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# Preoperative Clopidogrel Use and Its Effect on Adverse Events in Patients Undergoing Cardiac Operations

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***Abstract***

***Aim*** *– Preoperative clopidogrel use within 5 days of cardiac operations is controversial. Clopidogrel could reduce cardiovascular complications and yet might increase risk of bleeding. Recent reports showed conflicting results, and whether clopidogrel has variable effects for different cardiac surgical procedures is unclear. So this study was aimed at finding out the effect of clopidogrel on adverse events in patients undergoing cardiac suregry*

***Materials & methods*** *- A single-center retrospective cohort analysis was performed. After propensity score matching (PSM) for identified confounders, the relationship between preoperative clopidogrel use and 30-day all-cause mortality, postoperative renal failure, major adverse cardiocerebral events (MACE), blood transfusion, reoperation for bleeding, and postoperative infection were estimated with separate logistic regression models..*

***Result****- Preoperative clopidogrel therapy was associated with a 49% ($p < 0.04$) increased risk of reoperation for bleeding among 86 matched pairs of patients undergoing valve operations. Among 72 matched patients undergoing coronary artery bypass grafting (CABG), preoperative clopidogrel therapy was not associated with a statistically significant higher risk of reoperation for bleeding. However, preoperative clopidogrel use, compared with nonuse, was not associated with risks of MACE, 30-day mortality, postoperative renal failure, blood transfusion, or postoperative infection in the entire cohort, in patients undergoing valve operations only, and in patients undergoing CABG only after PSM.*

***Conclusion****- Preoperative clopidogrel use in all patients undergoing cardiac operations was not associated with risks of major cardiac, cerebral, or renal complications and infections and death; however, the risk of reoperation for bleeding was elevated among preoperative clopidogrel users compared with nonusers in a subpopulation of patients undergoing valve operations only.*

***Key words****- preoperative clopidogrel*
*Cardiovascular complications*
*Cardiac surgery*

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## I. Introduction

Clopidogrel has been widely used in nonsurgical settings to reduce mortality, myocardial infarction, and stroke for patients with cardiovascular diseases [1, 2]. To balance the risk of thrombosis during the hypercoagulopathic perioperative period and the risk of

bleeding from clopidogrel use, surgeons and anaesthesiologists look for guidance to decide when they should discontinue clopidogrel and safely restart clopidogrel in the perioperative period.

In cardiac surgical settings, this issue is even more complex because all patients have cardiovascular disease and could be protected by clopidogrel. In the postoperative period, early clopidogrel therapy has been consistently reported to improve clinical outcomes for patients undergoing coronary artery bypass grafting (CABG), including better graft patency [3–6] and a reduced risk of death and ischemic complications [7]. However, whether clopidogrel should be used in the preoperative period remains controversial [8–13]. Several studies showed lower mortality [8, 9] in patients undergoing CABG, whereas others found a similar mortality rate and higher transfusion requirement [10, 14–17]. Decisions about preoperative clopidogrel therapy in patients undergoing CABG are made widely on the basis of individual and institutional experiences [11–13]. Actually, the American Heart Association, American College of Cardiology [18], The Society of Thoracic Surgeons (STS) [19], and the European Association for Cardio-Thoracic Surgery [20] even make different recommendations about when preoperative clopidogrel therapy should be terminated, ranging between 2 and 10 days before elective cardiac operations.

For valve operations, the risk and benefit of clopidogrel is even less clear, and there is only 1 report evaluating combined CABG and valve operations that found that clopidogrel was associated with similar adverse events and more blood transfusions in CABG and valve operations [21]. Cao and associates [11, 12] assessed a cohort consisting of all cardiac procedures and found that clopidogrel was associated with a lower cumulative incidence of major adverse cardiocerebral events (MACE), renal failure, intensive care unit stay, and 30-daymortality [11, 12].

Our goal was to separately evaluate the effects of clopidogrel for patients undergoing CABG only and patients undergoing valve operations only. In addition, we evaluated the overall effects of clopidogrel in all cardiac procedures to reflect current real-life clinical practice. To elucidate possible mechanisms for clopidogrel effects, we further analyzed and compared the coagulation status between clopidogrel and nonclopidogrel groups.

