Revista Brasileira de Enfermagem
REBEn

Analysis of diagnostic criteria for ventilator-associated pneumonia: a cohort study

Análise dos critérios diagnósticos de pneumonia associada à ventilação mecânica: estudo de coorte

Análisis de criterios diagnósticos de neumonía asociada a la ventilación mecánica: estudio de cohorte

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How to cite this article:
Campos CGP, Pacheco A, Gaspar MDR, Arcaro G, Reche PM, Nadal JM, et al. Analysis of diagnostic criteria for ventilator-associated pneumonia: a cohort study. Rev Bras Enferm. 2021;74(6):e20190653. https://doi.org/10.1590/0034-7167-2019-0653

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Submission: 12-09-2019 **Approval:** 05-09-2021

ABSTRACT

Objectives: to analyze the diagnostic criteria for ventilator-associated pneumonia recommended by the Brazilian Health Regulatory Agency and the National Healthcare Safety Network/Centers for Disease Control and Prevention, as well as its risk factors. **Methods:** retrospective cohort study carried out in an intensive care unit throughout 12 months, in 2017. Analyses included chi-square, simple linear regression, and Kappa statistical tests and were conducted using Stata 12 software. **Results:** the sample was 543 patients who were in the intensive care unit and under mechanical ventilation, of whom 330 (60.9%) were men and 213 (39.1%) were women. Variables such as gender, age, time under mechanical ventilation, and oral hygiene proved to be significant risk factors for the development of ventilator-associated pneumonia. **Conclusions:** patients submitted to mechanical ventilation need to be constantly evaluated so the used diagnostic methods can be accurate and applied in an objective and standardized way in Brazilian hospitals.

Descriptors: Pneumonia, Ventilator-Associated; Risk Factors; Intensive Care Units; Delivery of Health Care; Cross Infection.

RESUMO

Objetivos: analisar os critérios diagnósticos da Pneumonia Associada à Ventilação Mecânica recomendados pela Agência Nacional de Vigilância Sanitária e pela *National Healthcare Safety Network/CDC*, bem como os fatores de risco. **Métodos:** estudo de coorte retrospectivo realizado em uma Unidade de Terapia Intensiva, no período de 12 meses, no ano de 2017. A análise foi realizada por meio de testes estatísticos Qui-Quadrado, regressão linear simples e teste de *Kappa,* pelo programa STATA 12. **Resultados:** a amostra constitui-se de 543 pacientes hospitalizados na UTI em ventilação mecânica, destes, 330 (60,9%) eram do sexo masculino e 213 (39,1%) eram do sexo feminino. As variáveis, como sexo, idade, tempo de ventilação e higiene oral, foram significativas como fatores de risco para o desenvolvimento da Pneumonia Associada à Ventilação Mecânica (PAV). **Conclusões:** os pacientes em uso da ventilação mecânica necessitam de constante avaliação para acurácia dos métodos de diagnósticos, de forma objetiva e padronizada, nas instituições hospitalares brasileiras.

Descritores: Pneumonia Associada à Ventilação Mecânica; Fatores de Risco; Unidades de Terapia Intensiva; Assistência à Saúde; Infecção Hospitalar.

RESUMEN

Objetivos: analizar los criterios diagnósticos de neumonía asociada la ventilación mecánica recomendados por la Agencia Nacional de Vigilancia Sanitaria y la National Health Care Safety Network/CDC, así como los factores de riesgo. **Métodos:** estudio de cohorte retrospectivo realizado en una unidad de terapia intensiva durante 12 meses, en 2017. El análisis se realizó mediante pruebas estadísticas de Chi-cuadrado, regresión lineal simple y test de Kappa, utilizando el programa STATA 12. **Resultados:** muestra constituida por 543 pacientes hospitalizados en UTI con ventilación mecánica, de ellos 330 (60,9%) eran de sexo masculino, y 213 (39,1%) de sexo femenino. Las variables como sexo, edad, tiempo de ventilación e higiene oral fueron significativas como factores de riesgo para el desarrollo de la NAV. **Conclusiones:** los pacientes en uso de ventilación mecánica requieren evaluación constante de precisión en los métodos de diagnóstico de manera objetiva y estandarizada en las instituciones hospitalarias brasileñas.

