**Section:** Transfusion Medicine

**Original Research Article**

# EVALUATION OF CORRECTED COUNT INCREMENT IN HEMATO-ONCOLOGICAL PATIENTS RECEIVING SINGLE DONOR PLATELETS TRANSFUSION

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## Abstract

**Background:** Single donor platelet (SDP) transfusion is an essential component of supportive therapy in patients with hemato-oncological patients. SDP transfusion is given either prophylactically to reduce the risk of bleeding or therapeutically to control active bleeding. Although many patients have an appropriate increase in platelet count when transfused with single donor platelets, less than adequate results tend to be seen in 15%-25% of the hemato-oncology patient. The objective is to evaluate the response to SDP transfusion by the calculation of Corrected Count Increment (CCI) in hemato- Oncological Patients after transfusion at specified time period. **Materials and Methods:** The study was conducted over a period of one year (July2018 to June 2019). In total, 85 hemato-oncological patient samples were tested for CCI at 1 hour and 24 hours after SDP transfusion. Descriptive statistical analysis was performed to calculate the percentage and mean count. **Result:** The mean count of transfused platelets was $3.1\times10^{11}$/unit. The mean platelet count before transfusion was $18.3\times10^{3}/\mu L$. The mean platelet increment at 1 hour was $24.7\times10^{3}/\mu L$ and 24 hours was $13.04\times10^{3}/\mu L$. The mean CCI at 1 hour and 24 hours was 12875.49 and 6372.518 respectively. In total, 14(16.4%) out of 85 patients received suboptimal dose of platelets, 7(8.2%) of the patients showed unsuccessful CCI at 24 hours despite successful CCI at 1 hour. All these 7 patients had clinical factors possibly responsible for failure of increment. However, in 7(8.2%) of the remaining patients also had associated clinical factors despite successful CCI at 24 hours. 71(83.6%) of the total 85 patients received optimal dose of platelets. Out of these 71 patients, 70 who had successful 1 hour CCI, 19 of these patients showed failure of expected CCI at 24 hours. The remaining one patient showed unsuccessful CCI after 1 hour of transfusion itself. **Conclusion:** In our study, almost 2/3rd of the hemato-oncological patients on chemotherapy showed successful CCI after 24 hours of SDP transfusion. The probable reason for unsuccessful CCI at 24 hours despite successful CCI at 1 hour after SDP transfusion is attributed to certain non-immunological clinical factors like fever, splenomegaly and sepsis. Further, the reason for unsuccessful CCI at 24 hours observed in few of our cases is suboptimal dose of platelets. However, it is imperative to conduct further study on larger number of cases to arrive at a definitive conclusion.

## INTRODUCTION

Platelets are extremely small 2 to 3µ, discoid shape and anucleated structure derived from the cytoplasm of bone marrow megakaryocytes. So, whenever bleeding occurs, platelet become activated and release the substances stored within the granules, form clots to arrest the bleeding.

Platelet transfusion is given either prophylactically to reduce the risk of bleeding or therapeutically to control active bleeding. The decision whether to

transfuse platelets depends on clinical condition of the patient, reason for the thrombocytopenia, platelet count, and functional ability of the patient's own platelets.[1,2] Most platelets are transfused to patients with severe hypo-proliferative thrombocytopenia due to hematological malignancies (Leukemia, Lymphoma), cytotoxic chemotherapy and hematopoietic stem cell transplantation. These patients are most likely to develop refractoriness. Hence, to prevent such refractoriness ABO, HLA and HPA-matched platelets are preferred.

Plateletpheresis procedure is a relatively simple, safe and important adjunct to blood bank inventory.[3] In recent years in developing countries like India, the demand for SDP has been increased considerably. The most common reason behind the growing demand for plateletpheresis is the increasing awareness of specific component therapy, reducing multiple donor exposures to the recipient.[4] To reduced risk of alloimmunization, reducing the risk of transfusion transmitted infections (TTI), and high quality product with full effective transfusion dose. In addition, SDPs transfusion reduces the chance of a sepsis due to bacterial contamination.[5]

