LVAD and for which the hospital day of each procedure was available. Procedures during the hospitalization in addition to LVAD placement, including orthotopic heart transplant, extracorporeal membrane oxygenation, intubation, hemodialysis, invasive hemodynamic monitoring, and surgical revision were identified by associated ICD9 codes (Supplementary Table A). Additionally, hospital mortality and perioperative morbidity such as post-operative infections, cardiopulmonary complications, and hemorrhagic complicationsrequiring endoscopy were identified.

**Statistical Analysis**

Python 2.7 (Python Software Foundation, www.python.org) and R 2.13 (R Foundation, www.r-project.org) were used for statistical analysis. P-values for numerical and count data was calculated by two-sided t-tests and Chi-squared tests, respectively, with significance thresholds of 0.05.

**Results**

**Baseline Patient Characteristics**

We identified 2200 patients greater than 18 years of age in the NationwideInpatient Sample between 1998 and 2011 who underwent LVAD implantation and for which hospital day of procedure was listed. The mean age of all patients was 53.4 years (SD = 13.7, range = 18-92 years). Baseline patient demographics, patient comorbidities, and hospital characteristics were well matched between LVAD patients who also underwent transplant during the hospitalization and LVAD patients who did not undergo transplant during the hospitalization (Table 1). There was no significant difference in patient age, comorbidities, or hospital characteristics between patients taken care of before 2006 and after 2006

The mean day of LVAD implantation was 9.4 days (SD = 12.5 days) into the hospitalization. The overall in-hospital mortality rate was 26.8%, although p

**TIME TREND BEFORE AND AFTER TIME**

Respiratory failure, cardiac dysrhythmias, right heart failure, and renal failure are among the most frequent in-hospital complications immediately following LVAD implantation (Table 3). Baseline patient demographics, patient comorbidities, and hospital characteristics were also similar between LVAD patients who underwent early and late OHT.

**Timing of Post-LVAD Orthologous Heart Transplant**

Of these patients who underwent LVAD implantation, 164 (7.5%) patients also underwent orthotopic heart transplant during the same hospitalization (Figure 3). OHT occurred a median of 32 days (IQR 7.75 to 66 days) after LVAD implantation (Table 3). Of patients who underwent OHT, increased in-hospital mortality was identified in patients who underwent transplantation within 7 days of LVAD implantation compared to patients who underwent transplant after 8 days (26.8% vs. 12.2%, p = 0.0483). There was no statistically significant difference in patient demographics with regards to age, sex, race, household income, or number of comorbid diagnoses. . Compared to patients who underwent LVAD implantation but did not undergo OHT, patients who underwent late OHT after LVAD had decreased mortality (12.2% vs. 27.0% p < 0.001). Patients who underwent early transplant after LVAD did not show a similar mortality benefit (26.8% vs. 27.0%, p = 0.946).

Patients who waited longer after LVAD implantation for OHT had longer hospital stays (39.3 ± 33.2 days for the first quartile, 48.87 ± 25.6 days for the second quartile, 85.8 ± 40.1 days for the third quartile, 151.2 ± 52.6 days for the fourth quartile). The majority of time during the hospitalization was before OHT, as there was no statistically significantly different in post-OHT length of stay (23.8 ± 21.4 days for the first quartile, 21.7 ± 15.8 days for the second quartile, 27.6 ± 37.1 days for the third quartile, 27.1 ± 22.8 days for the fourth quartile, p = 0.6571) .

**Discussion:**

This is the first study, to our knowledge, to address the difficult question of timing of OHT after LVAD implantation. Our main finding was that mortality was decreased for patients who underwent OHT greater than 8 days after LVAD implantation compared to patients who underwent OHT within 1 week of LVAD implantation, and that post-transplant length of stay after LVAD placement was not significantly different between patients who underwent early OHT and patients who underwent late OHT.

