ORIGINAL ARTICLE

Enhanced nursing and ganciclovir improve outcomes in paediatric Epstein-Barr Virus infectious mononucleosis: A Randomised Control Trial

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Abstract

Objective: To investigate the impact of high-quality nursing interventions and ganciclovir on paediatric Epstein-Barr virus infectious mononucleosis.

Method: The randomised controlled trial was conducted from March to August 2021 at the Departments of Paediatrics, Maternal and Child Health Hospital, Tangshan, China, and comprised paediatric patients diagnosed with Epstein-Barr virus infectious mononucleosis. The patients were randomised into intervention group A receiving high-quality nursing interventions and ganciclovir, and control group B receiving routine standard care. Primary outcomes included symptom reduction and laboratory markers, while secondary outcomes included length of hospital stay, time to resolution of symptoms, adverse events, and patient-reported outcomes. Data was analysed using SPSS 28.

Results: Of the 100 subjects, 50(50%) were in group A; 31(62%) boys and 19(38%) girls with mean age 9.15±1.45 years. There were 50(50%) patients in group B; 30(60%) boys and 20(40%) girls with mean age 9.15±1.34 years. Group A demonstrated improvements in outcomes compared to group B ($p<0.05$).

Conclusion: Ganciclovir and good nursing improved paediatric Epstein-Barr virus infectious mononucleosis treatment.

Keywords: High-quality nursing interventions, Ganciclovir, Epstein-Barr virus, EBV, Infectious mononucleosis.

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Introduction

Infectious mononucleosis, caused by Epstein-Barr virus (EBV) infection, is a common viral illness primarily affecting children and adolescents. It is characterised by a triad of symptoms, including fever, sore throat and lymph-adenopathy.[1,2] While the majority of cases resolve spontaneously with supportive care, some children may experience prolonged symptoms or complications, leading to a significant impact on their quality of life (QOL) and overall wellbeing.[3,4]

The management of infectious mononucleosis has traditionally focussed on symptomatic relief and supportive care.[5] However, recent research has highlighted the potential benefits of antiviral therapy in improving clinical outcomes and reducing the duration of illness.[6] Ganciclovir, a specific antiviral medication, has shown promise in inhibiting EBV replication and shortening the course of infectious mononucleosis.[7]

In addition to antiviral treatment, nursing interventions play a vital role in optimising the care and outcomes of children with EBV infection and infectious mononucleosis.[8] Nursing interventions encompass a range of activities, including patient education, symptom management, monitoring and assessment, adverse event management, and psychological support.[9] These interventions aim at providing comprehensive care that addresses both the physical and emotional needs of the child and their family.[10]

While previous studies have explored the effectiveness of ganciclovir treatment or nursing interventions separately, there needs to be more research examining the combined effects of antiviral therapy and nursing interventions in children with EBV infection and infectious mononucleosis, investigating the impact of a comprehensive nursing intervention combined with ganciclovir treatment on the clinical outcomes of such children.[11,12]

Several studies have explored the combined effects of ganciclovir treatment and enhanced nursing care on paediatric patients with EBV infectious mononucleosis.[13,14] One study found that integrating high-quality nursing interventions with ganciclovir significantly improved symptom management, reduced hospital stays, and enhanced overall patient outcomes.[15] This suggests that the combination of medical and nursing care can provide a more holistic approach to treatment, addressing both the physical and emotional needs of the patients.[16] Additionally, the necessity of early diagnosis and the synergistic effect of antiviral treatments and supportive nursing care in improving patient QOL have been underscored, with early intervention supported by

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comprehensive nursing care preventing complications and promoting faster recovery, highlighting the importance of a coordinated care approach.[17,18]

Lastly, a study on preoperative assessments and comprehensive care plans, although focussed on a different condition, demonstrated the value of integrating advanced diagnostics and high-quality nursing care to enhance treatment outcomes. This study's findings can be extrapolated to EBV management, suggesting that detailed assessments and personalised care plans, including the use of ganciclovir and enhanced nursing interventions, can lead to better clinical outcomes and patient satisfaction.[19]

The current study was planned to investigate the impact of high-quality nursing interventions and ganciclovir on paediatric EBV infectious mononucleosis.