SDP are indicated for the prevention and treatment of hemorrhage in patients either with qualitative/ quantitative disorders of platelets or both.[6] SDP transfusions are an essential component of supportive therapy in patients with hematological malignancy disorders. Following a platelet transfusion, the platelet count should rise, with a peak at 10 minutes to one hour and a gradual decline over 72 hours. Platelet count increment is typically measured within 24 hours in patients given prophylactic platelet transfusions. For patients undergoing invasive procedures, it is prudent to check that the desired platelet count was achieved before performing the procedure, which can be done within 10 minutes of the transfusion. For actively bleeding patients, cessation of bleeding is a more important clinical endpoint than the post- transfusion platelet count.[7]

As per DGHS standards, each unit of single donor platelet should contain a minimum of $\geq 3\times10^{11}$ platelets per bag.[8] The efficacy of platelet transfusion is assessed by Corrected Count Increment (CCI).[6] The corrected count increment $\times 10^9$/L is calculated from the Platelet Increment, the body surface area of the patient in $m^2$ (BSA) and the dose of platelets transfused $\times 10^{11}$ (PD). CCI = Absolute Platelet Increment × Body Surface Area × $PD^{-1}$. A CCI of $>7.5\times10^9$/L at 1 hour and $>5\times10^9$/L at 20-24 hours is considered to be a successful transfusion. Although many patients have an appropriate increase in platelet count when transfused with single donor platelets, less than adequate results tend to be common in 15% to 25% of the hemato-oncology patient. This poor response to platelet transfusion leads to an increased risk of morbidity and mortality, as well as longer hospital stays.[9]

Unsatisfactory response to single donor platelets transfusion is often multifactorial, with 80 percent of refractoriness being predominantly due to nonimmune causes.[10] The pattern of unsatisfactory response following SDP transfusion due to nonimmune causes is typically observed with a normal increment at one hour (normal platelet recovery) and return to the baseline count within 24 hours (reduced platelet survival). Most often, this pattern of response is associated with sepsis, disseminated intravascular coagulation (DIC), fever, splenomegaly, active bleeding and cytotoxic medications. This type of pattern is not consistent with alloimmunization.

Hence, this study is aimed to assess the clinical (nonimmunological) factors responsible for the failure of corrected count increment at 24 hours after SDP transfusion in haemato-oncology patients.

## MATERIALS AND METHODS

This study prospective observational study conducted in the Department of Transfusion Medicine, The Tamil Nadu Dr.M.G.R Medical University, Guindy, Chennai and the Blood Bank and Haematology Department, Adyar Cancer Institute (WIA), Adyar, Chennai. The study was approved by the respective Institutional Research and Ethics committee.

**Study Population**

Study population includes Hemato-Oncological Patients receiving Single donor platelets transfusion in the Department of Transfusion Medicine, The TN Dr.M.G.R Medical University, Guindy, Chennai and in the Blood Bank and Haematology Department, Cancer Institute, Adyar during the study period from July 2018 to June 2019. Minimum sample size was estimated to be approximately 85 patients.

**Inclusion Criteria**

All age groups of Hemato-Oncological Patients receiving Single Donor Platelet transfusion. Only one transfusion event was analyzed per patient

**Exclusion Criteria**

- Patient those who are not willing to participate in the study are excluded.
- Patients receiving non-ABO matched single donor platelet transfusion.
- Patients who have already been included in the study

**Informed Consent**

All details regarding the study has been explained and written informed consent obtained from the patients (patients with ≤18 years, consent will be obtain from parents or guardians) in either English or in the local vernacular language, whichever is preferred by the patient.

**Statistical Analysis**

Data was entered into Microsoft-EXCEL sheet and statistically analyzed using IBM SPSS software Version 21.0. Demographic details will be given in descriptive statistics. Quantitative data will be given in the summary statistics. P value <0.05 was considered significant.


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## RESULTS

A total of 85 patients who were found to be evaluated for CCI following a single donor platelet transfusions were analyzed in the study period from July 2018 to June 2019. Of these 85 patients, 58 were males (68.2%) and 27 were females (31.8%).

The majority of patients was between 18-40yrs (32.9%) and the age group of <18yrs and >60yrs had the same number of patients(n=18). The mean age was 38.2yrs. The youngest was 11yrs old and the oldest patient was 70yrs of age.

Diagnosis of patients enrolled in our study was as shown below, with the largest group contributed by patients with ALL (32.9%) and followed by AML (19%).

