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ORIGINAL ARTICLE

Comparison Between The Impact Of TPN With Laminar Flow And Without Laminar Flow On Outcomes Of Neonatal Intensive Care Units In Zagazig University Children's Hospital

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ABSTRACT

Background: Total parenteral nutrition (TPN) is the feeding of special nutritional products to the neonates intravenously, to bypassing the usual process of eating and digestion.

The aim of this study was to determine the outcomes of neonates on total parenteral nutrition prepared on ward (retrograde) or through laminar flow in Neonatal Intensive Care Units of Zagazig University Children's Hospital.

Methods: this retro and prospective cohort study was conducted on 420 neonates in Neonatal Intensive Care Unit in ZUH, 150 neonates admitted to neonatal intensive care unit (NICU) received TPN in the past (the without laminar group), and 270 neonates received TPN in the time of the study (the with laminar group) where TPN prepared with the laminar flow , All patient groups were exposed to full medical history, physical examination, Routine lab investigations ,CT and CSF culture were done for indicated cases.

Results: The percent of neuro developmental delay cases were 20.7% in the without laminar group and 8.1% in the laminar group, and The percent of broncho pulmonary dysplasia cases were 30.7% in the without laminar group and were 10% in the laminar group. Also there were decrease in number of days according to stay on oxygen and stay on hospital in the laminar group. **Conclusion:** there were decrease in occurrence of short term outcomes like number of days of stay on oxygen and stay on hospital in the laminar group and long term outcomes like neuro developmental delay and broncho pulmonary dysplasia in the laminar group.

Keywords: Total parenteral nutrition ,laminar flow, neuro developmental delay, broncho pulmonary dysplasia

List of abbreviations: (TPN) Total parenteral nutrition.

**INTRODUCTION**

Total Parenteral Nutrition (TPN) is a form of nutritional support given completely via the bloodstream, intravenously with an IV pump. TPN administers proteins, carbohydrates, fats, vitamins, and minerals. (1) Parenteral nutrition can be provided as individualized or standardized formulation (either produced at the hospital pharmacy or acquired commercially); for most preterm babies standardized solutions will be adequate (2) It is indicated in preterm infants <32 weeks gestational age or <1.5kg to prevent subsequent growth failure, Intestinal failure, e.g. pseudo-obstruction, and short bowel ,Necrotising enterocolitis ,Congenital gastrointestinal defects, e.g. gastroschisis, and intestinal atresia, infants or children who are not expected to receive adequate enteral intake within 3-5 days ,Inflammatory bowel disease and Malabsorption syndromes. (3) *Laminar*

flow is an indication of the direction of movement of air entering a closed compartment intended for aseptic processing of formulations or at working desk to avoid contamination. (4)

The complications of TPN are cholestasis as TPN-induced hepatobiliary dysfunction ,Catheter-related complications ,Local and blood stream infection ,Mechanical problems, Thrombosis, Hypersensitivity to the components of parenteral nutrition (PN), Acid-base disturbances ,Hypoalbuminemia ,Hypertriglyceridemia and Refeeding Syndrome .

(5) For detection of sepsis as a short term outcome the blood culture remains the gold standard for the management of neonatal sepsis. Blood Culture reports aids physician in either optimizing therapy or timely discontinuation of antibiotics. (6).

Aim of the work: The aim of this work is to compare the impact of TPN between neonates that

received TPN prepared with the laminar flow with the neonates received TPN prepared without laminar flow in Neonatal Intensive Care Units of Zagazig University Children's Hospital.

METHODS

Site of the study: This study will be carried out in Neonatal Intensive Care Unit in Zagazig University Children's Hospital.

Type of the study: retro and prospective cohort study.

Sample size: Assuming that percentage of sepsis among total parenteral nutrition on laminar flow versus on ward are 6.5% versus 20% confidence level 95% power 80% so total sample size is 420 calculated by epi info7.

Inclusion criteria:

- 1- Age from (0-28) day
- 2- Cases on total parenteral nutrition admitted to Neonatal Intensive Care Unit in Zagazig University Children's Hospital.
- 3- Gestational age from (26-42) week.

Exclusion criteria:

1. Age above one month
2. Neonates diagnosed with genetic defects by coarse features.

Administrative design: Approval was obtained From Zagazig University Institutional Review Board (ZU-IRB 5712/25-11-2019).