Descriptores: Neumonìa Asociada Al Ventilador; Factores de Riesgo; Unidades de Cuidados Intensivos; Prestación de Atención de Salud; Infección Hospitalaria.

INTRODUCTION

Ventilator-associated pneumonia (VAP) is the most frequent and serious healthcare-associated infection affecting patients in intensive care units (ICUs)[1-2]. The pathogenesis of VAP originates in the inflammatory response of the pulmonary parenchyma, which triggers severe respiratory signs and symptoms resulting from uncontrolled penetration and multiplication of infectious agents, especially multidrug-resistant microorganisms. These problems are followed by immunity impairment, reduction of the cough reflex, and swallowing alterations[3-4].

One of the therapeutic measures most used in ICUs is mechanical ventilation (MV), which guarantees adequate oxygen supply by means of tracheostomy or endotracheal intubation[5]. The presence of the tube used in this procedure has been pointed as an important risk factor for developing VAP, because this situation deprives patients of the normal mechanism of airway cleaning and increases production of secretion as a consequence of the reduced cough reflex[6-7].

Ventilator-associated pneumonia is a pulmonary infection that appears after at least 48 hours of endotracheal intubation in patients submitted to invasive MV[8]. Its incidence ranges from 9% to 28% according to international studies[9-10], and in Brazil this rate is between 23.2% and 36.01%[11]. Mortality resulting from VAP ranges from 20% to 60%[12], and its impacts include longer hospital stay (around 12 days) and increased costs (which are estimated to be US$ 40,000 per episode)[8,10].

Confirming a VAP diagnosis requires professionals to follow diagnostic criteria. However, the clinical condition of these patients is complex and there are bedside difficulties[13-14]. In Brazil, the VAP diagnosis is defined by the Brazilian National Criteria for Respiratory Tract Infections, which establishes the sum of clinical findings and the interpretation of radiologic and laboratory tests in accordance with the Brazilian Health Regulatory Agency (Anvisa, as per its acronym in Portuguese)[5,7].

However, it is known that subjective criteria are still used in health services. In 2013, the National Healthcare Safety Network/Centers for Disease Control and Prevention (NHSN/CDC) developed a new approach based on objective criteria to diagnose ventilator-associated events (VAE) rather than VAP and issued a new protocol that minimizes subjectivity in diagnostic criteria[14-15].

The criteria proposed by this institution encompasses the comprehensive classification of VAE, which is divided into three specific categories defined by using objective standards: ventilator-associated conditions (VAC), infection-related ventilator-associated complications (IRVAC), and possible ventilator associated-pneumonia (PVAP)[15-16]. According to this classification, all the data necessary to meet the criteria are objective. The used method facilitates comparison of incidence rates in different ICUs and makes the results more reliable[17].

Applying comprehensive and objective diagnostic criteria allows to identify the disease and propose a safe and optimized treatment to patients under MV, a population with high morbimortality rates[12,18]. Since there is a lack of Brazilian studies that evaluate VAE, the present study intends to contribute for health professionals to carry out effective procedures in critical patients submitted to MV.

OBJECTIVES

To analyze the diagnostic criteria for VAP recommended by Anvisa and NHSN/CDC, as well as its risk factors.

METHODS

Ethical aspects

The study observed the guidelines and norms established in Brazilian National Health Council Resolution no. 466/2012, which regulates human research, and the proposal was approved by the Human Research Ethics Committee at the institution.

Study design, period, and location

This was a retrospective cohort study, guided by the Strengthening the Reporting of Observational Studies in Epidemiology and carried out in a general adult ICU at a teaching hospital in the municipality of Ponta Grossa, a medium-sized city located in the Brazilian state of Paraná, between January and December 2017.

This ICU had 20 beds and one multiprofessional team for every 10 beds. The places were distributed over clinical care, surgical care, and trauma care, and the average number of assisted patients was 80 per month.

Population or sample; inclusion and exclusion criteria

From January to December 2017, 953 patients stayed in the ICU at issue. Non-probability convenience sampling was applied and resulted in a sample of 543 patients who were under MV. According to the inclusion criteria, these patients had the following characteristics: being adult or elderly people, being 18 years old or older, and having been submitted to MV over a period longer than 48 hours. Patients whose condition evolved into death in less than 48 hours were excluded, as advocated by the two criteria[5,17].

