Il dr. Pintaudi Basilio dichiara di aver ricevuto negli ultimi due anni compensi o finanziamenti dalle seguenti Aziende Farmaceutiche e/o Diagnostiche:

- Johnson & Johnson
- Roche S.p.a.
- Healthware per Sanofi

Dichiara altresì il proprio impegno ad astenersi, nell'ambito dell'evento, dal nominare, in qualsivoglia modo o forma, aziende farmaceutiche e/o denominazione commerciale e di non fare pubblicità di qualsiasi tipo relativamente a specifici prodotti di interesse sanitario (farmaci, strumenti, dispositivi medico-chirurgici, ecc.).



Lo studio STRONG: quali evidenze per ottimizzare la pratica clinica corrente

Dr. Basilio Pintaudi
Niguarda Ca' Granda Hospital
Interdisciplinary Diabetes and Pregnancy Center
Milan, Italy

METHODS

✓Observational, retrospective, multicenter study

✓Women with pregnancy complicated by GDM in the period between January 2012 and June 2015

✓Italian diabetes centers with more than 30 cases of GDM/year followed in the period of study.

PRIMARY ENDPOINT

The study aimed to assess the **risk of adverse neonatal outcomes** in women with a diagnosis of gestational diabetes by identifying **subgroups of women at higher risk** in order to recognize the characteristics most associated with an excess of risk.

SECONDARY ENDPOINTS

-Prevalence of fetal growth large or small for gestational age.
-Prevalence of neonatal malformations.
-Prevalence of shoulder dystocia.
-Prevalence of other neonatal trauma.
-Prevalence of childbirth requiring hospitalization in neonatal intensive care.
-Prevalence of neonatal hypoglycemia.
-Prevalence of neonatal hypocalcaemia.
-Prevalence of neonatal hyperbilirubinemia.
-Prevalence of respiratory distress.
-Prevalence of neonatal mortality.
-Prevalence of maternal mortality.
-Percentage of insulin treated women according to the adverse outcomes.
-Type of insulin patterns used and insulin doses according to the occurrence of adverse neonatal outcomes.
-Percentage of pregnancies hesitated in operative or spontaneous delivery .
-Prevalence of abortions.
-Percentage of women in need of antihypertensive therapy during pregnancy.
-Percentage of women in need of antiplatelet therapy during pregnancy.
-Prevalence of adverse outcomes according to the single altered OGTT points.

COLLECTED INFORMATION

- socio-demographic characteristics
- anthropometric and clinical characteristics
- risk factors for GDM
- laboratory parameters and screening tests
- therapy
- self-monitoring blood glucose
- ultrasound examinations performed
- maternal-fetal outcomes