**Blood Group Distribution**

Blood group and Rh typing of the patients enrolled in our study was as shown below, with the Majority blood group contributed by patients with 'O'Rh Positive (32%) followed by 'B'Rh Positive (27%) and least by 'AB'Rh Negative, 'B'Rh Negative and 'O'Rh Negative had the same number n=1 (1%).

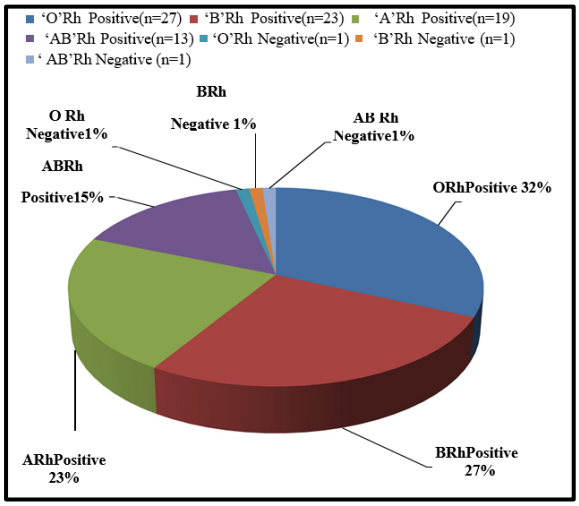


**Figure 1: Blood Group Distribution**

All patients enrolled in our study have been transfused ABO group specific single donor platelets. Of which majority of patients have been transfused 'O'Rh Positive followed by 'B'Rh Positive SDPs.

The mean height 160.153 cm (range125–178) and mean weight 56kg (range 29–85). The mean body surface area of the patients was 1.57 $m^2$ (range 1–2.03).

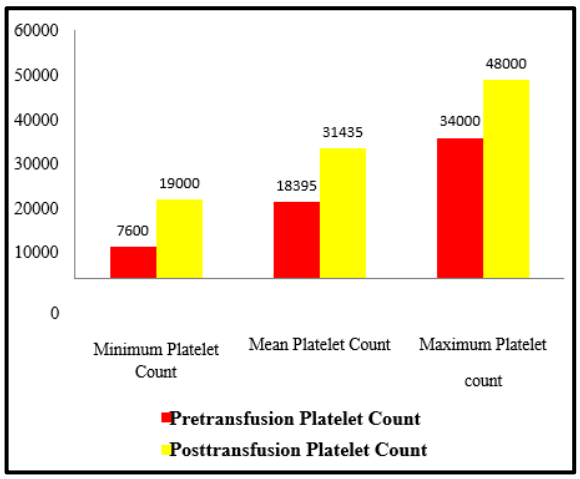


**Figure 2: Pretransfusion and Posttranfusion Platelet Count**

Among the total 85 Hemato-oncology patients, Majority of them 58 patients have CCI >5000 at 24 hours following single Donor Platelet Transfusion. However, 27 patients have CCI <5000 at 24 hours.