Study protocol

Data collection was carried out by two trained researchers by means of analysis of medical records of patients submitted to MV, which were made available by the ICU's electronic record system. Access to data on VAP incidence counted on the support of the institution's Infection Control System. All the information was collected over a period of four months in 2018.

Data were recorded and tabulated in Microsoft Office Excel 2007® spreadsheets that showed the following variables: age, gender, number of comorbidities, classes of comorbidities, admitting diagnosis, days spent under MV, days spent in the ICU, and monitoring of oral hygiene with chlorhexidine.

For the VAP diagnosis, the criteria established by Anvisa[4-5] and NHSN/CDC[14-15] were used to analyze the data, as described below.

The diagnostic criteria for VAP established by Anvisa are described in Chart 1. They consider pneumonia diagnosed in patients under MV over more than two days, with time counted from the beginning of MV[4-5].

Chart 1- Diagnostic criteria for Ventilator-associated pneumonia established by Anvisa in 2019

Diagnostic criteria for VAP
Clinical: • Having underlying heart or lung disease with two or more sequential imaging tests showing the following findings (new and persistent or progressive and persistent): infiltrate, opacification, or cavitation; • Showing one of the following signs and symptoms: fever (temperature > 38 ºC), leukopenia (< 4,000 cells/mm^3), or leukocytosis (> 12,000 cells/mm^3). For patients 70 years old or older, alteration in the level of consciousness with no other apparent cause; • Showing two of the following signs and symptoms: appearance of purulent discharge, or change in the characteristics of the discharge, or increase in the respiratory discharge, or increase in the need for aspiration; worsening of gas exchange (desaturation, for instance PaO2/FIO2 < 240, or increase in oxygen supply, or increase in ventilation parameters); auscultation with rhonchi or rales; onset of cough or dyspnea.
Microbiological: • Positive blood culture, with absence of another focus of infection; • Positive culture of the pleural fluid; • Positive quantitative culture of pulmonary discharge obtained by means of a procedure with minimum contamination potential (bronchoalveolar lavage, protected brushing, and endotracheal aspirate).

VAP - Ventilator-associated pneumonia.

Chart 2 - Diagnostic criteria for Ventilator-associated pneumonia established by National Healthcare Safety Network/Centers for Disease Control and Prevention

Diagnostic criteria for VAE
Ventilador-associated condition (VAC) • At least two days of stability or improvement of ventilation parameters followed by worsening oxygenation; • Increase in positive end-expiratory pressure (PEEP) (≥ 3 cm H2O); or • Fraction of inspired oxygen (FIO2) ≥ 20% sustained for two days or longer.
Infection-related ventilator-associated complications (IRVAC) • Temperature < 36 °C or > 38 °C; or • Leukocyte count ≤ 4 or ≥ 12 x 10^3 cells/mm^3; and • ≥ one new antibiotic kept for ≥ four days (within two days after VAC initiation, excluding the two first days in the ventilator).
Possible ventilator-associated pneumonia (PVAP) • Purulent sputum in bronchoalveolar lavage with ≥ 25 neutrophils/field and ≤ 10 epithelial cells/field; and/or • Positive respiratory culture (within two days after VAC initiation, excluding the two first days in the ventilator) .

VAE - ventilator-associated events.

Regarding the new criteria established by NHSN/CDC, the VAE definition algorithm uses three new indicators: VAC, IRVAC, and PVAP[15-16]. These are described in Chart 2.

Ventilator-associated conditions are the first surveillance step that seeks to identify any complication in patients submitted to MV. According to the definition, for a VAC diagnosis to be made it is necessary that the patient be under stable MV for 48 hours followed by 48 hours of worsening oxygenation (decrease in PEEP or FIO2). Infection-related ventilator-associated complications, in turn, are VAC associated with an abnormal leukocyte count or increase in temperature and are potentially related to infections. Last, PVAP is identified when there is presence of purulent discharge in oropharyngeal aspiration or positive microbiological results[14,17].

Results analysis and statistics

The dependent variable was VAP diagnosed by applying the Anvisa criteria, and the independent variables were risk factors: age, gender, time under MV, admitting diagnosis, and oral hygiene with chlorhexidine, with calculation of relative risk considering a 95% confidence interval.