COLLECTED INFORMATION

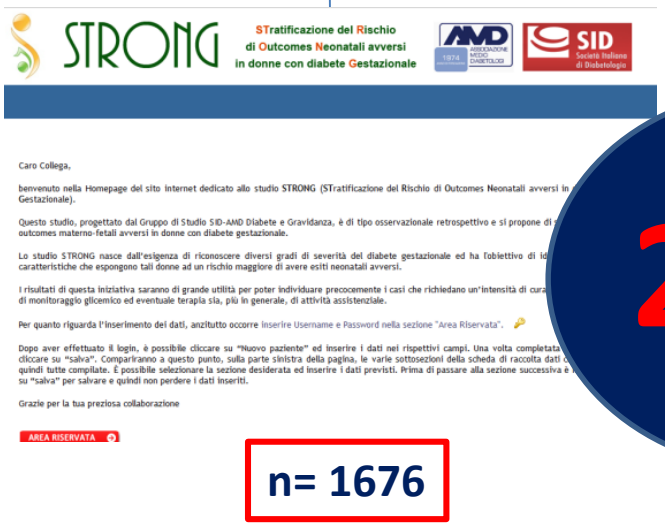
71 Centers desired to participate

18 Centers without local approval

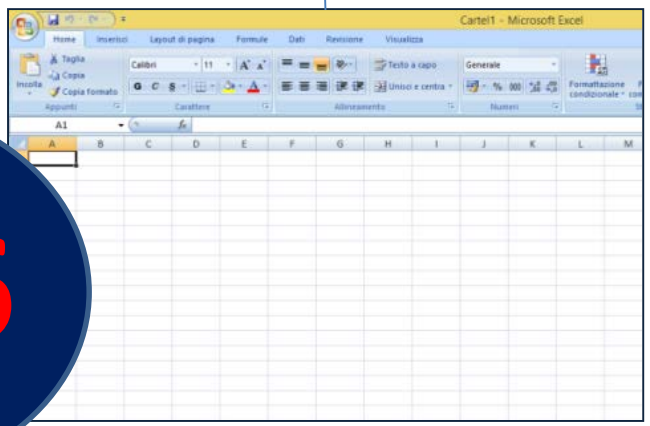
5 Centers withdrew adhesion

39 Centers collected information on a dedicated website

