Indian Journal of Clinical Practice, Vol. 31, No. 3, August 2020

One-Step versus Two-Step Diagnostic Test for Gestational Diabetes Mellitus

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ABSTRACT

Aim: Comparison between one-step Diabetes in Pregnancy Study Group India (DIPSI) and American Diabetes Association (ADA) recommended two-step oral glucose tolerance test (OGTT). **Material and methods:** This study has a sample size of 200; 100 participants each were subjected to either of the two tests. Gestational diabetes mellitus (GDM) and non-GDM diagnosed by one-step test versus two-step test, respectively, were compared to one another and results were compared on the basis of various antenatal complications and fetomaternal outcomes. **Results:** No statistical difference was found between both the groups on the basis of various antenatal and fetomaternal outcomes. **Conclusion:** In Indian subcontinent with poor resources and lack of follow-up, single-step DIPSI can be preferred to ADA recommended two-step OGTT; however, large database studies are still required.

Keywords: Gestational diabetes mellitus, Diabetes in Pregnancy Study Group India, one-step test, two-step oral glucose tolerance test

Diabetes mellitus is a disorder of carbohydrate metabolism. Diabetes complicating pregnancy has become more common worldwide. Gestational diabetes mellitus (GDM) refers to carbohydrate intolerance that is recognized or develops during pregnancy, irrespective of the treatment with diet or insulin. Women with a history of GDM have a higher risk of future diabetes, particularly type 2 diabetes, and the same holds true for their children.[1] Besides, any glucose intolerance in pregnant women without GDM has been linked with escalated adverse maternal and fetal outcomes. Thus, GDM should be considered as a key opportunity to develop, test and implement clinical strategies for the prevention of diabetes. Action taken at the right time to screen all pregnant women for glucose intolerance, achieve euglycemia and ensure adequate nutrition could help prevent the vicious cycle of passing on glucose intolerance from one generation to another.

In the Indian context, screening for diabetes becomes all the more crucial during pregnancy as Indian women have an 11-fold increased risk of developing glucose intolerance during pregnancy compared to Caucasian women.[2]

The world prevalence of diabetes among adults was around 6.4% in 2010, affecting 285 million adults and is estimated to increase up to 7.7% and 439 million adults by 2030. Abnormal maternal glucose regulation has been noted in nearly 3-10% of pregnancies.

Routine screening is required in the Indian subcontinent because of multifactorial pathology predisposing women to this pregnancy associated comorbidity, the associated risk factors and long-term side effects. Also to mention, the low-cost of screening in a country like India with limited resource availability.

The American College of Obstetricians and Gynecologists (ACOG) recommends universal screening for GDM with a 50 g 1 hour loading test at 24-28 weeks followed by 100 g, 3-hour oral glucose tolerance test (OGTT) for diagnosis. In this approach, a 50 g glucose challenge test, or the O'Sullivan test, is first performed which, if positive, is followed by an OGTT.[3]

After the Hyperglycemia and Adverse Pregnancy Outcome (HAPO) study, the World Health

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Organization (WHO) validated Diabetes in Pregnancy Study Group India (DIPSI) as a single step procedure in screening GDM. In the antenatal clinic, after preliminary examination, the pregnant women will be given 75 g glucose load orally, irrespective of her fasting status or timing of previous meal. GDM is diagnosed, if post 2-hour blood glucose value is found to be ≥140 mg/dL.[4-6] This single step procedure has been approved by the Ministry of Health, Govt. of India and also recommended by the WHO.

The International Association of Diabetes and Pregnancy Study Groups (IADPSG) in 2010 recommended new terminology and diagnostic cut offs for GDM based on the hyperglycemia and pregnancy outcome study. According to IADPSG guidelines, diabetes first recognized in pregnancy can be classified as gestational or overt. The criteria for diagnosing include:

- Fasting plasma glucose (FPG) ≥126 mg/dL
- Glycated hemoglobin (HbA1c) ≥6.5%
- Random plasma glucose >200 mg/dL.