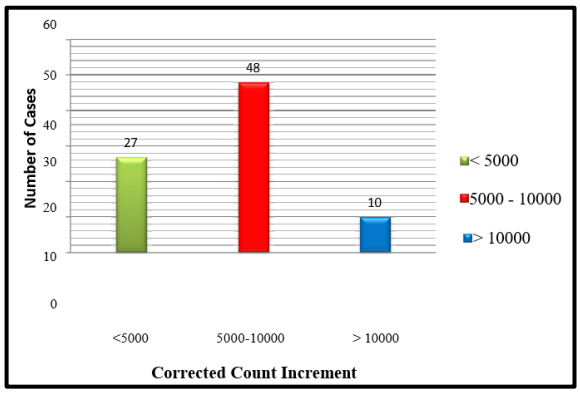


**Figure 3: Distribution of Corrected Count Increment in Study Population**

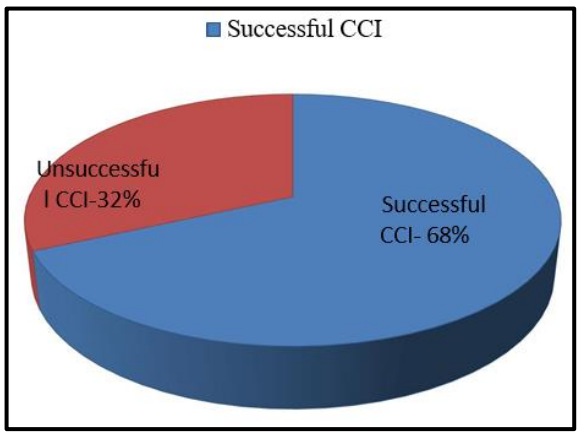


**Figure 4: Successful Vs Unsuccessful CCI following SDP Transfusion**

CCI <5000 at 24 hours consider as Unsuccessful transfusion seen in 27 patients (32%). CCI >5000 at 24 hours consider as Successful transfusion seen in 58 patients (68%).

Majority of them has been transfused with Platelet Dose of $0.05\times10^{11}$/Kg seen in 33 patients followed by


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$0.06\times10^{11}$/Kg seen in 23 out of total 85 Hemato-oncology patients.

14 out of 85 patients received suboptimal dose of platelets, 7 of the patients showed unsuccessful CCI at 24 hours despite successful CCI at 1 hour. All these 7 patients had clinical factors possibly responsible for failure of increment. However, in 7 of the remaining patients also had associated clinical factors despite successful CCI at 24 hours

Among the 85 Hemato-oncology patients, 27 of them observed to have an unsuccessful transfusion. In the 27 patients, one patients does not have expected CCI >7500 at initial 1-hour and remaining twenty five patients fail to achieve CCI>5000 at 24-hours.

Clinical factors such as Fever n=38(44.7%), Sepsis n=15(17.7%), DIC n=3(4.7%), Splenomegaly n=35(41.2%), Drugs n=73(86%) seen in total 85 Hemato- oncology patients.

In present study, the sign and symptom of fever has been present in 38 patients out of 85 total Hemato-Oncological patients. In correlating presence of fever with CCI will show the mean value of 5600 and in their shows the mean value of 6981.532. Hence, the fever influencing the CCI clinical and statistic significance with 'P'value 0.000 (<0.05 is statistics significant).

In our study, the clinical diagnosis of Splenomegaly has been seen in 35 patients out of 85 total Hemato-Oncological patients. In correlating presence of Splenomegaly with corrected count increment will show the mean value of 5304 and in the absence of splenomegaly shows mean value of 7105. There was a significant influence of splenomegaly on 24-hours CCI in Hemato-Oncological patients with 'P'value 0.000 (<0.05 is statistics significant).

In our study, the diagnosis of sepsis has been made in 15 patients out of 85 total Hemato-Oncological patients. In correlating presence of sepsis with corrected count increment will show the mean value of 6616.667. However, absence of sepsis shows mean value of 6309.847. Independent sample test shows no statistic significance of sepsis on the corrected count increment in Hemato-Oncological patients with 'P'value 0.450 (<0.05 is statistics significant).

In our study, the diagnosis of DIC has been seen in 3 patients out of 85 total Hemato-oncological patients. The statistical significance of DIC influence the corrected count increment in Hemato-Oncological patients with 'P'value 0.953 (<0.05 is statistics significant). Though DIC has not been show the statistical significance on corrected count increment but the presence of DIC influencing CCI show the mean value of 4958. The absence of DIC shows mean value of 6415.

In the present study, on correlating presence of drugs with corrected count increment will show the mean value of 6610 and in the absence of drugs on influencing CCI shows mean value of 6310. There was no much difference in the mean CCI and statistical significance of drugs on the CCI in Hemato-Oncological patients with 'P'value 0.900 (<0.05 is statistics significant).

The analysis of multiple clinical factors influencing the response to platelet transfusion is given in table above. From the Hosmer and Lemeshow logistic regression analysis, shows the presence of fever ('P=0.001) and splenomegaly ('P'=0.007) significantly contributed to unsuccessful corrected count increment. However, in our study sepsis ('P'=0.167), DIC ('P'=0.099), and drug used ('P'=0.111) in treatment, did not have statistically significance.

