

IMPACT OF PERIOPERATIVE SYNBIOTICS ON INFECTIOUS COMPLICATIONS AFTER PANCREATODUODENECTOMY- AN INTERIM ANALYSIS OF A RANDOMIZED CONTROLLED TRIAL

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Background : This study evaluated whether perioperative synbiotics reduce infective complications after pancreatoduodenectomy(PD) in the Indian scenario.

Methods : This single-centre, open-label randomised control trial, started in May 2024, compared perioperative synbiotics with conventional management after PD, with stratification based on preoperative biliary stenting. Synbiotics group received one synbiotic capsule/day(six probiotic bacteria and one prebiotic) 2 days before and 8 days after PD. The primary outcome was composite 30-day infective complications. The sample size was 36 patients/group, with planned interim analysis after 75% recruitment. (Trial Protocol registered in [ctri.nic.in](https://clinicaltrials.gov/ct2/show/study?term=CTRI/2024/05/067619), CTRI/2024/05/067619)

Results : Sixty-one patients - 32 in synbiotics and 29 in conventional group, were recruited. The demographic and preoperative disease characteristics were comparable with similar rates of pre-operative biliary stenting(14/32, 44% synbiotics vs 10/29, 35% conventional). The commonest indication was ampullary cancer in about 60%, with similar operative duration(median 600 min in both groups) and intraoperative blood loss (Median 300ml vs 350ml). Overall infectious morbidity(14/32, 45% vs 21/29, 72.4%, p=0.006), passage of stool(median 2 vs 3 days, p<0.001) and hospital stay (median 8 vs 11 days, p=0.019) were significantly better in the synbiotics group. Overall non-infectious morbidity (19/32, 61% vs 24/29, 82.7%, p=0.086), Clavien-Dindo > IIIA grade morbidity(4/32, 12.9% vs 10/29, 34.5%, p=0.15) and 30-day mortality (4/32, 12.5 vs 3/29,10.3, p=0.78) were similar.

Conclusions : Perioperative synbiotics may reduce post-operative infectious complications and hospital stay with a non-significant trend towards lower major morbidity, after PD for malignancy. The final analysis after complete recruitment may offer more insight on the utility of perioperative synbiotics after PD.

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