Statistical Analysis Plan **(15/07/2022)**

Title： ***A Prospective Randomized Controlled Trial of the Effect of Different Pancreaticojejunostomy After Pancreaticoduodenectomy on Postoperative Pancreatic Fistula Based on the Position of the Pancreatic Duct in Pancreatic Section***

Randomization was generated by a computer program and sealed envelopes labels were opened in the operating room before pancreaticoduodenectomy was performed. The participants were randomly divided into the experimental group and the control group. The experimental group underwent intraoperative measurements (A: short distance from the center of the pancreatic duct to the edge of the pancreas) and (B: pancreatic thickness). When the ratio of the thickness of the short distance from the center of the pancreatic duct to the edge of the pancreas at the pancreatic section was ≥0.401, it was divided into the N1 group (central pancreatic duct). If the ratio was <0.401, it was divided into the N2 group (eccentric pancreatic duct). The "central pancreatic duct" group was given "1+1 mode" pancreaticojejunostomy; the "eccentric pancreatic duct" group was given "1+1² mode" pancreaticojejunostomy. The patients in the control group were given "traditional pancreaticojejunostomy".

The sample-size determination was based on the estimate of a previous retrospective study to detect a two-sided difference. Using clinically relevant pancreatic fistula of 23.5% in the control group and 15.8% in experimental group group ($\alpha = 0.05$, power 80%) and the dropout rate was10%, therefore, it was calculated that 462 patients per arm would be required. Statistical analysis was carried out using SPSS software version 20 (IBM Corp., Armonk, NY, USA). Variables were compared using the χ test and independent samples t-test. Differences were considered significant at a *P*-value of < 0.05.

Tests for Two Proportions

Numeric Results for Testing Two Proportions using the Z-Test with Unpooled Variance

H0: P1 - P2 = 0. H1: P1 - P2 = D1 ≠ 0.

Target Power	Actual Power*	N1	N2	N	P1	P2	Diff D1	Alpha
0.80	0.80085	415	415	830	0.1580	0.2350	-0.0770	0.0500

* Power was computed using the normal approximation method.

References

Chow, S.C., Shao, J., and Wang, H. 2008. Sample Size Calculations in Clinical Research, Second Edition. Chapman & Hall/CRC. Boca Raton, Florida.

D'Agostino, R.B., Chase, W., and Belanger, A. 1988. The Appropriateness of Some Common Procedures for Testing the Equality of Two Independent Binomial Populations', The American Statistician, August 1988, Volume 42 Number 3, pages 198-202.

Fleiss, J. L., Levin, B., and Paik, M.C. 2003. Statistical Methods for Rates and Proportions. Third Edition. John Wiley & Sons. New York.

Lachin, John M. 2000. Biostatistical Methods. John Wiley & Sons. New York.

Machin, D., Campbell, M., Fayers, P., and Pinol, A. 1997. Sample Size Tables for Clinical Studies, 2nd Edition. Blackwell Science. Malden, Mass.

Ryan, Thomas P. 2013. Sample Size Determination and Power. John Wiley & Sons. Hoboken, New Jersey.

Report Definitions

Target Power is the desired power value (or values) entered in the procedure. Power is the probability of rejecting a false null hypothesis.

Actual Power is the power obtained in this scenario. Because N1 and N2 are discrete, this value is often (slightly) larger than the target power.

N1 and N2 are the number of items sampled from each population.

N is the total sample size, N1 + N2.

P1 is the proportion for Group 1 at which power and sample size calculations are made. This is the treatment or experimental group.

P2 is the proportion for Group 2. This is the standard, reference, or control group.

D1 is the difference P1 - P2 assumed for power and sample size calculations.

Alpha is the probability of rejecting a true null hypothesis.

Summary Statements

Group sample sizes of 415 in group 1 and 415 in group 2 achieve 80.085% power to detect a difference between the group proportions of -0.0770. The proportion in group 1 (the treatment group) is assumed to be 0.2350 under the null hypothesis and 0.1580 under the alternative hypothesis. The proportion in group 2 (the control group) is 0.2350. The test statistic used is the two-sided Z-Test with unpooled variance. The significance level of the test is 0.0500.

Dropout-Inflated Sample Size

	Sample Size			Dropout-Inflated Enrollment Sample Size			Expected Number of Dropouts		
Dropout Rate	N1	N2	N	N1'	N2'	N'	D1	D2	D
10%	415	415	830	462	462	924	47	47	94