Immediate Delivery or Expectant Management in Gestational Diabetes at Term: the GINEXMAL Randomized Controlled Trial

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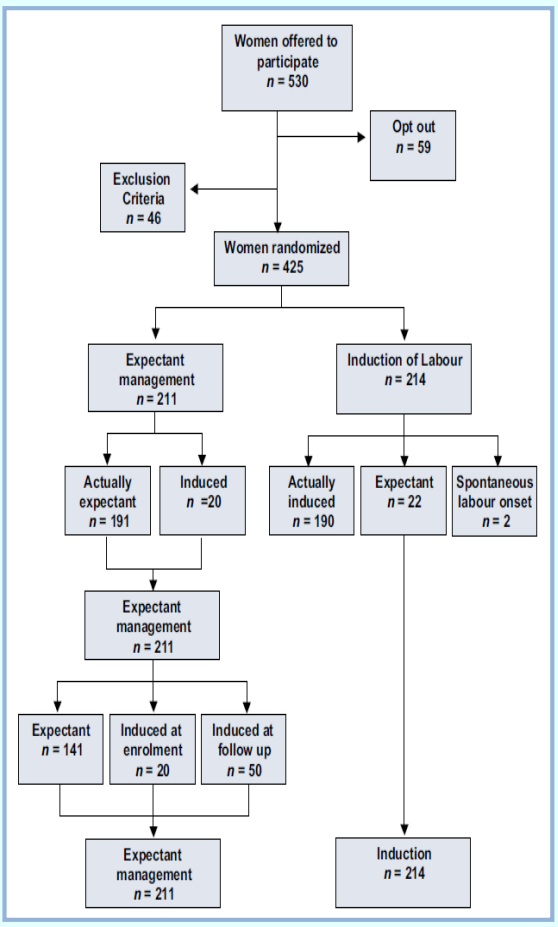
OBJECTIVE

To evaluate maternal and perinatal outcomes after induction of labor versus expectant management in pregnant women with gestational diabetes at term.

STUDY DESIGN

Multicenter open-label randomized controlled trial conducted at 8 centers teaching hospitals in Italy, Slovenia, and Israel. Women with singleton gestation, diagnosed with gestational diabetes, were randomized between 38+0 and 39+0 weeks of gestation, to induction of labor or expectant management and intensive follow-up. The diagnosis of GDM was based on the IADPSG criteria adapted by means of the standard practice at each center. Before the consensus was published some centers adopted Carpenter and Coustan criteria, according to the study protocol. Data were analyzed by 'intention to treat'. The primary outcome was incidence of cesarean delivery and secondary outcomes were maternal and perinatal mortality and morbidity.



RESULTS

425 women were randomized. There were no significant differences between the two groups for various maternal characteristics among the women randomised into the two study arms, except for GDM treatment.

The incidence of cesarean delivery was 12.6% in the induction group versus 11.7% in the expectant group (RR 1.06; 95% CI 0.64-1.77; p=0.81).

The incidence of non-spontaneous delivery, either by cesarean delivery or by operative vaginal delivery, was 21.0 and 22.3%, respectively (RR 0.94; 95% CI 0.66-1.36; p= 0.76).

No maternal or perinatal deaths occurred and no significant difference was found in maternal outcomes. Among neonatal outcomes, the only difference was identified with regards to neonatal hyperbilirubinemia. Relative risk for developing hyperbilirubinemia among neonates born in the induction group was two-fold greater compared with neonates in the expectant group (RR 2.46; 95% CI 1.11-5.46; P = 0.03). The few cases of shoulder dystocia were solved without any significant birth trauma.

Primary, Maternal and Neonatal Outcomes of the Study Groups

	Induction n=214	Expectant n=211	Relative Risk (95% CI)	P
Cesarean Delivery	27 (12.6)	25 (11.8)	1.06 (0.64-1.77)	.81
Cesarean or Operative Delivery	45 (21.0)	47 (22.3)	0.94 (0.66-1.36)	.76
Assisted 3rd Stage	22 (10.3)	27 (12.8)	0.8 (0.47-1.36)	.42
Intact Perineum	53 (37.3)	46 (35.1)	1.0	-
Grade I-II Perineal Tear	89 (62.7)	82 (62.6)	1.04 (0.76-1.42)	.82
Grade III-IV Perineal Tear	0	3 (2.3)	Not estimable	.12
Post Partum Hemorrhage	13 (6.1)	11 (5.2)	1.16 (0.53-2.54)	.7
ICU Admission	3 (1.4)	2 (0.9)	1.48 (0.25-8.76)	1.0
Gestational Age at Birth > 39w	74 (22.0)	157 (74.4)	0.30 (0.23-0.38)	**<.001**
Macrosomia	13 (6.1)	24 (11.4)	0.53 (0.28-1.02)	.06
Apgar 1 <7	12 (5.6)	4 (1.9)	2.96 (0.97-9.03)	.05
Apgar 5 <7	2 (0.94)	0	Not estimable	.5
Shoulder Dystocia	3 (1.4%)	1(0.5)	2.96 (0.31-28.21)	.62
Biochemical Hypoglycemia	6 (3.0)	8 (4.1)	0.74 (0.2-2.09)	.6
Hyperbilirubinemia	20 (10.0)	8 (4.1)	2.46 (1.11-5.46)	**.03**
Respiratory Distress	3 (1.4)	2 (0.9)	1.48 (0.25-8.76)	1.00
NICU Admission	2 (0.9%)	2 (0.9)	0.99 (1.14-6.94)	1.00

Data presented as n(%)

CONCLUSIONS

In women with gestational diabetes, without other maternal or fetal conditions, no difference was detected in birth outcomes regardless of the approach used (i.e. active versus expectant management). Although the study was underpowered, the magnitude of the between-group difference was very small and without clinical relevance.