9 Centers collected information on an Excel file



2736



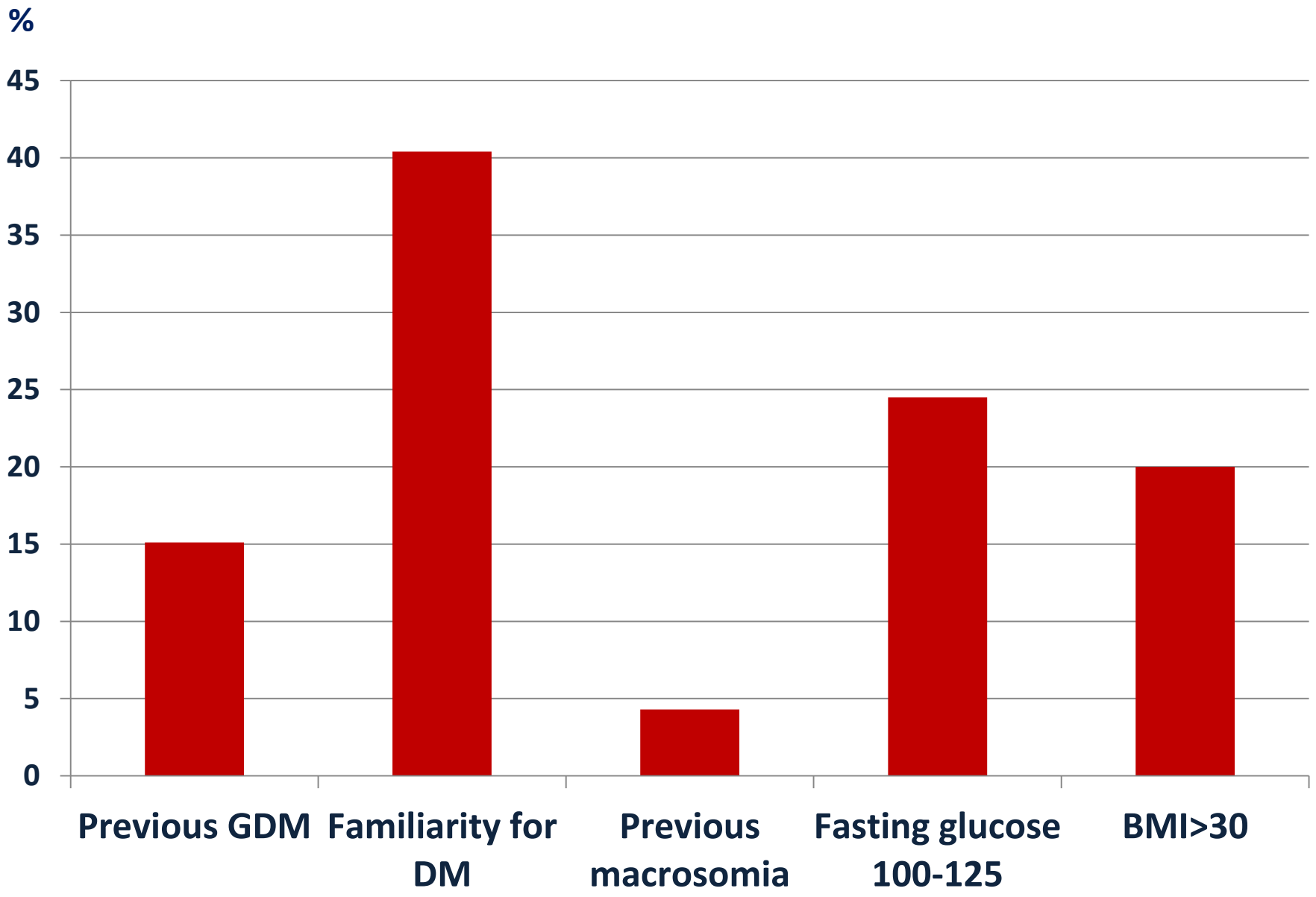
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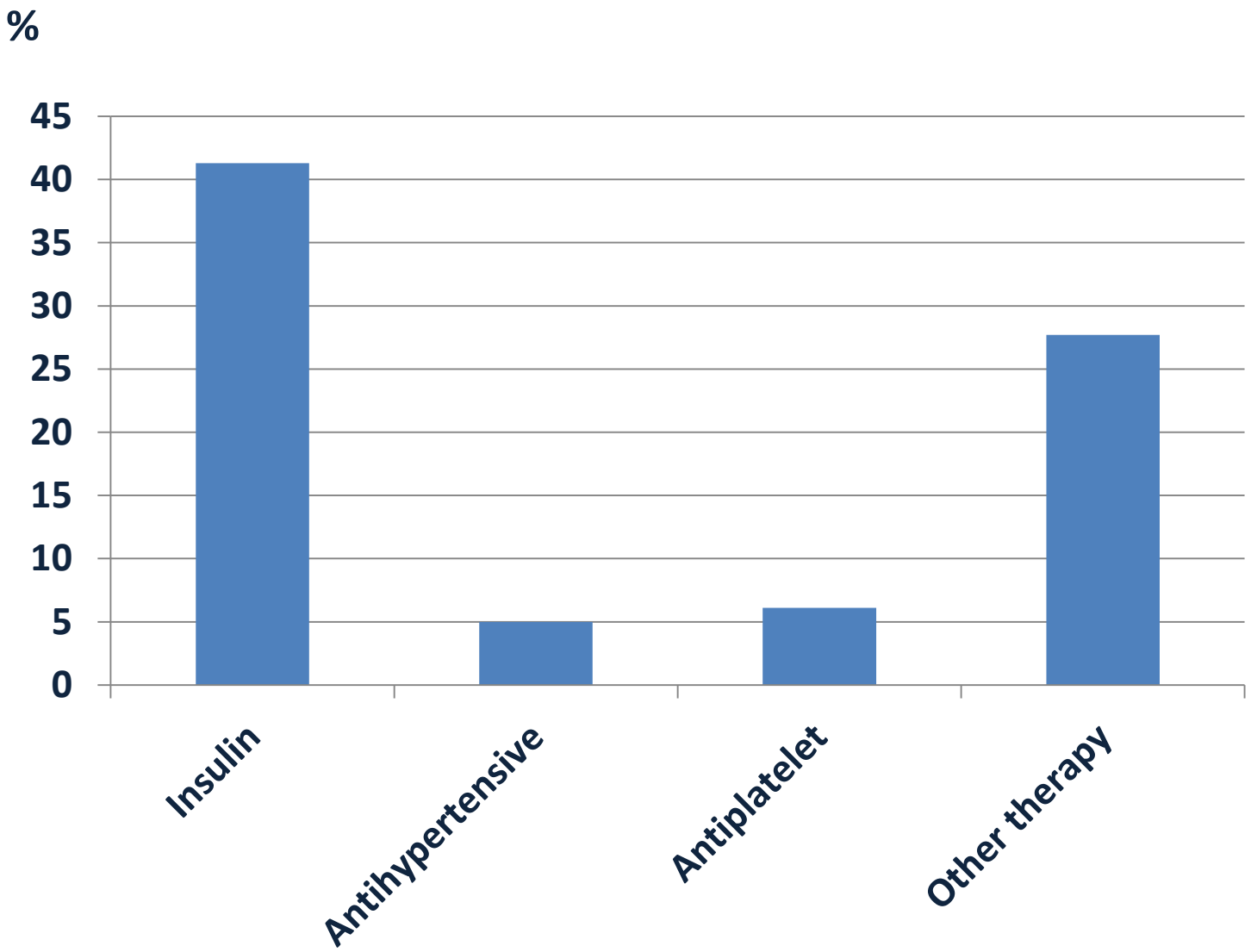
RESULTS: GENERAL CHARACTERISTICS

