NEW-ONSET DIABETES AFTER TRANSPLANTATION (NODAT) AND GLUCOSE METABOLISM IN AT-RISK PATIENTS RECEIVING CYCLOSPORINE VERSUS TACROLIMUS: A RANDOMISED CONTROLLED TRIAL

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- Financial Disclosure-None

AIMS AND OBJECTIVES

- **Primary objective:**

1) Incidence of “New-onset diabetes after transplant (NODAT)” in high-risk patients received tacrolimus versus cyclosporine.

- **Secondary objectives:**

1) FBS, OGTT, and HbA1c in high-risk patients received cyclosporine versus tacrolimus.

2) Insulin sensitivity , insulin resistance (IR) and beta cell function in high risk patients received cyclosporine versus tacrolimus.

3) Incidence of acute rejections in patients received cyclosporine versus tacrolimus.

Materials and Methods

Study Design:

•Open-label, randomized controlled trial

•Conducted at PGIMER, Chandigarh

Duration:-1.5 years (Jan 2017 - Jun 2018)

Participants:

ESRD patients post-living donor renal transplantation randomized to receive Tac or Cyc

Inclusion Criteria: ESRD with any one of below

- Pre-diabetes (FPG >100 and <126 mg%)
- Family h/o DM
- BMI > 25
- Untreated Hepatitis C patients

Exclusion Criteria:

- De novo diabetes mellitus pre-transplant
- Diabetic nephropathy
- High-risk transplants

Intervention:

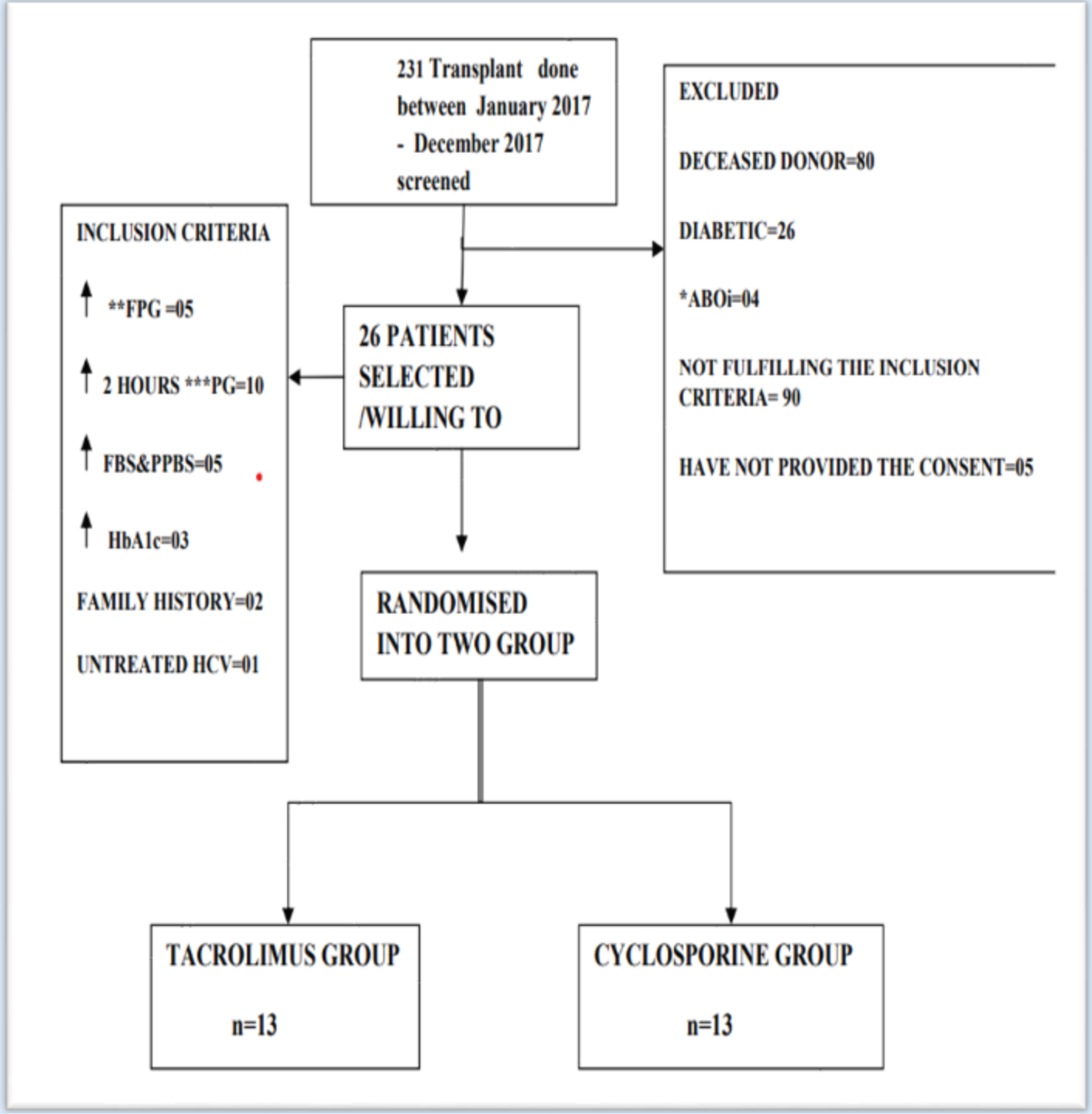
•**Cyclosporine:** 3-5 mg/kg/day, target trough 100-350 ng/ml as per protocol