**Table 1: Diagnosis.**

| S. No. | Diagnosis | Number of Cases |
|---|---|---|
| 1 | ALL | 28 |
| 2 | AML | 19 |
| 3 | CML | 12 |
| 4 | APL | 5 |
| 5 | CLL | 3 |
| 6 | HL | 4 |
| 7 | NHL | 7 |
| 8 | MM | 5 |
| 9 | SLL | 2 |
| Total | | 85 |

**Table 2: Platelet Dose Transfused to Successful and Unsuccessful Patients**

| Platelet Dose Transfused$\times10^{11}$kg | Corrected Count Increment | |
|---|---|---|
| | <5000 | >5000 |
| 0.03 | - | N=1 (1.2%) |
| 0.04 | N=7 (8.2%) | N=6 (7.1%) |
| 0.05 | N=8 (9.4%) | N=25 (29.4%) |
| 0.06 | N=6 (7.1%) | N=17 (20.0%) |
| 0.07 | N=5 (5.9%) | N=5 (5.9%) |
| 0.08 | N=1 (1.2%) | N=3 (3.5%) |
| 0.11 | - | N=1 (1.2%) |
| Total | N=27(31.8%) | N=58(68.2%) |


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**Table 3: Platelet Dose (<0.05×10$^{11}$/Kg*) Study in Unsuccessful and Successful Patients**

| Unsuccessful CCI <5000 | | | Successful CCI>5000 | |
|---|---|---|---|---|
| **Sl. No.** | **Clinical Factors** | **Number of Cases** | **Clinical Factors** | **Number of Cases** |
| 1 | Fever+ Splenomegaly +Drugs | 2 | Fever+ Drugs | 1 |
| 2 | Fever + Sepsis + Splenomegaly+ Drugs | 1 | | |
| 3 | Fever+ Drugs | 1 | Sepsis+ Drugs | 1 |
| 4 | Fever +Splenomegaly +Drugs | 1 | | |
| 5 | Splenomegaly+ Drugs | 2 | Splenomegaly +Drugs | 3 |
| | | | Drugs Alone | 2 |
| | Total | 7 | Total | 7 |

*Platelet Dose <0.05×10$^{11}$/Kg is consider to be suboptimal dose.

**Table 4: Clinical Factors among the Successful and Unsuccessful CCI.**

| | | Clinical Factors | Fever | Sepsis | DIC | Splenomegaly | Drugs |
|---|---|---|---|---|---|---|---|
| CCI | <5000 | Present | 21 | 6 | 1 | 19 | 23 |
| | >5000 | | 17 | 9 | 2 | 16 | 50 |
| | <5000 | Absent | 6 | 21 | 26 | 8 | 4 |
| | >5000 | | 41 | 49 | 56 | 42 | 8 |
| Total | | | 85 | | | | |

**Table 5: Logistic Regression Variables**

| Factors | Coefficient | Odds ratio | 'P'value | 95% Confidence Interval | |
|---|---|---|---|---|---|
| | | | | Lower | Upper |
| Fever | 13.271 | .745 | .001 | 3.082 | 57.147 |
| Sepsis | 3.428 | .892 | .167 | .596 | 19.705 |
| DIC | 17.106 | 1.720 | .099 | .588 | 497.852 |
| Splenomegaly | 6.871 | .716 | .007 | 1.687 | 27.983 |
| Drugs | .214 | .969 | .111 | .032 | 1.428 |

## DISCUSSION

In the present study, a total of 85 Hemato-Oncological patients were transfused with Single Donor Platelets and samples were tested for Corrected Count Increment at 1 hour and 24 hours after transfusion. The study also tried to find out clinical factors associated with unsuccessful increment.

In the present study, the pattern of CCI at 1-hour was found to be successful in the majority of cases 84(98%), and then decline to 27(68%) at 24-hours. In a similar study by M.J. Dijkstra-Tiekstraet al,[11] on 79 Hemato-Oncological patients reported unsuccessful CCI at 1 and 24 hours in 13 (16%) and 15 (22%) patients respectively. Prawita et al in their study on 35 patients with various haematological and hemato-oncological conditions observed 13 (37%) of unsuccessful CCI at 1 hour and 14 (40%) patients showed failure of expected CCI at 24 hours.