For patients who receive an LVAD for bridge to transplant therapy (BTT), the optimal timing of post-LVAD OHT is controversial. The need for clinical stability and time to recover from major surgery is counterbalanced by the risk of LVAD complications and the formation of adhesions and scarring, particularly when OHT is considered early after LVAD implant..Our findings reinforce the changes in the UNOS allocation system(what are these changes)? The high failure rate of the early, pulsatile LVADs had in part led to the initial1999 UNOS allocation algorithm giving LVAD patients 30 days of IAstatus on the transplant list. The potential risk of this algorithm was of poor outcomes of OHT performed soon after LVAD implant. Our data suggesting early post-LVAD transplant can lead to inferior outcomes is consistent with other retrospective data suggesting the optimal time interval to be between 1 and 3 months after implantation. (references?)

Between 1998 and 2011, there was a significant increase in the number of LVAD implantations, but the characteristics of this population - including timing of LVAD, usage of invasive hemodynamic monitoring, and timing of post-LVAD OHT - has remained relatively unchanged. Our data is consistent with previous smaller studies using other databases with regard to age, gender, race, and other demographic characteristics. Our survival results are similar to multiple prior studies suggesting a downward trend in in-hospital mortality after 2005. The optimal management and timing of LVAD implantation is still mostly dependent on institutional experience and provider preference as there are no randomized control trials due to the relatively novel introduction of LVADs and small patient populations. We thus find our study representative of clinical practice.

Our study has a few limitations. First, the NIS is a deidentified administrative database dependent on the appropriate coding of individual ICD-9-CM codes. Studies using such databases are susceptible to errors related to coding such as undercoding complications or variation in the application of diagnostic codes. This database also lack many details available in registries and unmeasured confounders cannot be excluded. Additionally, the NIS only captures events during the hospitalization, so complications and adverse events after discharge are not recorded. This limitation is counterbalanced by the larger sample size and the absence of reporting bias introduced by the publication of institutional experiences from a few specialized centers. Additionally, patients who underwent LVAD implantation have long hospital stays that capture most, if not many, of the acute complications causing morbidity and mortality. Studies have shown excellent long-term outcomes in LVAD patients who have uncomplicated hospital courses past 30 days.

Another major limitation of our study is that our cohort only assessed outcomes of OHT after LVAD placement in inpatients. This represents a minority of patients in contemporary practice, as most institutions prefer to wait 2-3 months after LVAD implant to list patients for cardiac transplantation, a strategy our cohort could not evaluate. Nevertheless, there will continue to be patients in the future who receive OHT after LVAD implant while still in the hospital, and our study provides meaningful guidelines on the timing of such OHT.

In conclusion, our analysis demonstrates that early LVAD implantation during the hospitalization is associated with increased mortality. This understanding of the timing of OHT after LVAD implantation may improve post-LVAD transplant outcomes, though prospective data would enhance the validity of our findings..

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**Conflict of Interest Disclosures:** None of the listed authors have any disclosures or potential conflicts of interest.

**Perspectives:**

Competency in System-Based Practice: A multi-disciplinary team of cardiologists, cardiac surgeons, and other medical professionals work together to identify the benefits of various treatments of end stage heart failure.

Translational Outlook 1: The optimal timing for OHT after LVAD remains controversial. This study suggests that OHT soon after LVAD placement (less than 8 days) is associated with more in-hospital mortality. Depending on the clinical scenario, it might be reasonable to defer OHT immediately after LVAD placement.