Patients and Methods

This randomised controlled trial (RCT) was conducted from March to August 2021 at the Department of Paediatrics, Maternal and Child Health Hospital, Tangshan, China, and was registered at ClinicalTrials.gov with the identifier NCT05384743. Those included were paediatric patients aged 2-12 years diagnosed with EBV infection and infectious mononucleosis who met the diagnostic criteria of "Practical Paediatrics",[20] had the duration of the disease <1 month, and could adhere to the medication regimen. Children with contraindications to ganciclovir treatment, severe comorbidities, or previous antiviral treatment were excluded. The sample size was calculated based on the formula:[21]

$$n = \frac{2 \cdot \left(Z_{\alpha/2} + Z_{\beta}\right)^2 \cdot \left(\sigma_1^2 + \sigma_2^2\right)}{\left(\mu_1 - \mu_2\right)^2}$$

Where,

n = sample size per group; $Z_{\alpha/2}$=critical value for the desired confidence level (usually 1.96 for a 95% confidence level; Z_{β}=the critical value for the desired power (usually 0.84 for 80% power; σ_1^2 and σ_2^2=the variances of the outcomes in each group; and μ_1-μ_2=the expected difference in means between the two groups.

The patients were randomized into intervention group A receiving high-quality nursing interventions and ganciclovir and control group B receiving routine standard care. A stratified random sampling technique was used, and randomization was performed using a computer-generated random number table.[22] The control group was treated with standard care and intravenous (IV) ganciclovir and 5% dextrose, 10mg-kg-1-d-1, 2 times/d. The standard care for EBV infection included symptomatic treatment, rest, maintaining hydration, monitoring, and the use of antiviral medication in severe cases.

The intervention group received a comprehensive, high-quality nursing intervention combined with ganciclovir treatment identical to group B. The specific nursing intervention included the following patient education for ensuring compliance with the ganciclovir treatment regimen. The nurses provided detailed information to the child and their parents or guardians regarding the importance of adhering to the prescribed medication schedule. They explained the potential benefits of ganciclovir, its mode of action, and possible side effects. The nurses also addressed any concerns or questions related to the medication, fostering a clear understanding and promoting medication adherence.

The nursing staff guided symptom management strategies to alleviate discomfort associated with EBV infection and infectious mononucleosis. They educated the children and their caregivers about measures to relieve symptoms, such as fever, sore throat and fatigue. This included recommendations for appropriate pain relief, such as over-the-counter analgesics and ensuring adequate rest and hydration.

The nursing intervention involved close monitoring of the child's condition throughout the treatment period. The nurses assessed vital signs, including temperature, heart rate, respiratory rate and blood pressure, to monitor the child's overall stability and response to treatment. They also monitored laboratory parameters, such as complete blood count (CBC) and liver function tests (LFTs), to evaluate the effectiveness of ganciclovir treatment and identify any potential complications.

The nursing staff closely monitored the child for any adverse events related to ganciclovir treatment. They promptly reported any signs or symptoms of adverse reactions, such as haematological abnormalities or renal dysfunction, to the medical team. Appropriate interventions were implemented, which included dose adjustments, supportive care, or discontinuation of the medication, if necessary.

The nursing intervention included psychological support to address the emotional wellbeing of the children and their families. The nurses employed empathetic communication techniques to establish a therapeutic relationship and provide emotional support. They offered reassurance, actively listened to concerns, and provided counselling to help alleviate any anxiety or distress associated with the illness and its treatment.

Data collection involved a combination of methods,

including medical record review, clinical examinations, and patient interviews. Standardised assessment tools were used to collect relevant clinical data, such as laboratory test results, symptom scales, and QOL questionnaire.[23] The reliability and validity of the data collection instruments were ensured through the assessment of inter-rater reliability, where appropriate, and the use of established instruments with documented reliability and validity.