## II. Materials And Methods

### 2.1 Data Collection

Institutional ethical committee approval was obtained before conduct of the study and individual consent was waived. A retrospective cohort analysis of 1000 consecutive patients undergoing cardiac operations at Lokmanya tilak municipal medical college, Mumbai from January 2017 to December 2018 was performed. Patient data were collected and organized to demographics, patient history, medical record information, preoperative risk factors, preoperative medications, intraoperative data, postoperative cardiocerebral events, renal failure, and 30-day all-cause mortality. Preoperative use of clopidogrel in this analysis was defined as a patient's use of clopidogrel within the 5 days preceding the surgical procedure.

Fig 1 shows our study sample selection.

### 2.2 Definition of Major Outcomes and Other Covariates

Major outcomes of this study are 30-day all-cause mortality, requirement for postoperative renal failure/dialysis, reoperation for bleeding, blood transfusion (packed red cells, fresh frozen plasma, cryoprecipitate, or platelets), postoperative infection, and a composite outcome— major adverse cardiocerebral events (MACE). The latter included permanent or transient stroke, coma, perioperative myocardial infarction, heart block, and cardiac arrest. For coagulation studies, preoperative platelet count on the day of the operation, platelet aggregation test, activated partial thromboplastin time (APTT), and international normalized ratio (INR) were identified. The mean and standard deviation of those factors were used.

2.3 Statistical Analysis

Standardized difference scores were estimated to compare baseline covariates between users and nonusers of preoperative clopidogrel. Most of these variables were not balanced between preoperative clopidogrel use and nonuse. A 1:1 propensity score matching (PSM) of preoperative clopidogrel users and nonusers minimized this potential selection bias. The propensity scores were estimated with a multivariable logistic regression models. Standardize differences for all baseline covariates were less than 10 in the matched sample, which suggests a balance of covariates between the clopidogrel and nonclopidogrel therapy groups

[22]. The final PSM sample consisted of 1,59 identical pairs of preoperative clopidogrel users and nonusers for all cardiac procedures analyzed. Additionally, 72 pairs of patients who underwent CABG only and 87 pairs of patients who underwent valve operations only were matched with propensity scores for comparison.

Separate logistic regression models were used to estimate the associations (odds ratio [OR]) between preoperative clopidogrel therapy and each major outcome after cardiac procedures using both unmatched and PSM samples. Each of the models fitted to the unmatched data was adjusted with the logit of the propensity scores (quintiles) to control for preoperation confounders. The greedy matching algorithm was implemented for matching clopidogrel users and nonusers. This macro comes with prespecified parameters and has been extensively applied for matching cases and controls. We performed covariate adjustment by using the quintiles of propensity scores to estimate adjusted ORs for the association between preoperative clopidogrel therapy and postsurgical outcomes.

We reported unadjusted ORs from models fitted to the PSM sample because further propensity score adjustment did not alter the ORs. For prespecified subgroup analysis, similar statistical methods were applied to evaluate the associations between preoperative clopidogrel therapy and cardiac surgical outcomes in patient samples stratified by type of cardiac procedure. Separate PSM analysis was performed to create matched patient samples for patients undergoing CABG only and patients undergoing valve procedures only. All reported p values were 2-sided, and p values less than 0.05 were considered statistically significant. All statistical analyses were completed with SAS, version 9.3 statistical software.

## III. Results

3.1 Demographic analysis

Of 1000 patients in the database, 6,04 (61.0%) met the inclusion criteria and 389 (64.4%) patients received preoperative clopidogrel within 5 days before the surgical procedure compared with 215 (35.59%) patients who did not (Fig 1). The preoperative clopidogrel therapy group tended to be older male patients who had a higher body mass index and smoked more often and had more family history of coronary artery disease, diabetes, hypertension, peripheral vascular disease, cerebrovascular disease, chronic lung disease, and myocardial infarction (Table 1). Interestingly, there was a significantly lower prevalence of renal insufficiency and congestive heart failure in the preoperative clopidogrel group. In the unmatched sample, preoperative clopidogrel therapy was not associated with risk of MACE, postoperative renal failure, 30-day mortality, and reoperation for bleeding or postoperative infection after adjusting for all potential confounders listed in Table 1. Nonetheless, preoperative clopidogrel use was associated with statistically significant 32% (p ¼ 0.03) and 12% reductions (p ¼ 0.03) in postoperative permanent stroke and blood transfusions in all patients undergoing cardiac procedures.