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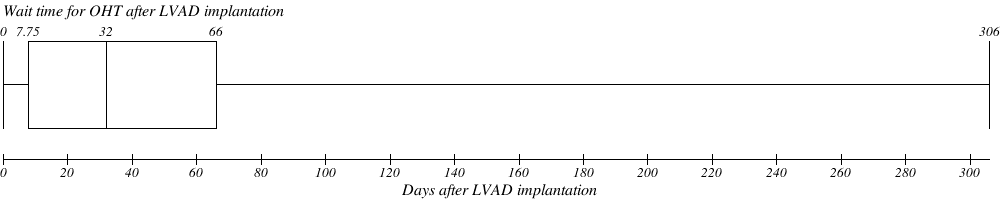
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| **Table 1.** Baseline demographics of all LVAD patients, LVAD patients who underwent OHT, and LVAD patients who did not undergo OHT. | | | |
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|  | **All LVADs (n = 2200)** | **OHT- (n = 2036)** | **OHT+  (n = 164)** |
|
| Mortality, n (%) | 590 (26.5) | 564(27.3) | 26 (15.9) |
| Length of stay, mean ± SD | 40.5 ± 38.9 | 37.1 ± 34.6 | 82.8 ± 59.3 |
| Age, mean ± SD | 53.4 ± 13.7 | 55.4 ± 13.2 | 48.2 ± 13.5 |
| Sex, n (%) | | | |
| Male | 1659 (75.4) | 511 (25.1) | 134 (81.7) |
| Female | 541 (24.6) | 1525 (74.9) | 30 (18.3) |
| Race, n (%) | | | |
| White | 1274 (57.9) | 1185 (58.2) | 89 (54.3) |
| Black | 352 (16.0) | 330 (16.2) | 22 (13.4) |
| Hispanic | 142 (6.5) | 125 (6.1) | 17 (10.4) |
| Asian/Pacific Islander | 51 (2.3) | 44 (2.2) | 7 (4.3) |
| Native American | 5 (0.2) | 5 (0.0) | 0 (0.0) |
| Otherǂ or unknown\* | 376 (17.1) | 347 (17.0) | 29 (17.7) |
| Median household income, n (%) | | | |
| $1-24,999 | 475 (21.6) | 447 (22.0) | 28 (17.1) |
| $25,000-34,999 | 491 (22.3) | 454 (22.3) | 37 (22.6) |
| $35,000-44,999 | 552 (25.1) | 509 (25.0) | 43 (26.2) |
| $45,000 or more | 631 (28.7) | 579 (28.4) | 52 (31.7) |
| Unknown\* | 51 (2.3) | 47 (2.3) | 4 (2.4) |
| Comorbidities | | | |
| Diabetes | 392 (17.8) | 373 (18.3) | 19 (11.6) |
| Hyperlipidemia | 310 (14.1) | 297 (14.6) | 13 (7.9) |
| Hypertension | 301 (13.7) | 291 (14.3) | 10 (6.1) |
| History of smoking | 144 (6.5) | 137 (6.7) | 7 (4.3) |
| BMI ≥ 30 kg/m2 | 96 (4.4) | 96 (4.7) | 0 (0.0) |
| Number of comorbid diagnosis, mean ± SD | 12.7 ± 2.9 | 12.8 ± 2.9 | 12.3 ± 3.1 |
| Location of hospital, n (%) | | | |
| Rural | 17 (0.8) | 17 (0.8) | 0 (0.0) |
| Urban | 2181 (99.1) | 2017 (99.1) | 164 (100.0) |
| Unknown\* | 2 (0.1) | 2 (0.1) | 0 (0.0) |
| Bedsize of hospital, n (%) | | | |
| Small | 38 (1.7) | 32 (1.6) | 6 (3.7) |
| Medium | 229 (10.4) | 211 (10.4) | 18 (11.0) |
| Large | 1931 (87.8) | 1791 (88.0) | 140 (85.4) |
| Unknown\* | 2 (0.1) | 2 (0.1) | 0 (0.0) |
| Teaching status of hospital, n (%) | | | |
| Nonteaching | 165 (7.5) | 160 (7.9) | 5 (3.0) |
| Teaching | 2033 (92.4) | 1874 (92.0) | 159 (97.0) |
| Unknown\* | 2 (0.1) | 2 (0.1) | 0 (0.0) |

\*Includes patients for whom data was invalid or not available

SD, standard deviation; LVAD, Left Ventricular Assist Device; OHT, Orthotopic Heart Transplant