Written informed consent was obtained from all participants' parents and the study was approved by the research ethical committee of Faculty of Medicine, Zagazig University. The work has been carried out in accordance with The Code of Ethics of the World Medical Association (Declaration of Helsinki) for studies involving humans.

All parents accepted the study and no one rejected the study.

METHODS

All the included children in the study were exposed to the following:

A- Detailed history taking including prenatal history including gestational age (full term – preterm) , maternal history including any chronic maternal disease and medical history, Rh, blood group, family history and treatment protocol during pregnancy, natal history including mode of delivery and obstetrical history and postnatal history including birth weight, appearance, color, activity and presenting symptoms..

B- Full Clinical examination: General examination, Abdominal examination., Chest examination and diagnose cases with special focus on diagnose the cases with BPD which defined as infants treated with supplemental oxygen for at least 28 days, Cardiac examination, and adequate Neurological examination through Follow up of

the laminar group for six month and the group without laminar by good history taking for detection of any neurodevelopmental delay with special focus on:

Motor milestone:By three months your baby can control his head when he's being supported to sit. By six months, he will have neck muscles that are strong enough to hold his head up and turn it from side to side.[7](De Sanctis et al., 2016).

Mental milestone:between 6 and 8 weeks of life, babies develop a "social smile" an intentional signal of warmth just for you. This is an important milestone. [8](Voytas, 2018).

C- Examination of neonatal sepsis , routine lab investigation for all cases included:

Liver functions, Serum electrolyte levels, Blood glucose level daily, Lipid profile, blood culture, CT and CSF for indicated cases and Inflammatory variables for detection of sepsis including:

Leukocytosis (WBC count $>34\ 000_{109/l}$) , Leukopenia (WBC count $<5000_{109/l}$) , Immature neutrophils $>10\%$, Immature:Total neutrophil ratio >0.2 , Thrombocytopenia $<100\ 000_{109/l}$ and CRP $>10\ mg/l$ or 2 SD above normal value.

STATISTICAL ANALYSIS

Data were fed to the computer and analyzed using IBM SPSS software package version 20.0. (Armonk, NY: IBM Corp) Qualitative data were described using number and percent. The Kolmogorov-Smirnov test was used to verify the normality of distribution Quantitative data were described using range (minimum and maximum), mean, standard deviation, median and interquartile range (IQR). Significance of the obtained results was judged at the 5% level All tests were two sided. $P < 0.05$ was considered statistically significant (Sig.), $p < 0.01$ was considered highly statistically significant (HS), and $p \geq 0.05$ was considered non-statistically significant (NS).

RESULT

There were 270 (64.3%) the with laminar group , 150 (35.7%) the without laminar group and there gestational age ranged from 26-42 weeks.

Results of tables and figures:

Table 1: shows that there is highly significant decrease in days of hospital stay and oxygen therapy in the laminar group., where according to days of stay on oxygen the range were 1-28day and median were 17 in the without laminar group while the range were 1-45 day and median were 7 in the laminar group , and according to days of stay in hospital the range were 3-37 day and median were 22 in the without laminar group while the range were 1-45 day and median were 7 in the laminar group($P\ value \leq 0.05$) .

Table 2: shows that there is highly significant decrease in occurrence of neuro developmental delay and bronchopulmonary dysplasia in the

laminar group where 20.7% developed neuro developmental delay in the without laminar group while 8.1% developed neuro developmental delay in the laminar group. And 30.7% developed bronchopulmonary dysplasia in the without laminar group while 10% developed bronchopulmonary dysplasia in the laminar group. **Table 3:** shows that there were increase in percent of negative blood culture in the laminar group but without significant value, and the most common organism was klebsiella by 9.2% in the laminar group and was 9.3% in the without laminar group and the most sensitive antibiotic was tygacil by 57.1 % in the laminar group and 58.1% in the without laminar group .

Figure 1: shows that Comparison between the two studied groups according to Hb level as the mean ± SD were 15.52 ± 3.21 in the laminar group while the mean ± SD were 13.48 ± 3.21 in the without laminar group.

