Endoscopic versus percutaneous biliary drainage for resectable pancreatic head cancer with hyperbilirubinemia and impact on pancreaticoduodenectomy: A prospective cohort study

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Statistical analysis plan

The minimum sample size required was 49 patients at 0.3% prevalence, accepting 5% error at 80% power and 0.05 level of significance.

Statistical analysis was done using Statistical Package of Social Science Program (SPSS) version 20. (Chicago: SPSS Inc.).

The qualitative variables were summarized by frequency and percentage. Chi squared test was used to test for association between the type of drainage and the other qualitative variables. Monte Carlo test or fisher exact test were used if more than 20% of the cells had expected cell counts < 5.

The quantitative variables were summarized by the mean and standard deviation. Student' test was used to compare between the two types of drainage as regards the quantitative variables. Paired t test was used to compare between the pre and post-operative changes in the mean values of the quantitative variables. Multivariate 5% level of significance was used.

All tests of association or tests of comparison were done at 0.05 level of significance (two tailed).