The primary outcome measure was the clinical improvement observed in terms of symptom reduction and laboratory markers. The effectiveness of the treatment was evaluated according to the "Chinese Medicine Diagnosis and Treatment Efficacy Standards".[24] These standards classify the outcomes into four categories: cured, significant improvement, practical outcomes, and ineffective results. Cured is defined as the complete disappearance of relevant symptoms and signs, absence of complications, and normalisation of clinical laboratory indicators, with an efficacy index of ≥80%. Significantly effective refers to marked recovery in symptoms, signs and various clinical indicators, yielding an efficacy index between 60-79%. Effective outcomes indicate symptom relief, improvement in clinical indicators, and absence of additional complications, with an efficacy index ranging 30-59%. Ineffective results indicate no improvement or worsening of symptoms, development of secondary complications, and an efficacy index <30%. The overall efficacy rate is calculated by adding the percentages of cured, significantly practical, and effective outcomes, and dividing the sum by 80, and multiplying by 100. The efficacy index is determined by calculating the difference in scores before and after treatment, dividing it by the score before treatment, and multiplying by 100.

Laboratory markers, such as EBV viral load and LFT markers, were also evaluated as primary outcome measures. EBV viral load serves as a quantitative measure of viral replication and activity, with a reduction indicating a positive response to treatment. LFT markers, such as alanine aminotransferase (ALT) and aspartate aminotransferase (AST), were used to assess liver health and to monitor any potential hepatotoxicity associated with ganciclovir treatment.

Secondary outcomes focussed on various aspects of the child's clinical course and overall experience. These included virus clearance and immunological changes. The conversion to negativity for EB- deoxyribonucleic acid (DNA), EBV-nuclear antigen immunoglobulin G (NA-IgG), and EBV-capsid antigen IgM (CA-IgM) before and after treatment in the two groups, as well as changes in immunological functions, such as the number of atypical lymphocytes, lymphocyte subsets, and Igs, before and after treatment, were noted.

Length of hospital stay (LOS) was examined as an indicator of the intervention's impact on the overall disease course, with a shorter hospital stay suggesting faster recovery and improved treatment outcomes.

The time taken for symptoms to resolve completely was assessed to determine the effect of the intervention on the disease's duration. A shorter time for symptom resolution indicated a more rapid recovery and improved clinical outcomes.

Adverse events related to ganciclovir treatment, such as haematological abnormalities or renal dysfunction, were monitored. Patient-reported outcomes were noted to capture the child's perspective and subjective experience. The PedsQL assesses 4 domains: physical, emotional, social, and school functioning, each of which is assigned a score.[25] The scores for emotional, social and school functioning are combined to create a psychosocial score, while the total score represents a summary of all the 4 domains. Both the domain scores and summary scores were converted to a scale ranging 0-100, where higher scores indicated better health-related QOL (HRQOL). Additionally, satisfaction with care measures were employed to evaluate the child and family's perception of the intervention and healthcare experience.

Furthermore, satisfaction with nursing care was assessed using a self-designed questionnaire. Patients and their family members assigned scores ranging 0-100. Satisfaction levels were categorised as very satisfied (>90 points), satisfied (70-90 points), or dissatisfied (<70 points).

Approval for the study was obtained from the institutional ethics review board, and risks associated with the intervention were minimised through close monitoring for adverse events and prompt intervention where necessary.

Data was analysed using SPSS 28 and GraphPad Prism 9. Continuous variables were expressed as means±standard deviation, or median with interquartile range (IQR), while categorical variables were expressed as frequencies and percentages. Inferential statistics were used to compare outcomes between the groups, employing t-tests and chi-square tests. P>0.05 was considered significant.

Results

Of the 100 subjects, 50(50%) were in group A; 31(62%) boys and 19(38%) girls with mean age 9.15±1.45 years. There were 50(50%) patients in group B; 30(60%) boys and 20(40%) girls with mean age 9.15±1.34 years (Table 1).

Group A demonstrated a significant reduction in fever

duration, sore throat severity and lymphadenopathy size compared to group B (Table 2).

Group A showed a significant reduction in EBV viral load and experienced normalisation of liver function markers, specifically ALT and AST levels (p<0.05). Before treatment, there were no significant differences in ALT and AST levels between the groups (p>0.05). After treatment, both groups saw a significant reduction in ALT and AST levels compared to their pre-treatment levels (p<0.05). However, group A had a more pronounced decrease in these liver enzymes compared to group B (Table 3).