3.2 Clopidogrel for All Patients Undergoing Cardiac Operations

Preoperative clopidogrel use, compared with nonuse, was not associated with MACE (OR, 1.01; 95% confidence interval [CI], 0.79–1.28; p ¼ 0.96). When stratified by various cardiac outcomes that constituted the definition of MACE, preoperative clopidogrel therapy was associated with a 34% lower risk of permanent stroke but a 41%, 10%, and 18% elevated risk of transient ischemic attack, heart block, and cardiac arrest, respectively (Table 2). These associations were not statistically significant. Regarding other major clinical outcomes after cardiac operations, preoperative clopidogrel use was associated with a nonstatistically significant 11% lower risk of 30-day mortality, a 10% lower risk of postoperative renal failure, and an 8% lower risk of blood product use. Conversely, the risk of reoperation for bleeding and postoperative infection was elevated by 19% and 7%, respectively (Table 2).

3.3 Clopidogrel Use in Patients Undergoing CABG Only

In our prespecified subgroup analysis, surgical procedure– specific stratified associations were estimated (Table 3). Among patients undergoing CABG only, preoperative clopidogrel use was associated with an elevated risk of MACE (OR, 1.10), reoperation for bleeding (OR, 1.05),and 30-day mortality (OR, 1.24); however, preoperative clopidogrel use was associated with lower risks of postoperative renal failure (OR, 0.91), blood transfusion (OR, 0.94), and infection (OR, 0.72). None of these associations was statistically significant.

3.4 Clopidogrel Use in Patients Undergoing Valve Operations Only

Among patients undergoing valve operations only, preoperative clopidogrel therapy was associated with a statistically significant 49% (OR, 1.49; 95% CI, 1.02–2.17; p ¼ 0.04) elevated risk of reoperation for bleeding. Even though preoperative clopidogrel therapy also elevated the risk of MACE and decreased the risk of postoperative renal failure, blood transfusion, and infection, these associations were not statistically significant (table 3).

## IV. Discussion

Effects of preoperative clopidogrel on clinical outcomes duringcardiac operations are predominantly retrospective, have had similar but variable results, and generally reflect only those patients undergoing CABG. In our entire cardiac procedure cohort study, there was no significant association between clopidogrel use and MACE, 30-day mortality, postoperative renal failure, reoperation for bleeding, and blood transfusion. Blood transfusion carries significant negative effects on clinical outcomes, including risk of infection [23]. If clopidogrel affects blood product use, clopidogrel might also affect postoperative risk of infection. However, we found that clopidogrel use was not associated with blood transfusion or postoperative infection.

Because different cardiac procedures carry nonsimilar clinical risks, and the influence of clopidogrel might be disparate, it is important to analyze clopidogrel use in individual cardiac procedures. Most clopidogrel studies have focused on patients undergoing CABG because of the

known protective actions of clopidogrel in coronary artery disease. Several retrospective studies demonstrated clinical outcome superiority of preoperative clopidogrel use in patients undergoing CABG [8, 9, 24]. In contrast, there is research supporting discontinuation of clopidogrel before cardiac operations [10]. In our study, we found that in patients undergoing CABG only, preoperative clopidogrel use was not associated with risks of MACE, postoperative renal failure, 30-day mortality, reoperation for bleeding, blood transfusion, or postoperative infection. Our study is a single-center retrospective study, which allowed for better control of institutional practice variation. Because there was no adverse event associated with preoperative clopidogrel use, this information might help clinicians to continue clopidogrel preoperatively and postoperatively without