Figure 2: Comparison between the two studied groups according to albumin as the mean ± SD were 3.51 ± 0.61 in the laminar group while the mean ± SD were 3.29 ± 0.54 in the without laminar group. **Figure 3:** shows that there is highly significant decrease in percent of sepsis in the laminar group, where 63.3% developed sepsis in the without laminar group and 42.2% developed sepsis in the laminar group .(P value ≤ 0.05)

Table (1): Comparison between the two studied groups according to stay on O₂ and stay on hospital (days).

	Without laminar (n=150)	With laminar (n=270)	U	P
Stay on O₂ (days)				
Min. – Max.	1.0 – 28.0	1.0 – 45.0	10249.50*	<0.001*
Mean ± SD.	15.89 ± 8.07	9.04 ± 7.56		
Median (IQR)	17.0 (9.0–22.0)	7.0 (4.0–12.0)		
Stay on hospital (days)				
Min. – Max.	3.0 – 37.0	1.0 – 45.0	7767.0	<0.001*
Mean ± SD.	20.94 ± 8.96	10.57 ± 8.17		
Median (IQR)	22.0 (14.0–29.0)	7.0 (5.0–13.0)		

U: Mann Whitney test

p: p value for comparing between the two studied groups

*: Statistically significant at p ≤ 0.05

Group A: Archive group

Group B: New group

Table (2): Comparison between the two studied groups according to long term outcome.

Long term outcome	Without laminar (n=150)		With laminar (n=270)		χ ²	P
	No.	%	No.	%		
Neuro developmental delay						
No	119	79.3	248	91.9	22.15*	<0.001*
C.P	9	6	0	0		
Cerebral infarction	5	3.4	5	1.9		
Hydrocephalus	11	7.3	10	3.7		
Meningitis	6	4.0	7	2.5		
Bronchopulmonary dysplasia						
No	104	69.3	243	90.0	28.681*	<0.001*
Yes	46	30.7	27	10.0		

C.P/cerebral palsy

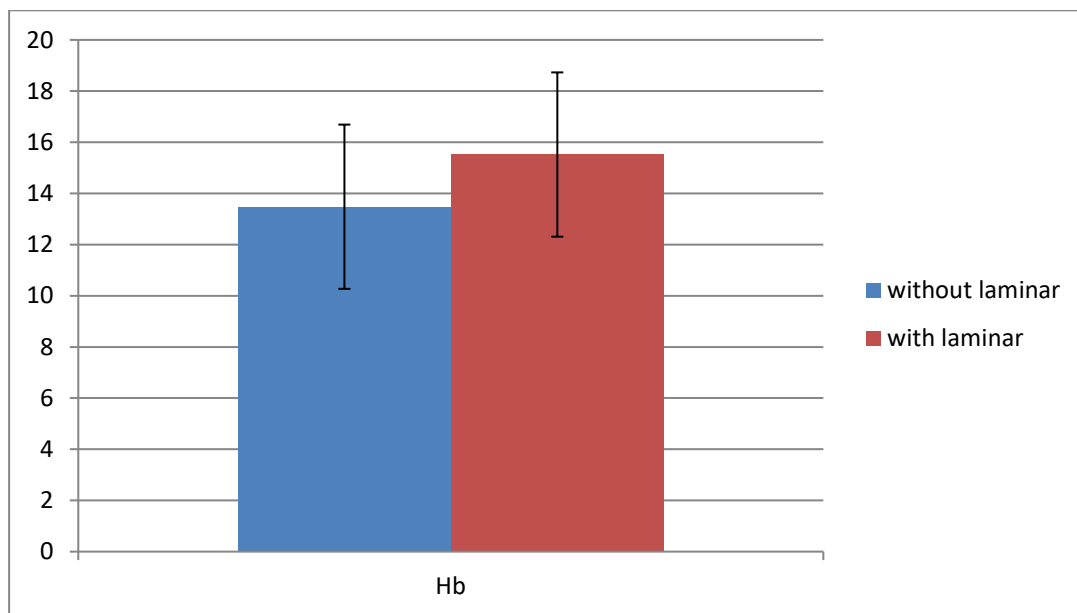
p: p value for comparing between the two studied groups *: Statistically significant at p ≤ 0.05

Group A: Archive group
Group B: New group

Table (3): Comparison between the two studied groups according to cultures.

