

# Safety and efficacy of Fish Oil-Based Lipid Emulsion in the treatment of Intestinal Failure Associated Liver Disease:

## 11 year experience in a quaternary neonatal intensive care unit

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### Background

- Soybean-oil based lipid emulsion, or SOLE (Intralipid®) has long been used as a parenteral source of lipids in neonates with intestinal failure. However, long term use of SOLE has been shown to cause intestinal failure associated liver disease (IFALD).
- Fish oil based lipid emulsion or FOLE (Omegaven®) due to its anti-inflammatory profile has been hypothesized to be therapeutic in IFALD.
- At Texas Children's Hospital, FOLE was provided to infants with IFALD under a compassionate use protocol from 2007 until its approval by the FDA in 2018.
- While the therapeutic effects of FOLE in IFALD are well known, whether the use of FOLE alters the risk of blood stream infection (BSI) in IFALD is unclear

### Objective

- To study the safety and efficacy of FOLE in the treatment of infants with IFALD at TCH, provided under a compassionate use protocol from 2007 to 2018
- To compare the rate of BSI during FOLE therapy with SOLE therapy in infants with IFALD

### Study Design

- 278 Infants enrolled in the compassionate use protocol to receive FOLE in the treatment of IFALD at Texas Children's Hospital, Houston Texas 2007-2018 were included in the initial study population.
- Eligibility criteria for FOLE therapy
  - Age > 14 days,
  - conjugated bilirubin (CB) ≥ 2 mg/dL,
  - Expected parenteral nutrition need of >28 days
- For analysis of BSI, 153 patients were included after excluding those with incomplete records (primarily due to transfer from outside institutions).
- Mixed effects Poisson regression models were used to assess associations of variables with BSI incidence rate per line day.
- Random effects Poisson regression models were used to investigate predictors' association with the BSI rate while accommodating repeated measures on the same patients over time.

### Results

Table 1. Patient Characteristics and Outcomes

|  |            |
|--|------------|
| Total infants in FOLE (Omegaven®) protocol               | 278        |
| M:F  | 183:95     |
| Gestational age (wks)#                                   | 29.7 ± 5   |
| Conjugated bilirubin (CB) at initiation of FOLE (mg/dL)# | 5.3 ± 3.9  |
| Resolution of cholestasis (n,%)                          | 232 (83.4) |
| Died (n,%)   | 43 (15.4)  |
| Liver Transplant (n,%)                                   | 3 (1.07)   |
| Time for resolution of cholestasis (d)#                  | 43 ± 29    |

Table 2. Blood Stream Infection Data

|  |               |
|--|---------------|
| Patients included in BSI analysis            | 153           |
| Total BSI                                    | 146           |
| Patients with BSI, n (%)                     | 93 (60.8)     |
| Overall BSI rate per 1000 patient days       | 8.9           |
| BSI rate per 1000 patient days SOLE vs. FOLE | 12.6 vs. 6.1* |