interruption. In addition, patients undergoing CABG frequently have peripheral vascular diseases and a history of ischemic stroke; continuing clopidogrel preoperatively might benefit these patients for the indicated diseases. Given the disparate studies showing variable benefit from preoperative clopidogrel use, and given the relatively safe outcomes associated with preoperative clopidogrel in our study, the benefit of clopidogrel on outcomes, if any, is likely to be small, and clopidogrel is relatively safe in patients undergoing CABG. There was only 1 study in PubMed reporting on patients undergoing combined CABG and valve operations. There were no differences in outcome except that more patients who used clopidogrel preoperatively (within 5 days of the surgical procedure) received transfusions [21]. Patients undergoing only valve operations might have increased bleeding from multiple factors, such as longer suture lines, subclinical von Willebrand deficiency, and platelet dysfunction. To make a fair comparison, we performed PSM between clopidogrel and nonclopidogrel groups in patients undergoing valve operations only to eliminate these confounding factors. After PSM, we still found that preoperative clopidogrel use was associated with a 49% increased risk of reoperation for bleeding among our 1,740 patients undergoing valve operations only. Nonetheless, the risk of MACE, 30-day mortality, postoperative renal failure, blood transfusion, and postoperative infection were not statistically significant. Patients undergoing valve operations only might take clopidogrel for various reasons, such as pain control, mild coronary artery disease, peripheral vascular disease, previous coronary artery stenting, or stroke. Physicians need to make a weighted decision about whether to discontinue clopidogrel in patients undergoing valve operations only. Despite the findings that clopidogrel use was not associated with other adverse events except reoperation for bleeding, the previously mentioned comorbidities should guide physicians to balance clopidogrel's risks and benefits in patients undergoing valve operations only.

To address whether bleeding risks associated with clopidogrel are greatest in high-risk patients, we analyzed the coagulation studies of our 2005 cohort. Platelet counts and function (platelet aggregation tests), APTT, and INR analysis showed similar results between the clopidogrel group and the nonclopidogrel group, and all were within normal limits. Commensurate coagulation status suggested that the increased risk of reoperation for bleeding might not be related to other preoperative bleeding risks. Because there was no significant difference in the whole cohort regarding reoperation for bleeding, patients undergoing other cardiac procedures might benefit even more without increasing risks of reoperation for bleeding from clopidogrel (excluding patients undergoing CABG only and patients undergoing valve operations only). Further studies in cardiac procedure–specific populations should be performed to identify which surgical procedures might benefit the most from preoperative clopidogrel use. Additionally, it is possible that clopidogrel interacts with other antiplatelet or anticoagulant drugs in a synergistic manner, causing either improved outcomes or increased bleeding. We are in the process of collecting preoperative platelet count, function (aggregation test), APTT, and INR determined on the day of operation in all cohort patients, including patients who received other anticoagulants.

The use of other anticoagulants would be reflected by those test results. A correlation analysis would then be performed between those factors and outcome variables to identify the possible associations. Platelet response to clopidogrel and other antiplatelet drugs is variable, and recovery of platelet function after stopping the medication is likewise inconsistent. Actually, Kempfer and coworkers [25] reported a 28.8% clopidogrel resistance in patients before CABG. One way to address the true influence of clopidogrel is to study the exact timing of preoperative clopidogrel stoppage. Unfortunately, this information is not reported on patient medical records. Although we could not perform a formal logistic regression platelet count and function test analysis in our 2005 cohort demonstrated that the effects of clopidogrel on platelet number and function appear to be small and insignificant. There are several limitations in this study. First, there are potential biases from uncontrollable confounding factors, including comorbidities, medication use, and physician selection bias. These potential biases were minimized in our study through PSM methods. However, exposure biases might still be present as a result of the noninclusion of unmeasured and unknown confounders in our PSM analysis. Second, postoperative use of clopidogrel might also affect the outcome in cardiac operations [26]. However, these data are not available in our database, and it is our standard order that clopidogrel be routinely started after cardiac operations. The influence of ] postoperative clopidogrel use on clinical outcomes should reasonably be expected to be evenly distributed in both groups. Third, clopidogrel dosage and the exact timing of last clopidogrel administration were not accessible in our database. Both of these factors might affect clinical outcomes significantly. We found that platelet counts and function analysis were similar between the clopidogrel and nonclopidogrel groups. However, lack of antithrombotic efficiency should not be the only reason for discontinuing clopidogrel preoperatively, because clopidogrel possesses anti-inflammatory and other important properties.

## V. Conclusion

Preoperative clopidogrel use was associated with an elevated risk of reoperation for bleeding compared with nonuse of clopidogrel in patients undergoing valve operations only. Clopidogrel was not associated with

MACE, 30-day mortality, postoperative renal failure, postoperative infection, and reoperation for bleeding in all cardiac procedures or patients undergoing CABG only. Further studies, including randomized and large prospective studies, are needed to elucidate potential roles of preoperative clopidogrel therapy in individual patients undergoing cardiac procedures.