Successful screening test requires that the condition should be prevalent in the target population (which diabetes is, in Indian subcontinent), screening improves the prognosis and available treatment is effective. There have been several screening guidelines based on the suitability of the test to the population characteristics, cost and screening accuracy. Numerous controversies still exist regarding the test to be used and when the screening strategy should be applied. Factors like clinical judgment and available resources have a key role in choosing the best possible mode for evaluation of GDM, the different screening and diagnostic practices for GDM, and in finally outlining the best suitable option for our economy and population. With so many routine screening options available for GDM, it becomes a challenge in itself for Indian obstetrics to choose the most suited testing method appropriate for a limited resource and poor follow-up economy like ours. Thus, this study was undertaken.

MATERIAL AND METHODS

Source of Data

It was a hospital-based study. All pregnant women in second trimester between 24 and 28 weeks of gestational age, who attend antenatal clinic at Shri Ram Murti Smarak Institute of Medical Sciences (SRMS-IMS), Bareilly, Uttar Pradesh, in a time of 2 years were enrolled in this study after providing informed consent.

Inclusion Criteria

- All consenting pregnant women in second trimester between 24 and 28 weeks who attended antenatal clinic at SRMS-IMS, Bareilly, Uttar Pradesh.
- Pregnant women of any parity.
- Singleton pregnancy.

Exclusion Criteria

- Pregestational diabetes.
- Chronic diseases/cardiac/hepatic/respiratory diseases/any other medical or surgical diseases.
- Taking drugs that alter glucose metabolism.
- Patients who refuse to participate.

Method of Collection of Data

Study design: A clinical study.

Sample size: Two hundred consecutive pregnant women between 24 and 28 weeks of gestational age who attended antenatal clinic of SRMS-IMS, Bareilly, Uttar Pradesh, over a time period of 2 years were included in the study after providing informed consent and were randomized into two groups having 100 patients in each group.

Sample: It is a hospital-based study.

Place: SRMS-IMS, Bareilly, Uttar Pradesh.

Duration: Two years; from October 2017 to November 2019.

Method:

- A hospital-based clinical study designed to compare one-step versus two-step screening test for GDM. A detailed clinical assessment of patient was performed in the outpatient department (OPD), including history (family history of diabetes, history of previous pregnancies and socioeconomic status, etc.), general physical examination and obstetric examination. Routine investigations during antenatal visits were done. Informed consent of participation was taken during this initial assessment.
- A standard form was used to record the date of the tests performed, detailed clinical assessment of patient, including history and examination findings, investigations, including the test results.

Cut-off values of one-step procedure in screening of GDM:[5,6]

Criteria for Positive Screening of GDM	
DIPSI criteria for screening GDM	2-hour PPBS
Nonfasting OGTT with 75 g glucose	>140 mg/dL

The American Diabetes Association (ADA) recommends, in a two-step procedure, an initial screening by measuring plasma glucose 1 hour after 50 g oral glucose challenge test (OGCT). Those found to be positive at the screening test undergo 100 g OGTT.

ADA Criteria for Diagnosis of GDM

100 g OGTT	Cut-off values
Fasting	95 mg/dL (5.3 mmol/L)
1 hour	180 mg/dL (10 mmol/L)
2-hour	155 mg/dL (8.6 mmol/L)
3-hour	140 mg/dL (7.8 mmol/L)

Two or more of the venous plasma concentrations must be met or must exceed the above values for a positive diagnosis.

Patients who had a positive outcome to either of the screening tests were followed up in high-risk antenatal clinic. Outcome was noted during antenatal period, and as type of delivery, mode of delivery and postpartum events. Fetal outcome was observed. Under high-risk antenatal clinic, they were called for a follow-up fortnightly from 28 to 32 weeks, and weekly thereafter.

Standard management protocol for GDM was followed in patients screening positive by one-step or two-step technique.

Patients in whom the screening test came out negative were followed-up in regular antenatal clinic.

OBSERVATIONS AND RESULTS

This clinical study was conducted in the Dept. of Obstetrics and Gynecology, SRMS-IMS, Bareilly, Uttar Pradesh, India.

The aim of this study was to compare one-step versus two-step diagnostic test for GDM on the basis of various maternal, intrapartum and fetal parameters. A total of 200 antenatal women were recruited in this study; 100 women in each group.

The fetal, maternal and intrapartum outcomes of GDM patients and non-GDM patients of Group A and Group B were compared.