Age (years)	37.4 (33.8-40.8)
Smokers (%)	8.6
Job activity (%)	
Housewife	33.8
Worker	65.4
Student	0.8
School (%)	
Secondary school	23.9
High school	28.2
University	47.9
Pre-gestational BMI (kg/m2)	24.6 (21.9-28.6)
Diastolic blood pressure (mmHg)	70.0 (60.0-78.0)
Sistolic blood pressure (mmHg)	110.0 (100.0-120.0)
First pregnancy (%)	48.4
Previous abortion (%)	25.9

RESULTS: RISK FACTORS PREVALENCE



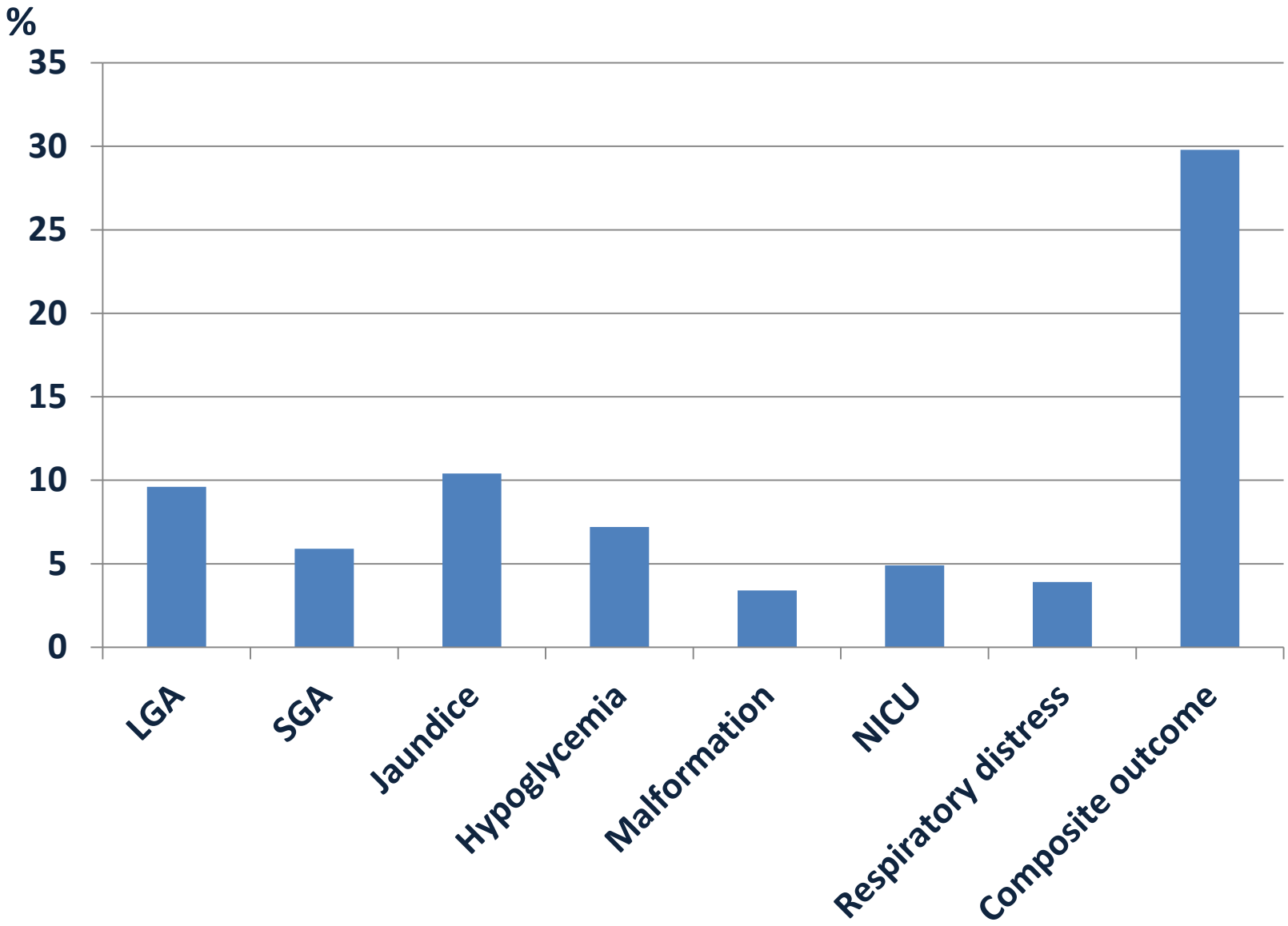
RESULTS: THERAPY



RESULTS: PREGNANCY OUTCOMES

- ✓2 stillbirths
- ✓No maternal death
- ✓1 neonatal death
- ✓46.4% cesarean section

RESULTS: NEONATAL OUTCOMES



	Composite Outcome NO	Composite Outcome YES	p
Pre-gestational BMI	24.4 (21.7-28.6)	25.3 (22.3-29.4)	0.003
OGTT 16-18 weeks T0	95.0 (88.0-99.0)	97.0 (91.0-102.0)	0.002
HbA1c at diagnosis	33.3 (30.1-36.6)	34.4 (31.2-37.7)	0.001
Previous macrosomia	2.3	6.2	<0.0001
Diastolic blood pressure	70.0 (60.0-78.0)	70.0 (60.0-80.0)	0.04
Gestational week at delivery	39.0 (38.0-40.0)	38.0 (37.0-39.0)	<0.0001