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**Table 1** showing demographic and clinical charactiristics of clopidogrel and non clopidogrel groups

| Patient characteristics | | Preoperative use of clopidogrel within 5 days before operation | | | |
|---|---|---|---|---|---|
| | | Before propensity score matching % | | After propensity score matching % | |
| | | NO ( n=185) | YES ( n=419 ) | NO ( n=159 ) | YES ( n= 159) |
| Age ( years ) | <60 | 45.9 | 36.0 | 42.8 | 42.1 |

| | | | | | |
|---|---|---|---|---|---|
| | 60-75 | 39.7 | 45.4 | 41.6 | 43.6 |
| | >75 | 14.3 | 18.6 | 15.6 | 14.3 |
| Male sex | | 59.7 | 67.1 | 60.5 | 61.9 |
| BMI (kg/m²) | <25 | 27.7 | 21.7 | 27.2 | 24 |
| | 25.0-30.0 | 32.4 | 35.9 | 31.9 | 34.7 |
| | >30.0 | 39.9 | 42.4 | 40.9 | 41.3 |
| Preoperative status | Elective | 72.5 | 65.6 | 72.9 | 72.4 |
| | Urgent | 21.6 | 32.3 | 22.8 | 23.7 |
| | salvage | 5.8 | 2.1 | 4.3 | 3.8 |
| Smoking | | 18.8 | 23.5 | 19 | 20.0 |
| Diabetes mellitus | | 26.4 | 36.4 | 28 | 29.5 |
| hypertension | | 75.7 | 86.5 | 78.8 | 79.1 |
| Cerebrovascular disease | | 13.1 | 17.1 | 13.3 | 13.3 |
| Myocardial infarction | | 5.5 | 10.7 | 6.0 | 6.5 |
| Renal insufficiency | | 8.1 | 6 | 7.6 | 8.6 |
| CPB time ( min) mean ( SD ) | | 105.7 ( 54.0) | 97.5 ( 44.8 ) | 103.0 (51.0) | 102.1(50.0) |
| Cross clamp time ( min) mean ( SD ) | | 77.4( 37.2) | 70.8 (32.5 ) | 75.3(34.2) | 75.2(36.3) |

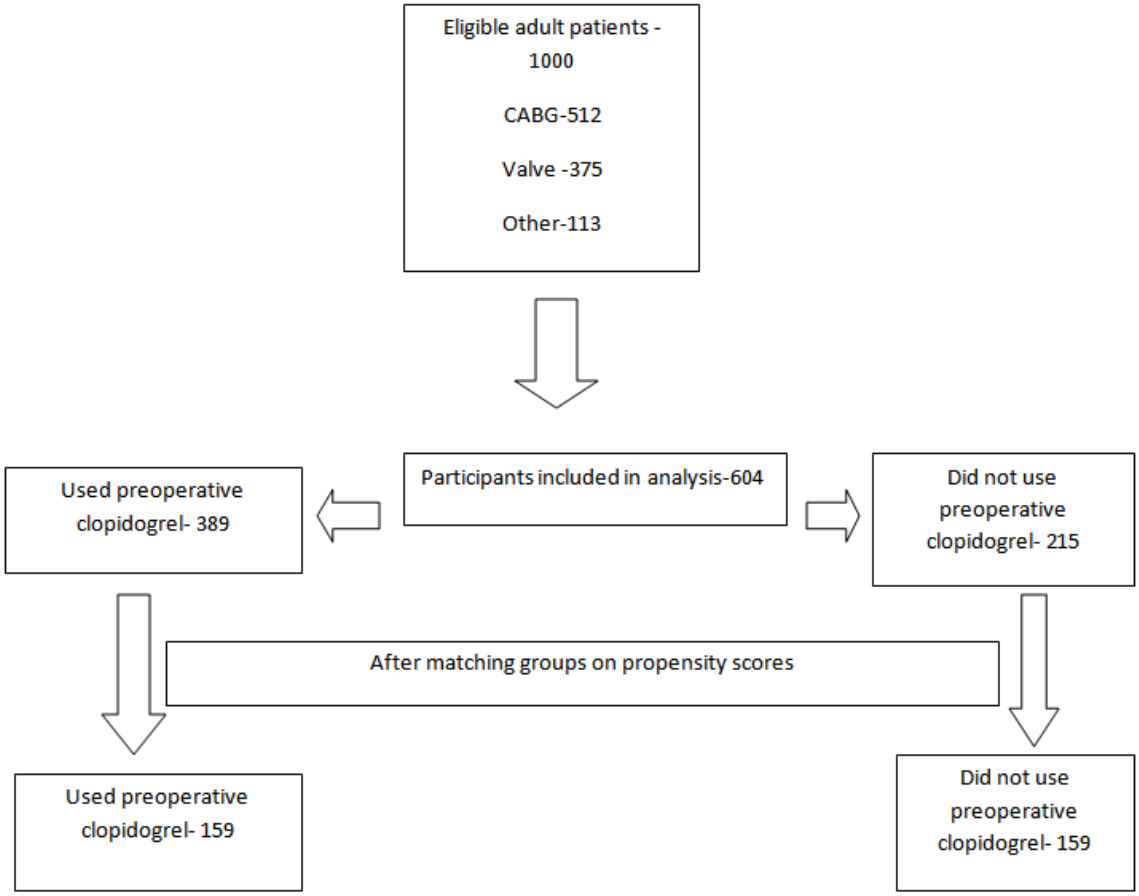
**Table 2** showing association between preoperative clopidogrel use and major clinical outcomes after cardiac operation in sample of propensity score matched patients