Statistical analysis was carried out by applying Pearson's chi-square test of association to categorical variables (described numerically and by percentages) and simple linear regression to evaluate the effect of predictors that may be statistically associated with VAP. For continuous variables (described by means), Fisher's test was applied by using Stata 12.

To calculate the incidence density of VAP and VAE in ICU patients, the number of episodes of VAP in ICU patients was divided by the number of patients under MV per day, and the result was multiplied by 1,000.

Cohen's kappa agreement analysis was used to verify agreement between the two diagnosis methods. The adopted level of significance was $p < 0.05$. Last, some stratified analyses were carried out to eliminate the effect of confounding variables, especially gender, age, and level of education, in the estimates of associations found by variables predictive of VAP.

RESULTS

The population was 543 patients who were in an ICU and were submitted to MV. Of these people, 330 (60.9%) were men and 213 (39.1%) were women. On average, the age of the analyzed patients was 59.8 years. Patients who developed VAP had lower mean age and longer MV time in comparison with those who did not develop this problem. For both variables, there was statistical significance, as shown in Table 1.

Patients who were submitted to oral hygiene had a probability of developing VAP nearly five times higher than that calculated for patients who did not receive this type of care (RR = 4.916; $p < 0.001$). Additionally, external causes, such as admitting diagnosis, proved risk factors associated with the development of the infection, with statistical significance (RR = 2.126; $p = 0.006$). The relationships between demographic and clinical variables and VAP are described in Table 1.

According to the diagnostic criteria established by NHSN/CDC for VAP, the incidence of VAE was 23.40%, as shown in Table 2. This value was higher than the incidence of VAE calculated by following the Anvisa criteria, 16.21%.

Regarding agreement between VAP diagnosis according to the criteria established by Anvisa and NHSN/CDC, there was statistical difference, as illustrated in Table 3. Of the total of 141 cases of respiratory complications, there was similarity in diagnostic criteria in 74 (52.5%), whereas 53 (37.6%) met the NHSN/CDC criteria and 14 (09.90%) met the Anvisa criteria.

Of the 88 VAP cases, 62 (70.50%) fulfilled the characteristics to be classified as PVAP (Kappa: 0.6028; $p < 0.001$), nine (10.20%) were diagnosed as IRVAC (Kappa: 0.0263), and three (3.40%) as VAC (Kappa: 0.0017), accounting for around 80.1% of coverage of VAE criteria in the detection of VAP cases based on the Anvisa criteria.

Table 1 – Characteristics of patients submitted to mechanical ventilation in an intensive care unit and their relationships with ventilator-associated pneumonia, Ponta Grossa, Paraná, Brazil, 2017

Variables	Ventilator-associated pneumonia		Relative risk	[95% CI]	*p* value
	No n(%)	Yes n(%)			
Gender					
Female	182 (85.45)	31 (14.55)	1.19	[0.79- 1.77]	0.401
Male	273 (82.73)	57 (17.27)			
Age group					
Average age (years)	60.85	54.31	-	[2.23- 10.85]	0.003*
Time under mechanical ventilation			-		
Average time (days)	05.07	15.03		[-11.84- 8.07]	**<0.001***
Initial diagnosis					
Cardiovascular	114 (85.71)	19 (14.29)	1.20	[0.68 – 2.11]	0.530
External causes	56 (74.67)	19 (25.33)	2.13	[1.23- 3.66]	0.006†
Respiratory	37 (77.08)	11 (22.92)	1.92	[1.00-3.66]	0.050
Infectious diseases	78 (82.98)	16 (17.02)	1.43	[0.79-2.57]	0.236
Others	170 (88.08)	23 (11.92)	-	-	-
Oral hygiene					
Yes	356 (80.91)	84 (19.09)	4.91	[1.84- 13.09]	**<0.001†**
No	099 (96.12)	04 (03.88)			
Total	455 (83.79)	88 (16.21)			

*Note: *Significant statistical difference according to linear regression test. †Significant statistical difference according to Pearson's chi-square test.*

Table 2 – Incidence of ventilator-associated events according to the diagnostic criteria of the National Healthcare Safety Network/Centers for Disease Control and Prevention. Ponta Grossa, Paraná, Brazil, 2017

Event classification	Incidence (%)	Incidence density (cases per 1,000 MV per day)
Ventilator-associated events	23.40	35.00
Ventilator-associated conditions	03.31	04.96
Infection-related ventilator-associated complications	02.21	03.30
Possible ventilator associated-pneumonia	17.86	26.71

MV - mechanical ventilation.