**Figure 1.**Trends in in-hospital mortality among LVAD patients from 1998 to 2011. Percent mortality for each year was calculated as number of deaths by total number of LVAD patients. LVAD, Left Ventricular Assist Device

A



B

**Figure 2.** (A) Box-and-Whisker plot of wait time for OHT after LVAD implantation. (B) Comparison of percent mortality in hospitalized patients by wait time for OHT after LVAD implantation and no OHT after LVAD implantation. Percent mortality for each quartile was calculated as number of deaths per quartile by total number of patients per quartile. LVAD, Left Ventricular Assist Device

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| **Table 2.** Baseline demographics for patients who waited 0-7 days, 8-31 days, 32-65 days, and ≥66 days for an Orthotopic Heart Transplant (OHT) after Left Ventricular Assist Device (LVAD) Implantation | | | | |
|
|  | **0-7 days (n = 41)** | **8-31 days (n = 38)** | **32-65 days (n = 42)** | **≥66 days  (n = 43)** |
|
| Length of stay, mean ± SD | 39.3 ± 33.2 | 48.9 ± 25.6 | 85.8 ± 40.1 | 151.2 ± 52.6 |
| Length of stay after OHT, mean ± SD | 23.8 ± 21.4 | 21.7 ± 15.8 | 27.6 ± 37.1 | 27.1 ± 22.8 |
| Mortality, n (%) | 11 (26.8) | 5 (13.2) | 5 (11.9) | 5 (11.6) |
| Age, mean ± SD | 50.6 ± 12.6 | 48.6 ± 12.7 | 47.4 ± 15.3 | 46.3 ± 13.1 |
| Sex, n (%) | | | | |
| Male | 33 (80.5) | 32 (84.2) | 35 (83.3) | 34 (79.1) |
| Female | 8 (19.5) | 6 (15.8) | 7 (16.7) | 9 (20.9) |
| Race, n (%) | | | | |
| White | 25 (61.0) | 19 (50.0) | 23 (54.8) | 22 (51.2) |
| Black | 3 (7.3) | 5 (13.2) | 8 (19.0) | 6 (14.0) |
| Hispanic | 3 (7.3) | 7 (18.4) | 2 (4.8) | 5 (11.6) |
| Asian/Pacific Islander | 2 (4.9) | 0 (0.0) | 1 (2.4) | 4 (9.3) |
| Native American | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) |
| Other or unknown\* | 8 (19.5) | 7 (18.4) | 8 (19.0) | 6 (14.0) |
| Median household income, n (%) | | | | |
| $1-24,999 | 4 (9.8) | 8 (21.1) | 8 (19.0) | 8 (18.6) |
| $25,000-34,999 | 10 (24.4) | 10 (26.3) | 10 (23.8) | 7 (16.3) |
| $35,000-44,999 | 12 (29.3) | 8 (21.1) | 10 (23.8) | 13 (30.2) |
| $45,000 or more | 12 9 (29.3) | 12 (31.6) | 14 (33.3) | 14 (32.6) |
| Unknown\* | 3 (7.3) | 0 (0.0) | 0 (0.0) | 1 (2.3) |
| Comorbidities | | | | |
| Diabetes | 8 (19.5) | 5 (13.2) | 4 (9.5) | 2 (4.7) |
| Hyperlipidemia | 5 (12.2) | 2 (5.3) | 3 (7.1) | 3 (7.0) |
| Hypertension | 5 (12.2) | 1 (2.6) | 2 (4.8) | 2 (4.7) |
| History of smoking | 5 (12.2) | 2 (5.3) | 0 (0.0) | 0 (0.0) |
| BMI ≥ 30 kg/m2 | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) |
| Number of concomitant diagnosis, mean ± SD | 11.9 ± 3.1 | 12.3 ± 3.0 | 12.5 ± 3.2 | 12.5 ± 3.2 |
| Location of hospital, n (%) | | | | |
| Rural | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) |
| Urban | 41 (100.0) | 38 (100.0) | 42 (100.0) | 43 (100.0) |
| Unknown\* | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) |
| Bedsize of hospital, n (%) | | | | |
| Small | 4 (9.8) | 0 (0.0) | 0 (0.0) | 2 (4.7) |
| Medium | 7 (17.0) | 6 (15.8) | 5 (11.9) | 0 (0.0) |
| Large | 30 (73.2) | 32 (84.2) | 37 (88.1) | 41 (95.3) |
| Unknown\* | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) |
| Teaching status of hospital, n (%) | | | | |
| Nonteaching | 1 (2.4) | 1 (2.6) | 2 (4.8) | 1 (2.3) |
| Teaching | 40 (97.6) | 37 (97.4) | 40 (95.2) | 42 (97.7) |
| Unknown\* | 0 (0.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) |