Cultures	Without laminar (n=150)		With laminar (n=270)		χ^2	P
	No.	%	No.	%		
Result						
No growth	119	79.3	221	81.9	3.589	^{MC} p=0.930
Actinobacter humini	2	1.3	3	1.1		
Klebseilla	14	9.3	25	9.2		
Pseudomonus	1	0.7	3	1.1		
Staph aureus	3	2.0	7	2.6		
Staph epidermides	4	2.7	3	1.1		
Staph hominus	4	2.7	4	1.5		
Staph hemolyticus	3	2.0	4	1.5		
Antibiotic sensitivity						
No	119	79.3	221	81.9	0.397	0.529
Yes	31	20.7	49	18.1		
Tyagcil	18	58.1	28	57.1	0.263	0.608
Linezolid	10	32.3	16	32.7	0.091	0.763
Vancomycin	12	38.7	18	36.7	0.258	0.611
Ciprofloxacin	6	19.4	8	16.3	0.322	0.571
Amikin	3	9.7	3	6.1	0.541	^{FE} p=0.671
Metronidazole	0	0.0	2	4.1	1.116	^{FE} p=0.540
SXT	0	0.0	2	4.1	1.116	^{FE} p=0.540
Azithromycin	2	6.5	2	4.1	0.359	^{FE} p=0.619

χ^2 : Chi square test FE: Fisher Exact MC: Monte Carlo p value for comparing between the two studied groups SXT/trimethoprim e sulfamethoxazole Group A: Archive group Group B: New group