Out of 100 patients in Group A, 12 were found to have GDM by DIPSI criterion and rest 88 were taken as controls (Table 1). In Group B, 10 had GDM and rest 90 were taken as controls (Table 1). In our study, we found that the mean age of patients in Group A was 24.77 years and in Group B was 24.75 years. While comparing parity, as shown in Table 2, 39% and 37% patients in Group A and Group B were primigravidas, and 30% and 37% in Group A and Group B were second gravidas, respectively. Maximum patients in both the groups were either primi- or second gravidas. The mean body mass index (BMI) in patients of Group A was 21.708 kg/m^2 and in Group B was 21.018 kg/m^2. Maximum patients in both the groups had a BMI in the range of 20-25 kg/m^2 (Table 2).

While comparing genitourinary infections, the occurrence rate was 11.36% in non-GDM patients in Group A compared to 7.77% in Group B in the given antenatal period. On the contrary, 33.33% in patients with GDM in Group A and 20% patients with GDM in Group B were found to have genitourinary tract infections (Tables 3 and 4).

About 9.09% non-GDM patients in Group A and 8.88% non-GDM patients in Group B had gestational hypertension as an antenatal complication. Twenty-five percent of GDM patients in Group A and 30% of GDM patients in Group B had gestational hypertension as an antenatal complication (Tables 3 and 4).

Table 1. Case Distribution

Case distribution	DIPSI (Group A)	GTT (Group B)	P value
GDM	12	10	0.651
Non-GDM	88	90	
Total	**100**	**100**	

Table 2. Demographic Features

Demographic feature	Group A	Group B
Mean age	24.77	24.75
Mean BMI	21.708	21.018
Parity	P1-P2	P1-P2

Table 3. Maternal Complications in GDM Patients

Maternal complications	GDM (Group A)	GDM (Group B)	P value
Genitourinary infections	4 (33%)	2 (20%)	0.348
Gestational hypertension	3 (25%)	3 (30%)	1
Pre-eclampsia	4 (33.33%)	3 (30%)	1
PROM	4 (33.33%)	2 (20%)	0.646
Preterm delivery	3 (25%)	2 (20%)	1

IJCP SUTRA: "Find the foods that trigger your symptoms and avoid them (fatty foods, spicy foods, tomatoes, garlic, milk, coffee, tea, cola, peppermint and chocolate)."

About 10.22% of non-GDM patients in Group A and 6.66% of non-GDM patients in Group B had pre-eclampsia as an antenatal complication; 33.33% GDM patients in Group A and 30% patients in Group B had pre-eclampsia as an antenatal complication (Tables 3 and 4).

About 5.68% non-GDM patients in Group A and 6.66% non-GDM patients in Group B had premature rupture of membrane (PROM) complicated pregnancies; 33.33% GDM patients in Group A and 20% GDM patients in Group B had PROM as an antenatal complication (Tables 3 and 4).

About 6.81% non-GDM patients of Group A and 6.66% non-GDM patients of Group B had premature deliveries (<37 weeks). Twenty-five percent of GDM patients in Group A and 20% of GDM patients in Group B had premature deliveries (<37 weeks) (Tables 3 and 4).

Around 5.81% non-GDM patients in Group A had preterm vaginal delivery, 68.60% had full-term vaginal delivery and 25.58% had cesarean section (Table 5). None of the patients underwent instrumental delivery.

Table 4. Maternal Complications in Non-GDM Patients

Maternal complications	Non-GDM (Group A)	Non-GDM (Group B)	P value
Genitourinary infections	10 (11.36%)	7 (7.77%)	0.416
Gestational hypertension	8 (9.09%)	8 (8.88%)	0.962
Pre-eclampsia	9 (10.22%)	6 (6.66%)	0.393
PROM	5 (5.68%)	6 (6.66%)	0.785
Preterm delivery	6 (6.81%)	6 (6.66%)	0.968

Table 5. Mode of Delivery in Non-GDM Patients

Mode of delivery	Non-GDM (Group A)	Non-GDM (Group B)	P value
Preterm vaginal delivery	5 (5.81%)	4 (4.59%)	0.908
Full-term vaginal delivery	59 (68.60%)	59 (67.81%)	
Instrumental delivery	0 (0)	0 (0)	
Cesarean section	22 (25.58%)	24 (27.58%)	
Total	**86 (100%) + 2 (Stillborn)**	**87 (100%) + 3 (Stillborn)**	

In Group B, 4.59% non-GDM patients underwent preterm vaginal delivery, 67.81% had full-term vaginal delivery and 27.58% patients had cesarean section. None in Group B also underwent instrumental delivery; 2 stillborn deliveries in Group A and 3 stillborn deliveries in Group B were excluded from the above distribution.