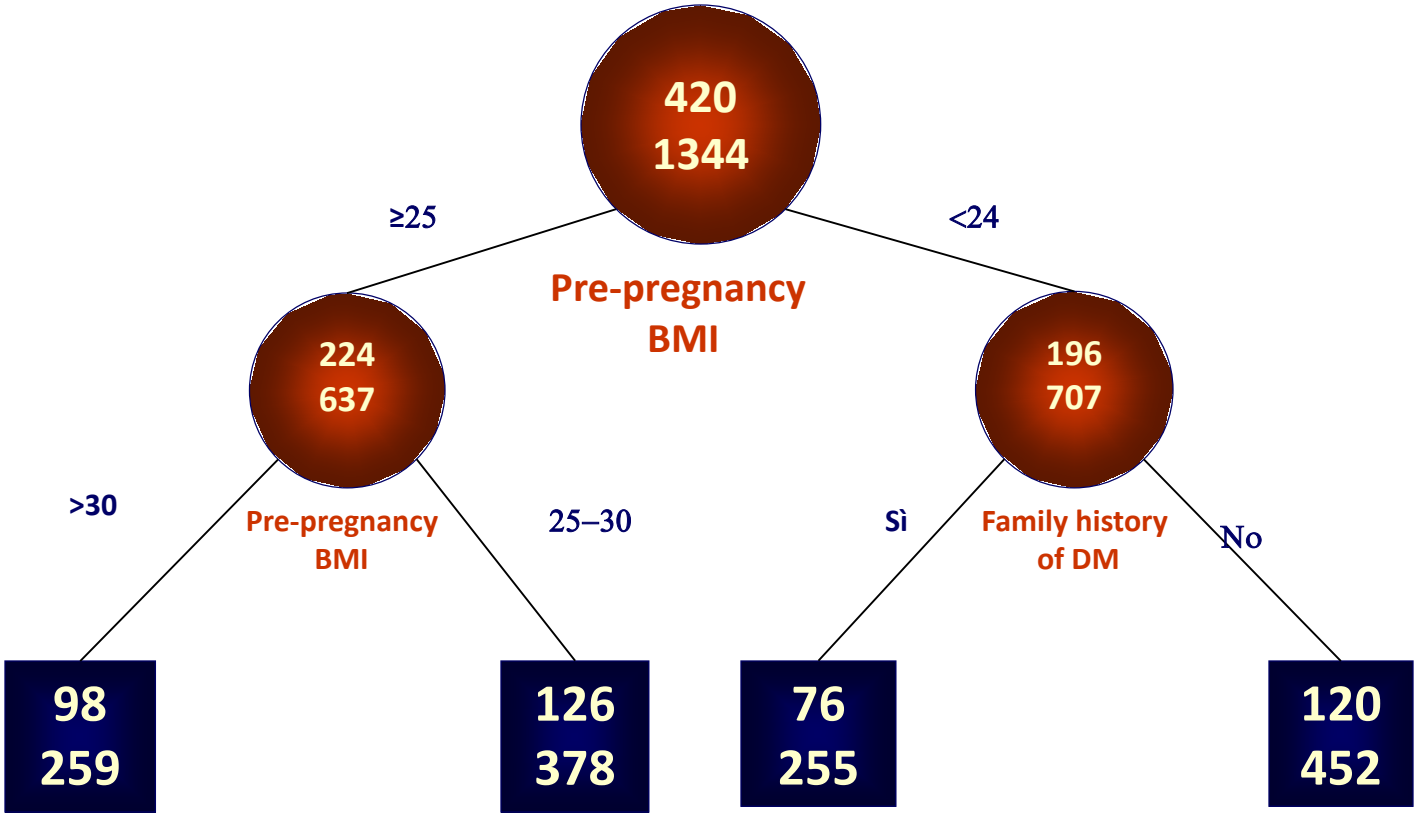




LO STUDIO STRONG: QUALI POSSIBILI RISVOLTI CLINICI PRATICI?