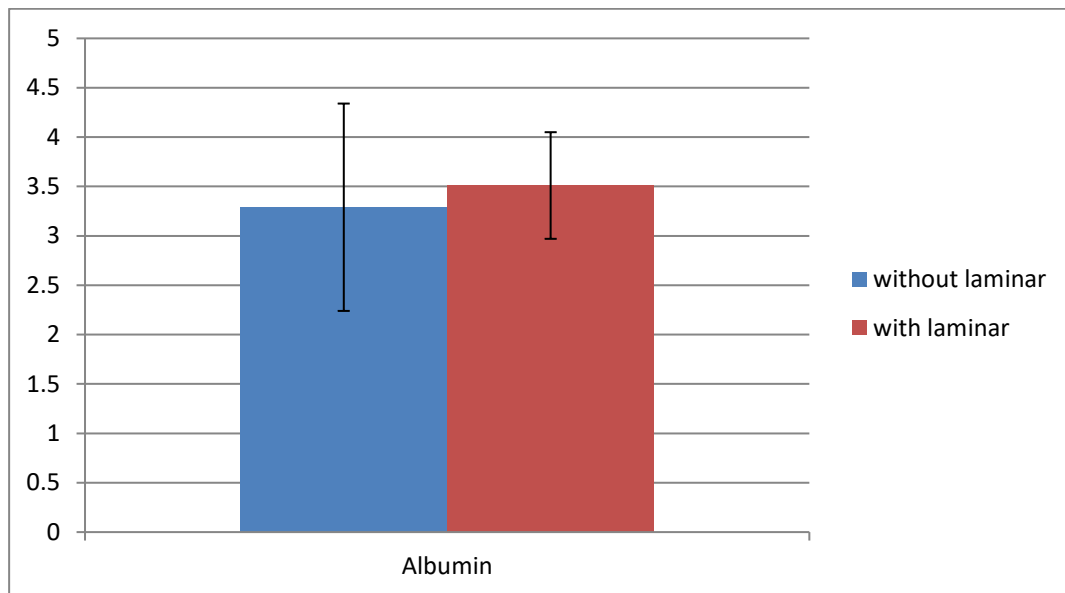


HB/hemoglobin

U: Mann Whitney test p: p value for comparing between the two studied groups

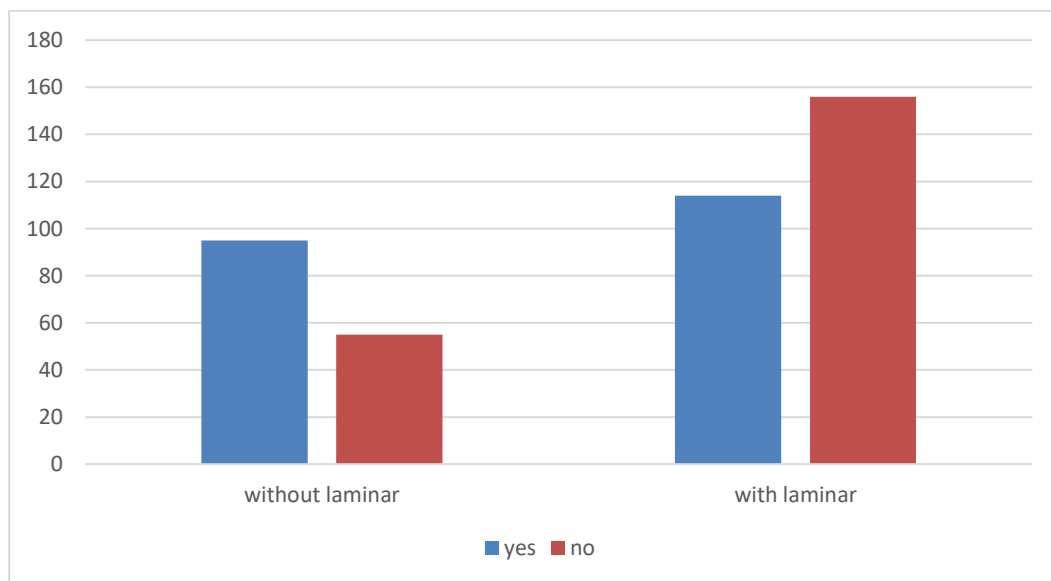
***: Statistically significant at $p \leq 0.05$ PLT/platelets Group A: Archive group Group B: New group**

Fig. (1): Comparison between the two studied groups according to Hb



U: Mann Whitney test t: Student t-test ALT/alanine transaminase: p value for comparing between the two studied groups *: Statistically significant at $p \leq 0.05$ Group A: Archive group Group B: New group

Fig. (2): Comparison between the two studied groups according to albumin



χ^2 : Chi square test U: Mann Whitney test p: p value for comparing between the two studied groups *: Statistically significant at $p \leq 0.05$ Group A: Archive group Group B: New group

Fig. (3): Comparison between the two studied groups according to Develop sepsis

DISCUSSION

This study showed that according to days of stay on oxygen the range were 1-28 day and median were 17 in the without laminar group while the range were 1-45 day and median were 7 in the laminar group, and according to days of stay in hospital the range were 3-37 day and median were 22 in the without laminar group while the range

were 1-45 day and median were 7 in the laminar group (P value ≤ 0.05)

In the study of **Capretti et al.,(9)** and **Hartman et al.,(10)** detected that using of TPN preparation guidelines will reduced the duration of endotracheal intubation and stay on hospital. Also **Jasani and Patole, (11)** reported that initiating of standard feeding guidelines was

improved the first day for enteral feeding initiation, decreased number of days of PN use and achievement of desired feeding volumes.

Regarding to long term outcome results of the current study were that in the without laminar group there were 20.7% with neuro developmental delay , and 30.7% with bronchopulmonary dysplasia, while In the laminar group there were 8.1% with neuro developmental delay, while 10% with bronchopulmonary dysplasia. There is increase in neurodevelopmental delay, and BPD between neonates in the without laminar group than the laminar group.

Those results were totally in agreement with **Ziegler et al., (12)** who suggested that poorly nourished infants were suffering from severe BPD. and suggested that the degree of under nutrition that contributes to poor neurocognitive outcomes. Also similar to us **Yeung (13)** who Detected that Nutritional deficiencies, affect somatic growth and brain growth results in irreversible long-term neurodevelopmental deficits.

Also **Pallotto and Kilbride (14)** who detected that Preterm infants that fail to catch-up growth as they took non computerized total parenteral nutrition have increased risk for cognitive delays, decreased academic achievement and significantly increased risk of neurologic disorders in adult life **Cormack et al.,(15)** who confirmed that Extremely preterm babies are at increased risk of less than optimal neurodevelopment compared with their term-born counterparts. Optimizing nutrition is a promising opportunity to diminish the adverse neurodevelopmental consequences of preterm birth.

the results of the current study showed that in the group without laminar the most common organism was,(9.3%) klebsiella ,followed by staph ,then actinobacter and pseudomonas, In the laminar group the most common organism was klebsiella (9.2%), followed by staph , then actinobacter and pseudomonas.