Table 3 – Agreement between diagnoses of respiratory complications, Ponta Grossa, Paraná, Brazil, 2017

NHSN/CDC criteria (n=127)	Ventilator-associated pneumonia Anvisa criteria		Total	Kappa	*p* value
	No	Yes			
Ventilator-associated conditions	15	03	18	0.0017	
Ventilator-associated infections	03	09	12	0.0263	
Possible ventilator-associated pneumonia	35	62	97	0.6028	**<0.001**
None	00	14	14	0	
TOTAL	53	88	141		

Note: Kappa: > 0.80: excellent agreement; between 0.60 and 0.80: strong agreement; between 0.40 and 0.60: moderate agreement, and < 0.40: weak agreement); NHSN/CDC - National Healthcare Safety Network/Centers for Disease Control and Prevention.

DISCUSSION

Regarding risk factors, the results for gender, age, and comorbidities were similar to those reported in other studies, that is, most patients with VAP were men and their average age did not exceed 60 years[15,19-20]. However, other studies have mentioned that elderly people are more likely to develop this problem than young adults because of aging physiological alterations, decline of the immunologic response, execution of invasive procedures, and greater predisposition to chronic diseases[21-22].

In the present study, the average number of days under MV of patients who developed VAP was significant in comparison to the mean number recorded for patients who did not show an infectious process. A study carried out in the Brazilian state of Minas Gerais[6] which used the Anvisa criteria identified that patients under MV for more than 10 days were susceptible to developing VAP, a finding that agrees with the results of the present study. In consonance with other Brazilian studies, the average time under MV reported for patients with VAP was 15.85 days, whereas patients who did not have this condition were under MV 8.55 for fewer days[7].

An increase in time under MV contributes to high mortality rates and, consequently, high hospital costs[23-24]. These indicators reinforce the need to implement strategies to reduce time under MV and the risk of developing VAP, as illustrated by MV weaning by early mobilization and daily sedation withdrawal as one of the components of preventive care[6,24-25].

Regarding comorbidities, because of the severity of the clinical manifestations of the underlying diseases present in these patients, including cardiovascular, respiratory, kidney, and liver

problems, these conditions have been seen as determining factors of the need for hospitalization in ICUs[25-26]. Analysis of Table 1 showed that the profile of the admitting diagnosis was different from that reported in other studies. Risk of VAP was higher in young adult patients (average age of 54.3 years) and may be related to the severity of their condition, since the second cause of hospital admission was trauma. Individuals in the adult age group are more likely to suffer accidents and, therefore, to need respiratory support, which contributes to developing VAP[27].

The incidence density calculated according to NHSN/CDC criteria was higher than the numbers shown in international studies. A study carried out in China reported incidence densities of 13.31 cases per 1,000 days for VAE, 7.53 cases per 1,000 days for VAC, 3.52 cases per 1,000 for IRVAC, and 2.26 cases per 1,000 for PVAP[24]. In another study, carried out in Saudi Arabia, the incidence densities for VAE and VAC were 11.12 and 7.93 cases per 1,000, respectively[28].

The incidence of VAP in the present study according to the Anvisa criteria was lower than that reported in Brazilian studies which have shown rates of 31.8%, 32.4%, and 36.01%[11,23,27]. However, the differences found may have been caused by different types of diseases in the patients and different levels of adherence to preventive measures[24,29]. According to a study performed in the Ceará Teaching Hospital, the incidence of VAP cases increased from 10 to 16 after implementation of preventive measures, which reinforced the need for the health team to develop greater adherence to and awareness of preventive measures[30].

Adhering to the bundle of measures advocated by Anvisa and NHSN/CDC has shown satisfactory results in decreasing infection risks, as mentioned by several studies[6,12,25]. This happens because there are factors that predispose patients to develop VAP, and some of these factors can be modified.