Ten percent GDM patients in Group A and 11.11% GDM patients in Group B had preterm vaginal deliveries. Forty percent GDM patients in Group A and 44.44% GDM patients in Group B had full-term vaginal delivery. None of the patients in both the groups had instrumental delivery. Fifty percent in Group A and 44.44% in Group B had cesarean section, respectively. Two patients from Group A and 1 from Group B were excluded from the above case distribution as they had stillborn delivery (Table 6).

Two non-GDM patients of Group A and 3 non-GDM patients in Group B had intrauterine fetal demise or stillborn deliveries. Two out of 12 GDM patients of Group A and 1 out of 10 GDM patients of Group B had stillborn deliveries or intrauterine fetal demise (Tables 7 and 8). None of the non-GDM patients in both

Table 6. Mode of Delivery in GDM Patients

Mode of delivery	GDM (Group A)	GDM (Group B)	P value
Preterm vaginal delivery	1 (10%) + 2 (Stillborn)	1 (11.11%) +1 (Stillborn)	0.971
Full-term vaginal delivery	4 (40%)	4 (44.44%)	
Instrumental delivery	0 (0)	0 (0)	
Cesarean section	5 (50%)	4 (44.44%)	
Total	**10 (100%) + 2 (Stillborn)**	**9 (100%) +1 (Stillborn)**	

Table 7. Fetal Complications in GDM Patients

Fetal complications	GDM (Group A)	GDM (Group B)	P value
Stillborn	2 (16.66%)	1 (10%)	1
Shoulder dystocia	1 (8.33%)	0	1
Fetal malformations	1 (8.33%)	0	1
Respiratory distress	2 (16.66%)	2 (20%)	1
NICU admission	5 (41.66%)	4 (40%)	1

Table 8. Fetal Complications in Non-GDM Patients

Fetal complications	Non-GDM (Group A)	Non-GDM (Group B)	P value
Stillborn	2 (2.27%)	3 (3.33%)	1
Shoulder dystocia	0	0	1
Fetal malformations	0	2 (2.22%)	0.497
Respiratory distress	3 (3.40%)	3 (3.33%)	1
NICU admission	4 (4.54%)	7 (7.77%)	0.371

the groups had shoulder dystocia during delivery. One out of 12 GDM patients in the Group A and none of the GDM patients in the Group B had shoulder dystocia during delivery (Tables 7 and 8).

None of the non-GDM patients in Group A had fetal malformations, whereas 2 out of 90 in the non-GDM patients of Group B had this complication. One neonate born to GDM mother in Group A had congenital malformation at the time of birth. However, none of the neonates born to GDM mothers in the Group B had this complication (Tables 7 and 8).

About 3.40% neonates of non-GDM women in Group A and 3.33% neonates of non-GDM women in Group B had respiratory distress. Two out of 12 GDM patients in Group A and 2 out of 10 GDM patients in Group B had neonates with respiratory distress (Tables 7 and 8).

About 4.54% infants of non-GDM patients in Group A and 7.77% infants of non-GDM patients in Group B had neonatal intensive care unit (NICU) admission after delivery (Table 8).

DISCUSSION

Gestational diabetes mellitus refers to any degree of glucose intolerance which arises or is recognized for the first time during pregnancy. It may or may not undergo remission after the end of pregnancy. In comparison with European women, GDM prevalence has increased 11-times in women from the Indian subcontinent.[7] In this study, 100 patients underwent one-step diagnostic test for GDM between 24 and 28 weeks of pregnancy, and same number of comparable antenatal women were subjected to two-step procedure. The diagnostic accuracy appears to be the same by both the tests as the detection rate of GDM was statistically same with insignificant p value between the two groups.