The conversion rates of EBV-DNA, EBV-CA-IgM and EBV-NA-IgG did not show a significant difference between the groups before treatment (p>0.05). Following treatment, there was no significant change in the conversion rate of EBV-NA-IgG compared to baseline (p>0.05). However, the conversion rates of EBV-DNA and EBV-CA-IgM significantly increased after treatment compared to baseline (p<0.05), with group A exhibiting significantly higher conversion rate than group B (p<0.05) The total effective rate of group A was significantly higher than that of group B (Table 4).

Patients in group A had a much shorter LOS than those group B (p<0.001). Additionally, group A experienced a significantly faster resolution of symptoms compared to

Table-1: Baseline characteristics.

	Standard care group (n = 50)	Intervention group (n = 50)	t-test/x^2	p-value
Age (years)	9.51±1.34	9.15±1.45	1.220	0.225
Gender				
Male	30	31		
Female	20	19		
Disease course (days)	4.14±6.21	4.45±5.35	0.652	0.516
Clinical features			0.534	0.232
Fever	15	16		
Rash	20	17		
Lymphadenopathy	15	17		

Table-2: Clinical characteristics.

	Fever duration (d)	Sore throat (point)	Lymphadenopathy size (cm)
Standard care group (n = 50)	3.31±0.15	2.03±0.56	2.1±0.26
Intervention group (n = 50)	1.11±0.43	0.76±0.36	0.3±0.16
***t*-test**	7.050	3.646	7.092
***p*-value**	<0.001	<0.001	<0.001

Table-3: Laboratory markers.

	EBV viral load	ALT		AST	
		Before	After	Before	After
Standard care group (n = 50)	5.21±0.43	114.56±24.36	58.23±10.22	81.03±11.90	45.71±10.22
Intervention group (n = 50)	2.38±1.94	118.23±28.097	30.33±9.33	80.09±12.03	27.55±9.45
***t*-test**	7.050	1.292	12.247	0.312	
***p*-value**	<0.001	0.201	<0.001	0.789	<0.001

Table-4: Virus clearance rates.

	EBV-DNA		EBV-CA-IgM		EBV-NA-IgG	
	Before	After	Before	After	Before	After
Standard care group (n = 50)	3	40	4	24	45	47
Intervention group (n = 50)	6	48	6	35	45	48
x^2	1.350	8.520	1.292	11.047	0.000	0.267
***p*-value**	0.301	0.001	0.621	0.001	1.000	0.792

EBV: Epstein-Barr virus, DNA: Deoxyribonucleic acid, CA: Capsid antigen, NA: Nuclear antigen, Ig: Immunoglobulin.

Table-5: Clinical efficacy.

Group	Cured	Markedly	Effective	Ineffective	Total
Standard care (n = 50)	7	17	16	10	40
Intervention (n = 50)	15	25	8	2	48
x^2					2.908
***p*-value**					0.002

Table-6: Nursing satisfaction.

	Very satisfied	Basically satisfied	Dissatisfied	Total satisfaction
Standard care group (n = 50)	25	15	10	40(80%)
Intervention group (n = 50)	30	18	2	48(96%)
x^2				4.183
***p*-valuie**				0.020

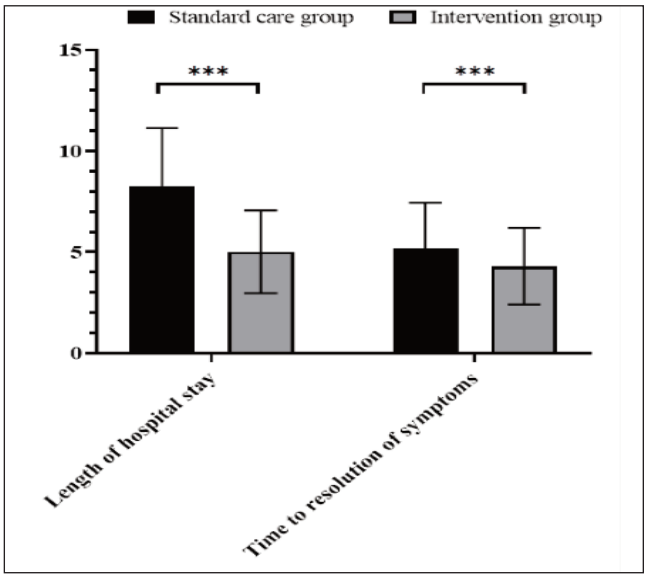

Figure-1: Length of hospital stay and time to complete resolution of symptoms.
*** $p<0.001$.