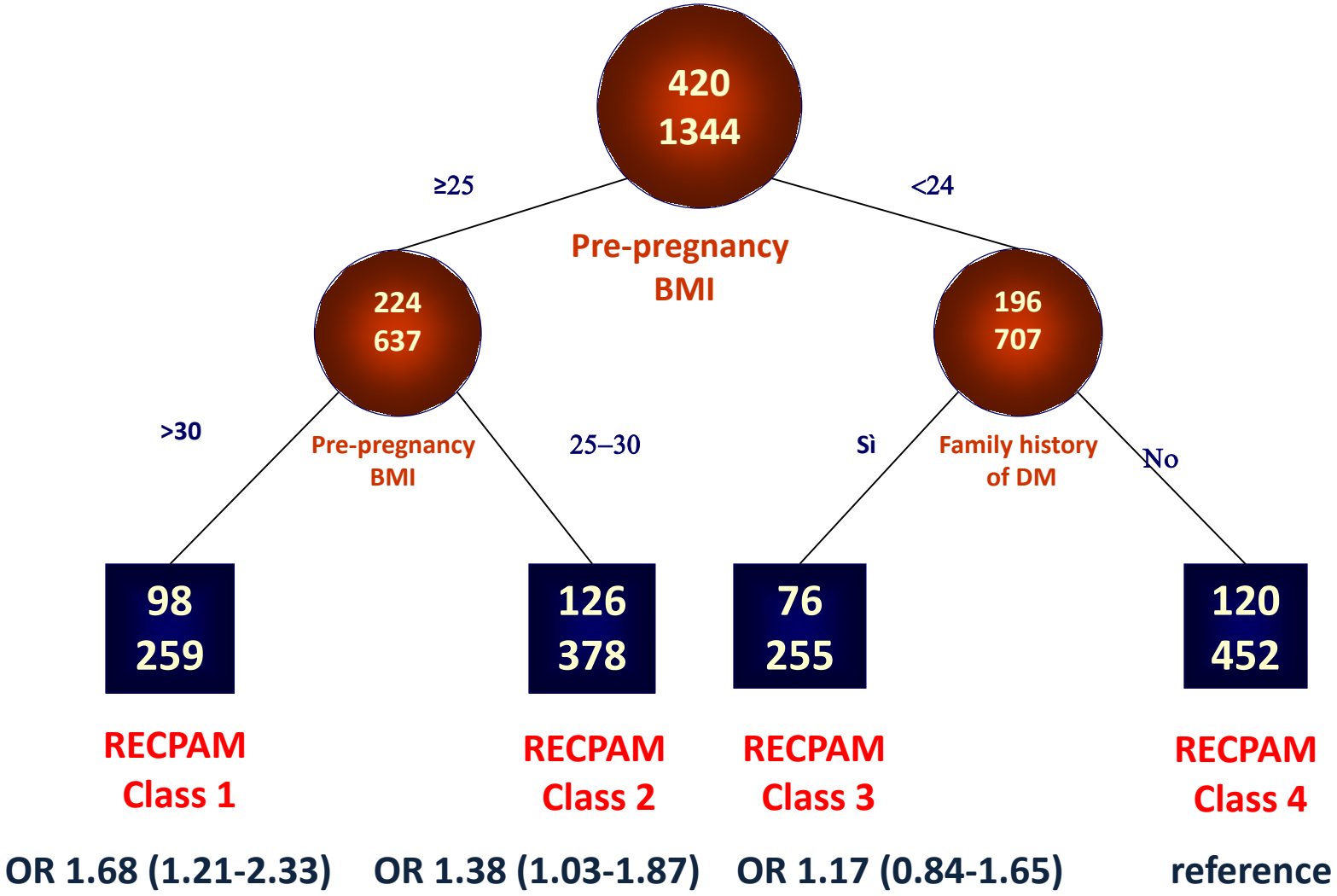
RECPAM ANALYSIS

(RECursive Partitioning and AMalgamation)



RECPAM ANALYSIS

(RECursive Partitioning and AMalgamation)



RESULTS: RECPAM ANALYSIS

	CLASS 1	CLASS 2	CLASS 3	CLASS 4	p
Systolic Blood Pressure (mmHg)	120.0 (110.0-127.0)	110.0 (100.0-120.0)	110.0 (100.0-120.0)	110.0 (100.0-120.0)	<0.0001
Diastolic Blood Pressure (mmHg)	70.0 (65.5-80.0)	70.0 (60.0-80.0)	70.0 (60.0-70.0)	70.0 (60.0-70.0)	<0.0001
Blood glucose at first trimester (mg/dl)	91.0 (84.0-98.0)	90.0 (83.0-96.0)	89.0 (80.0-97.0)	86.0 (79.0-93.0)	<0.0001
First trimester blood glucose between 100-125 mg/dl (%)	33.2	27.5	20.4	22.6	0.002
HbA1c at diagnosis (mmol/mol)	35.5 (33.0-38.0)	34.4 (32.2-37.7)	34.0 (31.2-37.7)	33.3 (31.0-35.5)	<0.0001
16-18 weeks OGTT fasting blood glucose (mg/dl)	98.0 (94.0-102.0)	97.0 (93.0-101.0)	95.0 (90.0-101.0)	88.0 (83.5-96.5)	<0.0001
24-28 weeks OGTT fasting blood glucose (mg/dl)	95.0 (88.5-100.0)	92.0 (85.0-97.0)	91.5 (81.0-96.0)	88.0 (81.0-95.0)	<0.0001
Insulin treatment rate (%)	53.3	38.1	34.5	29.7	<0.0001

RESULTS: MULTIVARIATE ANALYSES

Previous macrosomia	OR (95%CI)