The main preventive strategies include a basic set of interventions known as bundle, which, when applied together, result in improvements in care quality and lead to lower VAP incidence. These measures include: uplifting of bedheads, protocols of daily sedation withdrawal, daily practice of spontaneous breathing, oral hygiene with chlorhexidine, subglottic aspiration, cuff pressure verification, prophylaxis of thromboembolism, and prophylaxis of stress injuries. Education must be permanent, with emphasis on ICUs, especially when there are changes in protocols or when new ones are implemented[25,30].

Therefore, in the VAP bundle, oral hygiene is one of the key prevention components, since it reduces the chances of formation of biofilms in the mouth and endotracheal tube, which can cause infections in the respiratory tract[21,28]. Regarding this aspect, the present study showed a disagreement with the literature, because oral hygiene proved a risk factor to develop VAP. Knowing the general health and oral health conditions of patients admitted to ICUs is indispensable for health teams to deliver effective care with adequate techniques and, consequently, control biofilm formation, either in the oropharyngeal cavity or endotracheal tube, implementing an important strategy to prevent VAP[30-31].

Previous studies have reported the presence of microorganisms such as *Pseudomonas aeruginosa*, *Staphylococcus aureus*, *Klebsiella pneumoniae*, *Escherichia coli*, and *Streptococcus pneumoniae* in patients under MV[31-32]. As discussed above, preventing colonization of the oropharynx by microorganisms is essential for decreasing the chances of developing PAV. This can be achieved by performing oral hygiene with 0.12% chlorhexidine from three to four times a day[33-34]. However, the present study showed that oral hygiene can increase the risk of developing VAP when comparison with patients who were not submitted to cleaning with this antiseptic was made. This finding corroborated the result of a retrospective cohort study that evaluated 5,539 patients under MV and involved analysis of oral hygiene with chlorhexidine. The antiseptic was associated with increased risk of developing VAP and increased mortality in ventilated patients[34].

Regarding results related to the comparison of diagnostic criteria proposed by Anvisa and NHSN/CDC, the present study found a low level of agreement, expressed by the kappa coefficient, for VAC and IRVAC. However, for PVAP, the agreement value was considered moderate, with a p value < 0.001. Data analysis indicated that NHSN/CDC criteria showed greater sensitivity to PVAP. This result diverged from data in the literature. A study carried out in the Brazilian state of Santa Catarina pointed to low agreement between the two methods, which identified 18 cases of IRVAC and 14 of PVAP in a group of 168 patients under MV, with the NHSN method showing a sensitivity of 0.37 for PVAP cases[16]. Another study calculated that the combined sensitivity to PVAP in detection of VAP did not exceed 50%[29].

A Brazilian national consensus regarding use of NHSN/CDC criteria does not exist yet, because of conceptual differences between this method and that proposed by Anvisa. Studies have pointed out the need to develop clinical trials to outline the approach to be used with the NHSN/CDC criteria, aiming to understand risk factors for VAE and VAP prevention[35-36]. Based on the literature, it is suggested that Anvisa, together with State Infection Control Coordination Bodies, consider the feasibility of carrying out a pilot project with a group of previously selected hospitals and developing studies oriented toward comparing the current criteria with those established by NHSN/CDC so the applicability and viability of the latter in Brazilian hospitals can be assessed[4].

Limitations of the Study

The limitations of the present study were related to the study design and the fact that it was carried out in only one ICU at a teaching hospital. Future studies are necessary, focusing on the continuity of the prospective approach and that allow comparison between diagnostic criteria in other ICUs, which will bring benefits to health services.

Contributions of the Fields

It is considered that nurses play an important role in infection control commissions and ICUs, especially in the monthly epidemiological surveillance of infection topographies and use of diagnostic criteria for healthcare-associated infections and definition of cases belonging to this group of diseases. Professionals of this category must be used to promote standardization and interventions in patients submitted to MV affected by VAE, focusing mostly on care oriented toward preventing VAP.

CONCLUSIONS

The present study analyzed two diagnostic methods for VAP, those established by Anvisa and by NHSN/CDC, and found that the latter showed greater sensitivity for PVAP. The risk factors age, time under MV, external causes, and oral hygiene were significant for the development of the disease. It is suggested that other comparative studies be carried out to systematize diagnostic criteria for VAP that contribute to the assessment of epidemiological surveillance by healthcare-associated infection control commissions and provide ICU multidisciplinary teams with resources for daily discussions oriented toward VAP prevention and treatment.

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