Most of the women recruited in this study belonged to the age group of 21-25 years, thus indicating the increased awareness in the younger population toward antenatal check-ups and hospital delivery. A study done by Qadir et al,[8] had a higher incidence of GDM in higher age group women. In the study done by Priyanka,[9] it was noted that GDM cases belonged mostly to 26-30 years of age group. In our study, the distribution of cases according to parity showed that majority of cases i.e., 39%, were primigravida in Group A and 37% were primigravida in Group B. Only 5% women in Group A and 4% in Group B were of grand multiparity status. This further emphasizes our observation of willingness among young women for routine antenatal check-up, follow-up and institutional/hospital deliveries.

We observed that average BMI of GDM patients was 24.70 kg/m^2 in Group A and 24.51 kg/m^2 in Group B. However, a relatively lower mean BMI was observed in non-GDM patients of both the groups - 21.29 kg/m^2 in Group A and 20.63 kg/m^2 in Group B, respectively. The difference in BMI of both the groups was found to be statistically insignificant, but we observed a higher BMI in GDM patients as compared to the non-GDM patients.

In our study, we have compared the various feto-maternal and intrapartum complications of GDM in both the groups by applying different tests. No difference was observed between both the groups on comparing genitourinary complications. It was also noted that the incidence of genitourinary infections was much higher in the GDM when compared to non-GDM patients. In concordance with our study, a study done by Qadir et al also showed that the incidence of recurrent urinary tract infection and vulvovaginal infections in GDM patients is high when compared to non-GDM patients.

The incidence of gestational hypertension was observed to be much higher in GDM patients of Group A, i.e., 25% and of Group B (30%). In the non-GDM patients, the incidence was only 9.09% and 8.88% in both the groups, respectively (p = 0.962). Similar findings were noted on comparing the incidence of pre-eclampsia in GDM patients of both the groups with a p value of 1. In a study conducted by Sinha et al,[10] 22% of the DIPSI and 26% OGTT group had hypertensive disorders as comorbidity in their study. Similar to our study, this study also showed no significant difference in both the groups when the parameter hypertensive disorders was compared and an equal predictive value of GDM pregnancies complicated by hypertensive disorders was found by both the tests. Like our study, in the study conducted by Qadir et al, the frequency of hypertensive disorders was higher, though not statistically significant in the GDM patients. Also the parameter PROM was studied in the non-GDM and GDM patients of both the groups. The p value of both the groups in GDM and

non-GDM patients was 0.646 and 0.785, respectively, suggesting no statistical difference and the groups to be comparable. Also, the incidence of the parameter was much higher in GDM patients. Similar to our study, a study conducted by Qadir et al also showed higher occurrence of PROM in GDM patients. When the incidence in the GDM and non-GDM patients of both the groups was compared, no statistical difference was observed. However, the incidence of preterm delivery was much higher in GDM group as compared to non-GDM (25% and 20% in GDM patients of Group A and Group B). Saxena et al found an incidence of 12%.[11]

The incidence of normal vaginal deliveries were noted to be lower in GDM patients - 40% in Group A and 44.44% in Group B. None of the patients in both the groups had an instrumental delivery as all the difficult deliveries were mostly subjected to cesarean section in our institute. When the rate of cesarean section was compared, it was found to be twice as much higher in the GDM group as compared to the non-GDM group. Unlike our study, a study conducted by Priyanka stated that 73.33% GDM patients had vaginal deliveries and only 19.44% had cesarean section. Like our study, in the study conducted by Sinha et al, 50% patients diagnosed with GDM by both the tests underwent cesarean and thus the tests were proved to be comparable.

Stillbirth and intrauterine fetal demise are known complications of GDM in the third trimester, as stated in literature. In this study, the incidence of stillborn deliveries in the non-GDM patients was observed to be 2.27% and 3.33% in Group A and Group B, respectively. However, in the GDM patients, the incidence was found to be much higher, 16.66% and 10% in Group A and Group B, respectively. On applying statistical tests, the difference between the two groups in both GDM and non-GDM patients was found to be insignificant. A study conducted by Priyanka, showed that GDM complicated pregnancies had live birth rate of 87.22% and intrauterine death was noted in 7.22% women. On studying the case distribution of shoulder dystocia in non-GDM and GDM patients of both the groups, none of the non-GDM patients had this complication during delivery; however, in GDM complicated pregnancies, 1 patient in Group A and none in the Group B had shoulder dystocia.