\*Includes patients for whom data was invalid or not available

SD, standard deviation; LVAD, Left Ventricular Assist Device, OHT, Orthotopic Heart Transplant

**Table 3.**Complications in hospitalized patients with or without same-admission OrthotopicHeart Transplant (OHT) after Left Ventricular Assist Device (LVAD)

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  | **Early OHT (n = 41)** | **Late OHT (n = 123)** | **OHT- (n = 2036)** | **Total (n = 2200)** |
| Acute renal failure | 24 (58.5) | 64 (52.0) | 963 (47.3) | 1051 (47.8) |
| Reoperation | 28 (68.3) | 87 (70.7) | 803 (39.4) | 918 (41.7) |
| Bleeding requiring transfusion | 7 (17.1) | 30 (24.4) | 780 (38.3) | 817 (37.1) |
| Acute respiratory failure | 8 (19.5) | 37 (30.1) | 518 (25.4) | 563 (25.6) |
| Sepsis | 2 (4.9) | 17 (13.8) | 233 (11.4) | 252 (11.5) |
| Postoperative cardiac complication | 7 (17.1) | 15 (12.2) | 234 (11.5) | 256 (11.6) |
| Acute liver failure | 3 (7.3) | 9 (7.3) | 224 (11.0) | 236 (10.7) |
| Device failure | 0 (0.0) | 4 (3.3) | 62 (3.0) | 66 (3.0) |
| Stroke | 1 (2.4) | 1 (0.8) | 53 (2.6) | 55 (2.5) |

**SUPPLEMENTARY FIGURES**

**Supplementary Figure 1.**Percent mortality in hospitalized patients who received LVAD implantationby age.

**Supplementary Figure 2.**Percent mortality in hospitalized patients by day of LVAD implantation. The wait time for LVAD implantation was divided into quartiles with median = 6 days and IQR = 2-13 days. Percent mortality for each quartile was calculated as number of deaths per quartile by total number of patients per quartile. LVAD, Left Ventricular Assist Device

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| **Supplementary Table 1.** Definitions of diagnosis and procedures by ICD9 codes | |
|
| **Diagnosis/Procedure** | **ICD9 Code(s)** |
|
| Left ventricular assist device | 3766 |
| Orthotopic heart transplant | 3751, 375 |
| Swan-Ganz catheterization | 8964 |
| Diabetes | 25000-25099 |
| Disorders of lipoid metabolism | 2720-2729 |
| Hypertension | 4010-4019 |
| History of or current use of tobacco | V1582, 3051 |
| BMI ≥ 30kg/m2 | 27800, 27801 |
| Reoperation | 3403, 3764, 3479, 341, 3749 |
| Sepsis | 99591, 99592 |
| Acute respiratory failure | 51881 |
| Postoperative cardiac complication | 9971, 4294 |
| Acute renal failure | 5845-5849 |
| Postoperative bleeding | 4513, 4523, 9904, 9905, 9907, 9909 |
| Stroke | 43491 |
| Acute liver failure | 570 |
| Device failure | 99609 |