Composite adverse outcome	2.48 (1.59-3.87)
Large for gestational age	3.99 (2.40-6.63)
Fetal malformation	2.66 (1.00-7.18)
Respiratory distress	4.33 (1.33-14.12)

First trimester glucose	OR (95%CI)
Small for gestational age	1.96 (1.04-3.69)

Pre-pregnancy obesity	OR (95%CI)
Large for gestational age	1.46 (1.00-2.15)
Neonatal hypoglycemia	1.62 (1.04-2.51)

Pre-pregnancy overweight	OR (95%CI)
Neonatal hypoglycemia	1.52 (1.02-2.27)

AFTER THE PREGNANCY

46.2% of women performed post-partum OGTT

	Follow-up NO	Follow-up YES	P
Previous GDM	12.7	16.2	0.01
First pregnancy	47.0	41.7	0.007
Phisycal activity before pregnancy	22.9	30.1	0.001
Diastolic blood pressure	70.0 (64.0-80.0)	70.0 (60.0-75.0)	<0.0001
Insulin treatment	34.1	49.9	<0.0001

STRONG: IMPACT ON CLINICAL PRACTICE

- Greater attention to the development of pregnancies of women with multiple risk factors for adverse neonatal outcomes.

- Particular attention to the risk of single adverse neonatal outcomes occurrence according to specific antenatal mother's characteristics.

- More effective involvement of women with GDM in follow-up procedures.

THANK YOU