In our study, 2 out of 90 non-GDM patients in Group B and none in Group A had fetal malformations. In GDM pregnancies, the incidence rate of 8.33% was noted for the complication in Group A. However, none of the GDM pregnancies diagnosed by two-step test had fetal malformations. The study group was thought to be too small to draw a comparison between the GDM and non-GDM patients in regard to this parameter. On applying statistical tests, the value was found to be insignificant but not much relevant and the two groups were comparable. Sinha et al also found similar results.

On comparing the incidence of respiratory distress in infants of non-GDM group, it was found to be only 3.40% and 3.33% in Group A and Group B, respectively; however, diabetes complicated pregnancies had a much higher incidence of 16.66% and 20% in Group A and Group B. Lastly, on comparing the incidence of NICU admission in the two groups, 4.54% and 7.77% babies born to non-GDM mothers were admitted to NICU in Group A and Group B, respectively, immediately after birth. However, a very high incidence was observed in the babies of GDM mothers, i.e., 41.66% and 40% in Group A and Group B ($p = 1$). Like our study, in the study done by Sinha et al, 31% cases of DIPSI group and 45.50% cases of GTT group developed respiratory distress. Difference between the two was not statistically significant.

In this study, we have compared various complications of GDM in both the groups and we observed no statistical difference. Also, no difference exits in the diagnostic accuracy of both the tests. Similar to our study, the study conducted by Sinha et al also observed no statistical difference between one-step and two-step procedure in respect to various maternal and fetal outcomes.

CONCLUSION

The incidence of GDM in this study was found to be 12% by one-step and 10% by two-step procedure. The high pick up rate was attributed to our institute being a tertiary care center with maximum cases of complicated pregnancy. The statistical difference between both the groups in regard to all the parameters studied was found to be insignificant.

Hence, we state that one-step test, which is more feasible, economical and applicable in population of India, may help in fighting to diagnose GDM, reducing feto-maternal morbidity associated with it, in comparison to a more cumbersome and robust two-step diagnostic test recommended by the ACOG.

In our study, we compared and studied the statistical difference of various maternal, fetal and intrapartum complications among two different groups. No statistical difference was observed between all the parameters assessed in this study. Thus, we conclude that both the

tests not only have an equal predictive rate for various complications but also equally effective in diagnosing GDM. Timely diagnosis and management of GDM will prevent diabetes in future life. If adequate obstetric care is provided to the antenatal patients with GDM, many maternal, fetal and intrapartum complications can be markedly reduced, especially in low resource countries like India.

Thus, we suggest that ACOG recommended two-step test, which is less feasible and applicable in Indian population can be safely replaced by one-step diagnostic test. However, to state such a fact, large scale studies, exhaustive follow-up and meta-analysis is required. For us, as clinicians, it's our role to fight against all odds in converting the Diabetes Capital of the World to a well-controlled diabetic country.

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Heart Attack Patients may be Dying Due to Coronavirus Fears, Says Study

Investigators from the Providence Heart Institute system in the US northwest analyzed the records of over 15,000 heart attack patients from December 30 to May 16 of this year and noted key changes in heart attack hospitalization rates. Writing in *JAMA Cardiology*, investigators noted a considerable reduction in hospitalizations early in the pandemic, with the case rates beginning to fall on February 23. Patients hospitalized for a heart attack during the pandemic appeared to be younger by about 1-3 years versus patients prior to the pandemic. The authors believe that older patients may have been more reluctant to get medical help if they had symptoms… (*CNN*)

FDA OKs Oral Treatment for Spinal Muscular Atrophy

The US FDA has granted approval to risdiplam for the treatment of patients aged 2 months and older with spinal muscular atrophy (SMA), making it the second drug and the first oral drug approved to treat this disease.

The efficacy of the drug for the treatment of patients with infantile-onset and later-onset SMA was assessed in two clinical studies. The infantile-onset SMA study included 21 patients, average age 6.7 months when the study began. After 12 months of treatment, 41% of the patients were able to sit independently for more than 5 seconds. After ≥23 months of treatment, 81% of patients were alive without permanent ventilation. A randomized, placebo-controlled study assessed the drug in patients with later-onset SMA and involved 180 patients aged 2-25 years. Patients taking the drug had an average 1.36 increase in MFM32 (a test of motor function) score at the 1-year mark, compared to a 0.19 decrease in patients on placebo (inactive treatment)… (*FDA*)