•**Tacrolimus:** 0.1-0.2 mg/kg/day, target trough 5-15 ng/ml as per protocol

Follow-Up:

•Monitored at 1, 3, and 6 months

•Assessed for NODAT, glucose metabolism, HOMA-2



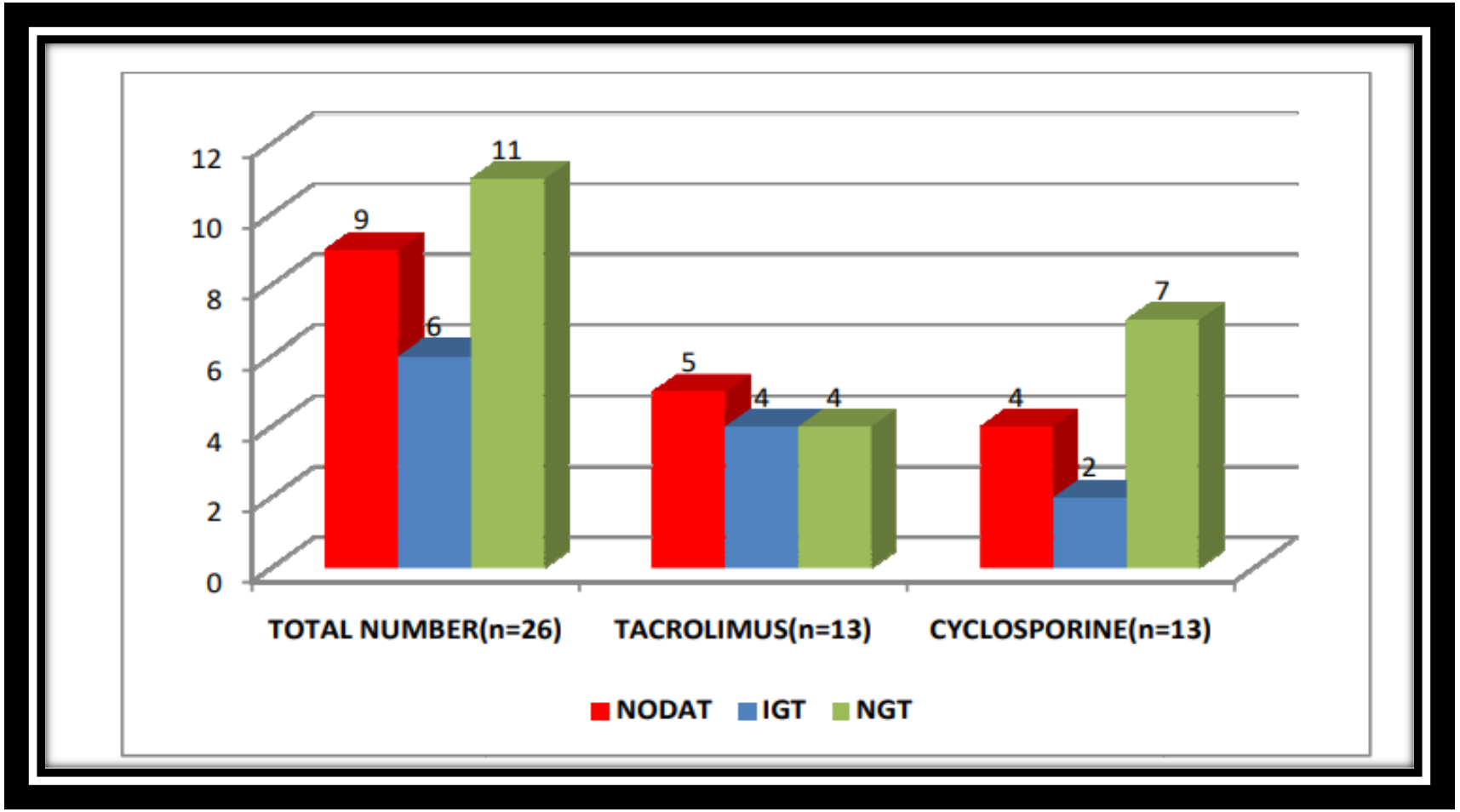


Fig : Incidence of NODAT /IGT/NGT in Tacrolimus and Cyclosporine arm

- NODAT - New-onset Diabetes After Transplant
- IGT -Impaired Glucose Tolerance
- NGT -Normal Glucose Tolerance

CONCLUSIONS

1. Glucose Metabolism Monitoring: Assess glucose metabolism and NODAT risk in renal transplant patients, with OGTT recommended pre- and post-transplant.

2. Cyclosporine vs. Tacrolimus: Cyclosporine showed a lower incidence of NODAT or pre-diabetes at 6 months compared to tacrolimus.

3. β Cell Function: Cyclosporine demonstrated better β cell function and non-inferior graft rejection prevention.

4. Study Limitations: Small sample size and short follow-up limit the findings.

5. Need for Further Research: Larger studies are needed to confirm these results and optimize therapy.