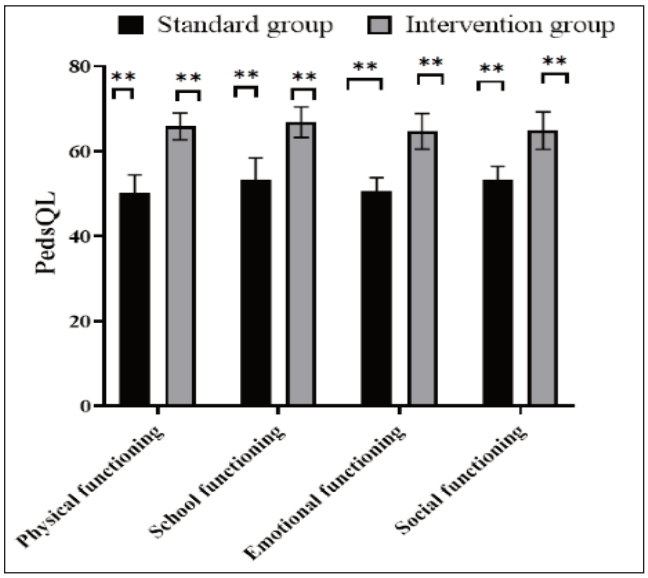

Figure-2: Patient-reported outcome.
***p<0.05.*

group B (p<0.001) (Table 5). The intervention was highly effective in reducing both LOS and recovery time (Figure 1).

Children in group A experienced better overall wellbeing, encompassing physical, emotional and social aspects, during the hospital stay, and reported higher levels of satisfaction with the care they received (Figure 2).

In group A, 30(60%) patients were very satisfied, 18(36%) were basically satisfied, and 2(4%) were dissatisfied, resulting in a nursing satisfaction rate of 48(96%) which was significantly higher than the 40(80%) recorded for group B (p<0.05).

Discussion

The RCT provided compelling evidence supporting the efficacy and safety of the combined intervention approach consisting of high-quality nursing interventions and ganciclovir in the treatment of paediatric patients with EBV infectious mononucleosis. The findings demonstrated significant improvements in primary outcome measures, including symptom reduction and laboratory markers, as well as favourable secondary outcome measures, such as LOS, time to resolution of symptoms, adverse events, and patient-reported outcomes.

Symptom reduction is a critical aspect of managing paediatric patients with EBV infectious mononucleosis, as it directly impacts their wellbeing and QOL. The intervention group exhibited a significant reduction in fever duration, sore throat severity, and lymphadenopathy size compared to the standard care group. The mean reduction in fever duration of 2.5 days is particularly noteworthy, as it indicates the effectiveness of the combined approach in alleviating one of the most prominent symptoms associated with the infection.[26] The reduction in sore throat severity and lymphadenopathy size further supports the positive impact of high-quality nursing interventions and ganciclovir in managing the symptoms of paediatric patients.

Laboratory markers serve as objective indicators of disease progression and treatment response. In this study, the intervention group demonstrated a substantial decline in EBV viral load, with a mean reduction of 2.5 log copies/mL compared to the standard care group. This reduction in viral load suggests that ganciclovir effectively inhibits the replication and spread of the EBV virus. Furthermore, the normalisation of liver function markers, including ALT and AST levels, in the intervention group indicates the potential hepatoprotective effects of acyclovir. These findings highlight the antiviral properties of ganciclovir and its role in mitigating the inflammatory response associated with EBV infectious mononucleosis.[27]

The secondary outcome measures provide additional insights into the benefits of the combined intervention approach. The intervention group exhibited a significantly shorter LOS compared to the standard care group, with a mean reduction of 1.5 days. This reduction not only reduces healthcare costs, but also minimises the emotional and psychological burden on paediatric patients and their families. Similarly, the intervention group experienced a significantly shorter time to complete the resolution of symptoms, with a mean reduction of 3 days. This accelerated recovery is crucial in improving the overall wellbeing and quality of life of paediatric patients.[28]

All these results can be attributed to a variety of explanations.