In our study, 14(16.4%) out of 85 patients received suboptimal dose (< 0.05 x10$^{11}$/ kg body weight) of platelets, 7(8.2%) of the patients showed unsuccessful CCI at 24 hours despite successful CCI at 1 hour. All these 7 patients had clinical factors possibly responsible for failure of increment. However, in 7(8.2%) of the remaining patients also had associated clinical factors despite successful CCI at 24 hours. 71(83.6%) of the total 85 patients received optimal dose of platelets (> 0.05 x10$^{11}$/ kg bodyweight). Out of these 71 patients, 70 who had successful 1 hour CCI, 19 of these patients showed failure of expected CCI at 24 hours. The remaining one patient showed unsuccessful CCI after 1 hour of transfusion itself.

In Roy et al,[12] study, among the high dose group (0.06 x10$^{11}$/kg body weight) of children 9.6% of them showed bleeding events, whereas in low dose group (< 0.03 x10$^{11}$/kg body weight) 6.3% showed bleeding events and concluded that the difference observed were not statistically significant.

In our study, Fever was one of the associated clinical factor among 38 (44.7%) out of total 85 patients. 21 (24.7%) of these patients showed unsuccessful CCI at 24 hours after SDP transfusion despite successful CCI at 1 hour. Which was statistically significant with "P" value of <0.05.

Kumawat et al,[13] in their study on 30 cases of Hemato-Oncological patients reported 13 (43%) cases of unsuccessful CCI associated with fever, the remaining 5 (16.6%) patients showed successful CCI at 24 hours despite fever.

Shastry et al,[14] in their study on 40 cases of various haematological and hemato-oncological conditions reported unsuccessful CCI among 4 (10%) cases with fever successful CCI among 10 (25%) cases.

The reason quoted by several authors for the cause of unsuccessful CCI in patients with fever is due to promotion of endothelial cell activation by elevated cytokines IL-1, and TNF-α.

In this study, 35 (41.2%) of the total 85 patients showed splenomegaly. 19 (22.3%) of them showed unsuccessful CCI at 24 hours despite successful CCI at 1 hour post-transfusion. 11 cases of CML with massive splenomegaly were included in our study, all cases showed unsuccessful CCI. Which was also statistically significant with "P" value of <0.05.

Shastry et al,[14] reported unsuccessful CCI in 4 out of 10 cases with splenomegaly. Alcorta et al,[15] in their study reported 8 out of 52 haemato and hemato-


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oncological patients with splenomegaly, 7 of them showed unsuccessful CCI. The probable reason for unsuccessful CCI in cases with splenomegaly is due to increased pooling of platelets in the enlarged spleen.

In our study, 15 (17.6%) cases had sepsis, 6 (7.05%) of them showed unsuccessful CCI. Kumawat et al,[13] reported 12 cases of unsuccessful CCI among 16 cases with sepsis. Shastry et al,[14] reported 4 cases of unsuccessful CCI among 9 patients with sepsis. This could be due to LPS induced thrombocytopenia by human platelet TLR4 recognised by PAMPS on invading microorganisms.

Out of 3(4.7%) cases of APML with DIC, 1 (1.17%) showed unsuccessful CCI. Similar findings were reported by Shastry et al,[14] The probable mechanism is due to higher consumption of platelets in DIC.

In this study, all the patients were treated with appropriate cancer chemotherapy and antibiotics along with blood component support. Since 84 out of 85 patients showed successful CCI at 1 hour post-transfusion of SDP, the probable drug induced immune mediated thrombocytopenia was not considered to be a cause.

Only one case in our study showed unsuccessful CCI after 1 hour of SDP transfusion. Since this patient was on antibiotics and antineoplastic therapy, the probable mechanism for unsuccessful CCI at 1 hour to be considered is an immune mediated thrombocytopenia.

## CONCLUSION

In our study, almost 2/3rd of the hemato-oncological patients on chemotherapy showed successful CCI after 24 hours of SDP transfusion. The probable reason for unsuccessful CCI at 24 hours despite successful CCI at 1 hour after SDP transfusion is attributed to certain non-immunological clinical factors like fever, splenomegaly and sepsis. Further, the reason for unsuccessful CCI at 24 hours observed in few of our cases is suboptimal dose of platelets. However, it is imperative to conduct further study on larger number of cases to arrive at a definitive conclusion.

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