Similar to our result **Duke (16)** who reported that klebsiella is the most common pathogen causing neonatal sepsis. Other researchers like **Sastre et al., (17)** found that klebsiella is the second common pathogen.

According to E.coli **Aurangzeb and Hameed (18)** who showed that E. coli (77.1%) was the commonest organism in early onset neonatal sepsis followed by Pseudomonas (8.9"/"), Klebsiella (7.4%), and Staphylococci (4.4%).and No E.coli reported by **Aftab and Iqbal (19)** from Lahore.la.

In contrast to our study **Zaidi et al., (20)** in Saudi Arabia who showed that gram-positive organisms predominated in both early and late onset sepsis. These differences due to difference in infection control strategies.

Regarding to antibiotic sensitivity the results of current study showed that the most common antibiotic sensitivity (58.1%) was tygacil, and (38.7%) was vancomycin in the without laminar group ,and (57.1%) with tygacil, and (36.7%) with vancomycin in the laminar group.

In contrast to our study **Macrae et al., (21)** who found that all isolated klebsiella were resistant to ampicillin, cefotaxime, cefuroxime, co-amoxiclav, mezlocillin, chloramphenicol, gentamicin, and ceftazidime (except in two), and all were susceptible to imipenem, amikacin and quinolones.this difference in antibiotic sensitivity may be due to the development of resistance of bacteria in our environment.

The results of the current study were that there is increase in hemoglobin level in the laminar group. We are similar to **Qiao et al.,(22)** who showed that early parenteral nutrition, mostly from day 2of life, improved the Hb level and mean corpuscular volume (MCV) levels at 3 months of age.

The results of current study showed in the laminar group the mean albumin 3.51 ± 0.61 ,while In the without laminar group the mean albumin 3.29 ± 0.54 . There is significant increase in albumin level in the laminar group.Similar to us **Butler et al.,(23)** who detected that standardized parenteral nutrition significantly increased amino acid and caloric intakes, and it reduced early weight loss than individualized type.

In The study of **Lenclen et al.,(24)** who confirmed that production of standardized solutions by the pharmacy, designed for premature neonates, enables the improvement of early nutrient supplies, resulting in a greater amount of amino acids during the first week (20%), compared with infants receiving individualized formula (prepared by nurses in ward), and a better balance in the calcium phosphate ratio without any biological disorders.

Yeung et al.,(25) also reported that neonates who received standard PN 42% improvement in gain amino acids than individualized group.

Regarding to sepsis the results of the current study were that there is significant decrease in sepsis in the laminar group. this study showed that in the group without laminar there were (63.3%) developed sepsis while in the without laminar group there were (42.2%) developed sepsis .

Similar to us the study of **Ziegler et al., (12)** who suggested that poorly nourished infants who were gaining weight slowly might be more prone to late-onset infection.

Also **McCallie et al.,(26)** proved by Culture that late-onset sepsis rates significantly decreased after the beginning of standardized feeding protocol.and in the study of **Krohn et al., ,(27)** aseptic solution preparation conditions in an isolator represents the

highest recognized level of microbiological safety. We are similar to **Butler et al.,(23)** who showed that implementation of the standardized TPN resulted in improved outcomes for the patients with no increase in adverse outcomes from NEC, sepsis, mortality or line infections.

StuČki et al.,(28) told us that microbial contamination in intravenous medication prepared on wards occurs in around 0.2%.

CONCLUSION

TPN with laminar flow unit is the cornerstone in prevention of complications and decrease mortality and morbidity in NICU as the laminar flow unit will achieve the following:

Maintain neonatal temperature. Good isolation and humidification by having closed compartment intended for aseptic processing to avoid contamination. Using laminar flow in TPN preparation decrease mortality rate, occurrence of neurodevelopmental delay, bronchopulmonary dysplasia and days of stay on hospital and oxygen therapy. Once enteral nutrition can be tolerated we must start, as parenteral nutrition is not a “natural” way of feeding but an invasive procedure and it may carry potential risks.

Proposed application: Determination of the outcomes of total parenteral nutrition prepared with laminar flow.

Study Limitations: Our study follows up the neonates for a short period of time. Moreover, the long-term outcome needs more time, so some problems which are not included in our study may appear later on according to the new cases.

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