| outcome | No preoperative clopidogrel ( n=159) | | Preoperative clopidogrel ( n=159) | | Odds ratio | P value |
|---|---|---|---|---|---|---|
| | number | % | number | % | | |
| MACE | 13 | 8.17 | 13 | 8.17 | 1.01 | 0.96 |
| Stroke | 4 | 2.51 | 3 | 1.88 | 0.66 | 0.05 |
| TIA | 1 | 0.62 | 2 | 1.25 | 1.41 | 0.32 |
| Heart block | 4 | 2.51 | 4 | 2.51 | 1.1 | 0.66 |
| Cardiac arrest | 3 | 1.88 | 3 | 1.88 | 1.18 | 0.47 |
| Renal failure | 17 | 10.69 | 13 | 8.17 | 0.90 | 0.36 |
| 30 days mortality | 5 | 3.14 | 4 | 2.51 | 0.89 | 0.52 |
| Reoperation for bleeding | 7 | 4.40 | 8 | 5.03 | 1.19 | 0.28 |
| Blood transfusion yes/no | 74 | 46.54 | 70 | 44.02 | 0.92 | 0.25 |
| Post operative infection | 5 | 3.14 | 5 | 3.14 | 1.07 | 0.75 |

**Table 3** showing Association Between Preoperative Aspirin Use and Major Clinical Outcomes After Cardiac Operations by Type of Surgical Procedure in a Sample of Propensity Score–Matched Patients

| outcome | | No preoperative clopidogrel | | Preoperative clopidogrel | | Odds ratio | P value |
|---|---|---|---|---|---|---|---|
| | | number | % | Number | % | | |
| CABG only (72) | MACE | 4 | 5.5 | 4 | 5.5 | 1.1 | 0.68 |
| | Renal failure | 8 | 11.11 | 7 | 9.72 | 0.9 | 0.59 |
| | 30 day mortality | 1 | 1.38 | 2 | 2.77 | 1.2 | 0.52 |
| | Reoperation for bleeding | 1 | 1.38 | 1 | 1.38 | 1.0 | 0.88 |
| | Blood transfusion yes /no | 31 | 43.05 | 30 | 41.66 | 0.98 | 0.59 |
| | infection | 2 | 2.77 | 1 | 1.38 | 0.76 | 0.32 |
| Valve only (87) | MACE | 10 | 11.49 | 10 | 11.49 | 1.1 | 0.45 |
| | Renal failure | 10 | 11.49 | 11 | 12.64 | 0.97 | 0.86 |
| | 30 day mortality | 4 | 4.59 | 4 | 4.59 | 1.0 | 0.96 |
| | Reoperation for bleeding | 4 | 4.59 | 7 | 8.04 | 1.4 | 0.04 |
| | Blood transfusion yes /no | 50 | 57.47 | 54 | 62.06 | 0.94 | 0.59 |
| | infection | 3 | 3.44 | 3 | 3.44 | 0.72 | 0.32 |

**Figure 1** showing study sample collection

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