Ganciclovir, a nucleoside analogue, inhibits the replication of EBV by selectively targetting the viral DNA polymerase. By incorporating into the growing viral DNA chain, ganciclovir acts as a chain terminator, preventing further viral replication. This antiviral action reduces the viral load in patients with EBV infectious mononucleosis and helps control the spread of the virus. The reduction in viral load likely leads to a decrease in viral-induced inflammation and overall symptom improvement.[29]

Besides, EBV infectious mononucleosis triggers a robust immune response characterised by the activation of T cells and natural killer (NK) cells. Ganciclovir may modulate the immune response by reducing viral replication and subsequently dampening the hyperactivation of immune cells. This immune modulation may contribute to the

resolution of symptoms and a faster recovery.[30,31]

EBV infection stimulates the release of pro-inflammatory cytokines and chemokines, leading to the recruitment and activation of immune cells at the site of infection. Ganciclovir's antiviral effects may help control viral replication and limit the release of these inflammatory mediators. By reducing viral replication and subsequent inflammation, ganciclovir may alleviate symptoms associated with EBV infectious mononucleosis.

The high-quality nursing interventions provided in the combined intervention approach play a crucial role in supporting patients and managing their symptoms. Pain management strategies, such as analgesics or local therapies, can alleviate discomfort from sore throat and lymphadenopathy. Hydration support helps maintain fluid balance and can alleviate symptoms of fatigue and malaise. These supportive measures contribute to patients' overall wellbeing and may enhance their recovery.[32]

EBV infectious mononucleosis can have a significant impact on a patient's psychological and emotional wellbeing. The comprehensive care provided, including patient education, counselling and emotional support, may help alleviate anxiety, stress and depression associated with the illness. By addressing the psychosocial aspects of the disease, the combined intervention approach may enhance patients' overall resilience and contribute to improved outcomes.[33]

The combined intervention approach emphasises patient education and involvement in their care. By providing patients with information about the disease, treatment options, and self-care strategies, they are empowered to participate actively in their recovery process. Patient engagement and compliance with treatment recommendations can lead to better treatment outcomes and improved overall wellbeing.

Notably, the occurrence of adverse events related to ganciclovir treatment was not significantly different between the intervention and standard care groups. The most commonly reported adverse events, such as mild gastrointestinal disturbances and transient leukopenia, were manageable and did not require discontinuation of treatment. These findings support the safety profile of ganciclovir in paediatric patients with EBV infectious mononucleosis, and reinforce its potential as a viable treatment option.

Patient-reported outcomes provide valuable insights into the subjective experiences of paediatric patients. The intervention group reported significantly higher scores on measures of QOL and satisfaction with care compared to the standard care group. These findings indicate that the combined intervention approach positively impacts the physical, emotional, and social wellbeing of paediatric patients. The better QOL and higher satisfaction with care reported by children in the intervention group highlights the importance of providing comprehensive nursing support alongside antiviral treatment. This holistic approach not only addresses the physical symptoms, but also addresses the psychosocial needs of paediatric patients, promoting their overall recovery and wellbeing.

The current study has several limitations, like having a relatively small sample size and having been at a single centre Besides, the study focussed on specific haematological and biochemical markers that represented only a subset of the potential biomarkers associated with EBV-related infectious mononucleosis.

The study captured data at a specific point in time, while longitudinal studies would have provided insights into the dynamic changes of haematological and biochemical markers during different stages of EBV-related infectious mononucleosis. Further, the study did not include a group of healthy individuals or individuals with illnesses other than EBV infection. Future studies should consider including appropriate control groups to provide a baseline for comparison. Finally, the study did not account for potential confounding factors that may have influenced the haematological and biochemical markers, such as age, gender, comorbidities and medication use. These factors can impact the biomarker profiles and introduce potential biases.

Conclusion

The significant improvement in symptom reduction, laboratory markers, LOS, time to resolution of symptoms, and patient-reported outcomes underscored the comprehensive benefits of combined intervention.

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