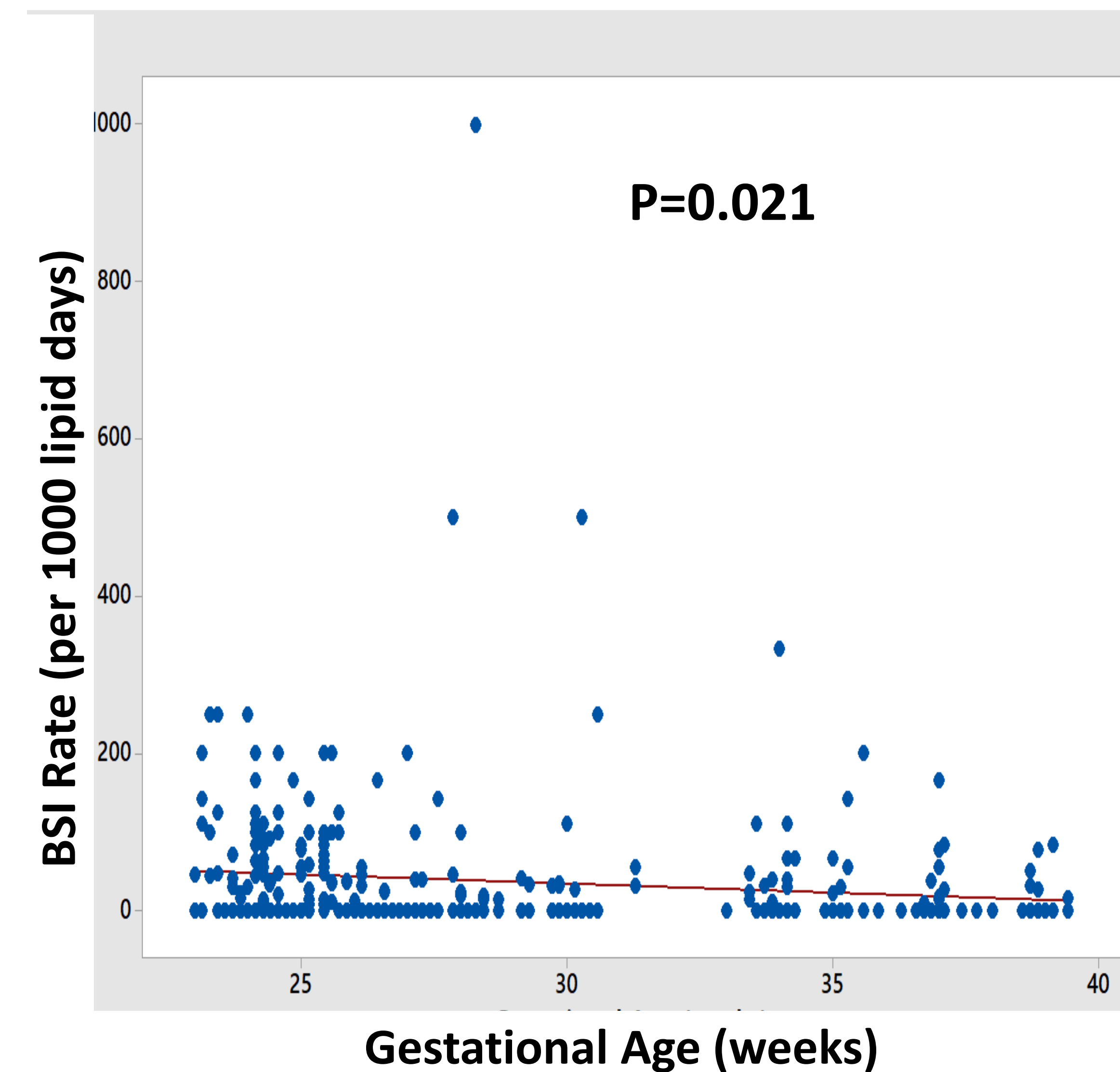
#= Mean SD, \*=p<0.05

Table 3. Predictors of BSI

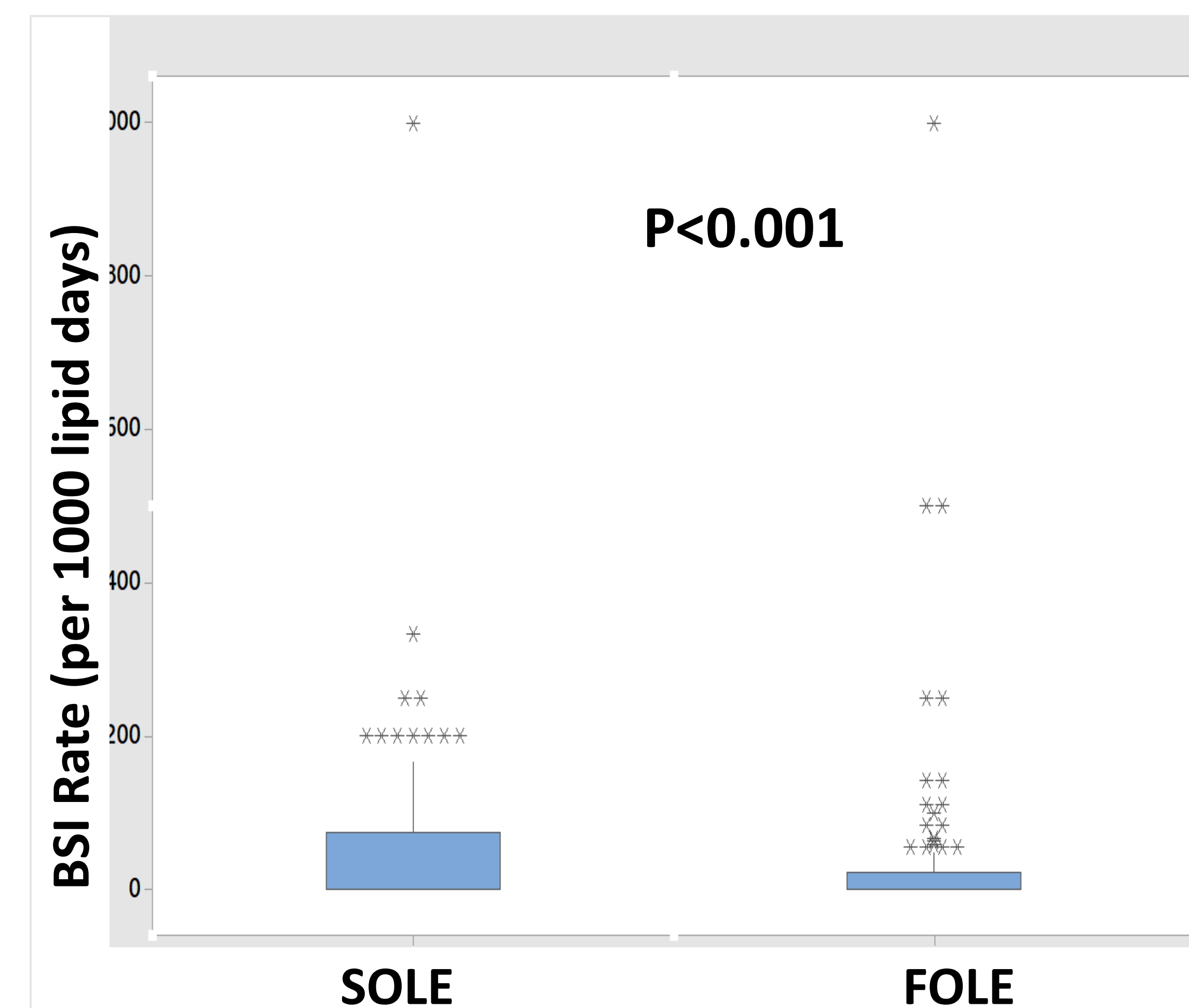
| Predictor   | Slope Coefficient | p-value |
|---|-------------------|---------|
| Gestational age                                       | -0.0465           | 0.021*  |
| Birth weight  | -0.00001          | 0.446   |
| Male sex  | 0.1713            | 0.383   |
| SOLE treatment  | 0.7213            | <0.001* |
| Total duration of therapy                             | -0.00605          | 0.009*  |
| Lipid dose at BSI or end of therapy                   | 0.3910            | <0.001* |
| Central line factors (prior to BSI or end of therapy) |                   |         |
| Line days on therapy                                  | -0.02765          | <0.001* |
| Cumulative number of lines                            | -0.5347           | <0.001* |
| Upper extremity line                                  | -0.4445           | 0.029*  |
| Lower extremity line                                  | -0.3380           | 0.121   |
| Double lumen  | -0.4517           | 0.031*  |
| Peak CB during therapy                                | 0.01326           | 0.300   |

\*=p<0.05

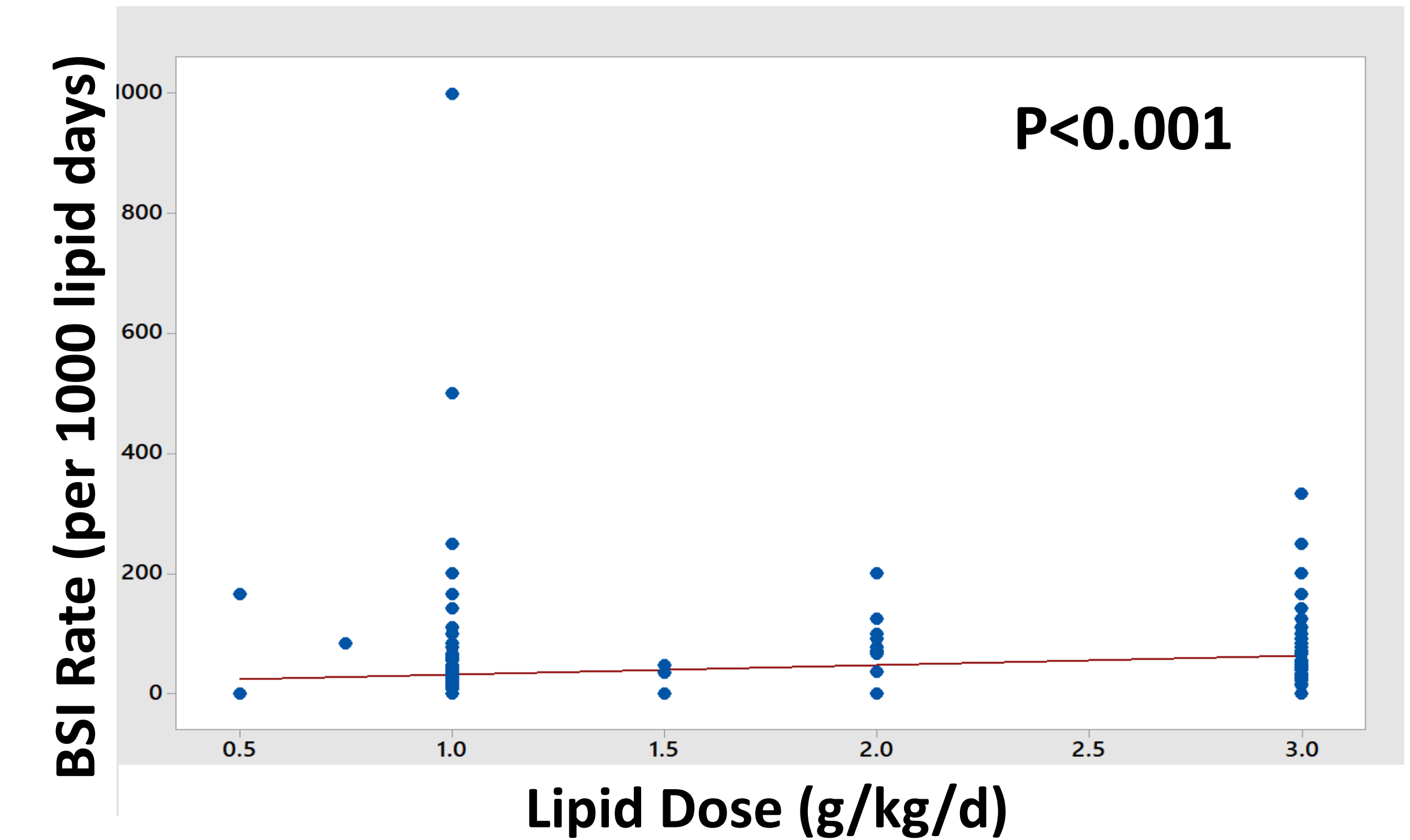
### Fig. 1. Gestational Age vs. BSI



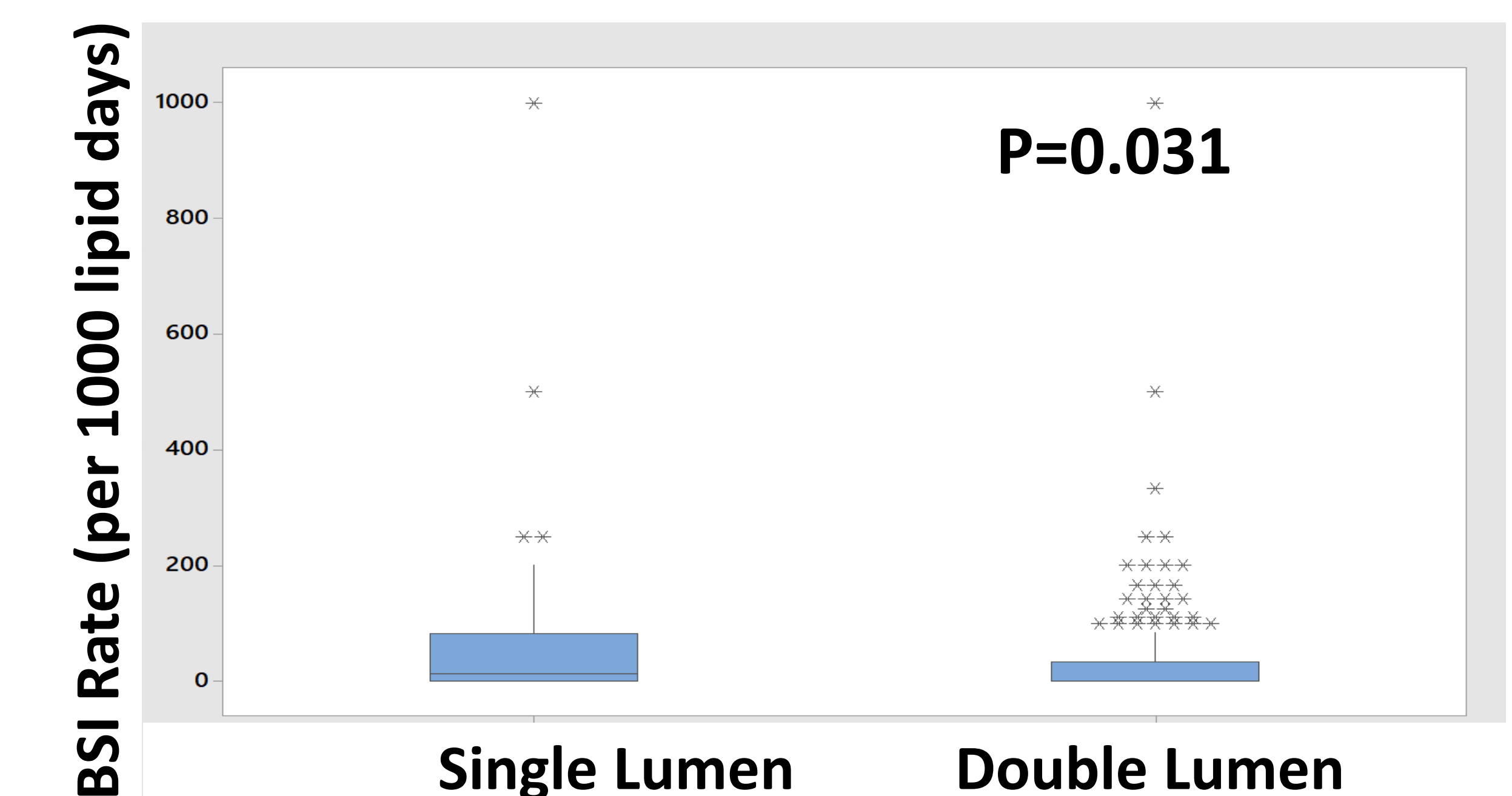
### Fig. 2. Rate of BSI SOLE vs. FOLE



### Fig. 3. Rate of BSI vs. Lipid dose



### Fig. 4. Rate of BSI vs. Lumen of CVL



### Conclusions

- FOLE facilitated a high rate of resolution of cholestasis, high survival, and a decreased need for transplant in infants with IFALD.
- Use of FOLE was associated with lower rate of BSI when compared to SOLE BSI when compared to SOLE.
- Furthermore, lower GA, longer duration of lipid therapy, higher lipid dose, and single lumen central venous line (CVL) were associated with higher incidence of BSI.