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Original Article

Outpatient Parenteral Antimicrobial Therapy in Pediatric Patients

Pediatrik Hastalarda Ayaktan Parenteral Antimikrobiyal Tedavi

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ABSTRACT

Objective: Outpatient parenteral antimicrobial therapy (OPAT) has been developed as an alternative approach to hospital stay for the effective treatment of infections requiring long-term therapy. The aim of this study is to evaluate the clinical outcomes and hospital readmission rates of pediatric patients receiving OPAT.

Method: Pediatric patients aged between 1 month and 18 years who received antimicrobial treatment under the OPAT program were included in this retrospective study. The duration of OPAT, the antimicrobial treatments used, bed-days saved by OPAT, OPAT-related complications, and readmission rates were examined.

Results: A total of 21 patients were included in the study, and the median age of these patients was 85 months. The most common diagnosis was leishmaniasis, observed in 33.3% of cases. OPAT shortened hospital stays for a median of 6 days (interquartile range: 2-12.5) per case. However, 14.3% (n=3) of the patients required readmissions to the hospital. No infusion-related side effects were observed in any patients receiving OPAT.

Conclusion: Our data suggest that OPAT could be a good option for selected pediatric patients. However, further research and increased awareness are needed to promote the widespread use of OPAT for pediatric patients.

Keywords: Antibiotic, hospitalization, OPAT, pediatric

ÖZ

Amaç: Ayaktan parenteral antimikrobiyal tedavi (APAT), uzun süreli tedavi gerektiren enfeksiyonların etkili tedavisinde hastaneye yatışa alternatif bir yaklaşım olarak geliştirilmiştir. Bu çalışmanın amacı, APAT programı kapsamında antimikrobiyal tedavi alan pediatrik hastalarda klinik sonuçları ve hastaneye yeniden yatış oranlarını değerlendirmektir.

Yöntem: Bu retrospektif çalışmaya, APAT programı kapsamında antimikrobiyal tedavi alan 1 ay-18 yaş arasındaki pediatrik hastalar dahil edilmiştir. Çalışmada APAT süresi, kullanılan antimikrobiyal tedaviler, APAT ile önlenen hastaneye yatış günleri, APAT'a bağlı komplikasyonlar ve yeniden yatış oranları incelenmiştir.

Bulgular: Çalışmaya toplam 21 hasta dahil edilmiştir ve bu hastaların ortanca yaşı 85 aydır. Hastalarda en sık tanı %33,3 oranı ile leishmaniasis olarak saptanmıştır. APAT, olgu başına ortanca 6 gün (IQR: 2-12,5) hastaneye yatışı önlemiştir. Bununla birlikte, hastaların %14,3'ü (n=3) hastaneye yeniden yatış gerektirmiştir. APAT uygulanan hiçbir hastada infüzyona bağlı yan etki gözlenmemiştir.

Sonuç: Bulgularımız, APAT'ın seçilmiş pediatrik hastalar için iyi bir seçenek olabileceğini göstermektedir. Bununla birlikte, pediatrik APAT'ın yaygın kullanımını teşvik etmek için daha fazla araştırmaya ve farkındalığın artırılmasına ihtiyaç vardır.

Anahtar kelimeler: Antibiyotik, hastaneye yatış, APAT, pediatrik

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INTRODUCTION

Outpatient parenteral antimicrobial therapy (OPAT) was first described in 1974 for the treatment of children with cystic fibrosis and has since been adopted as an alternative approach to hospitalization for the effective treatment of infections requiring long-term therapy[1]. The benefits of OPAT include short-term absenteeism from school, reduced risk of healthcare-associated infections, cost-effective use of resources, and increased patient and parent satisfaction[2].

This treatment approach can be implemented in several ways: patients receive treatment in outpatient care units, patients or caregivers learn how to administer intravenous antimicrobial therapy and carry out the treatment at home, or nurses visit patients' homes to administer the treatment[3].

Like other medical practices, OPAT has potential risks as well as proven benefits. While comprehensive studies exist regarding the use of OPAT in adult patients, data on the use of OPAT for pediatric patients (p-OPAT) remain limited[1,4-6]. Due to pharmacokinetic differences, challenges in vascular access, and other age-related risk factors, pediatric patients should be evaluated separately from adults[6]. These factors highlight the need for further research on pediatric OPAT.

In this study, we aimed to evaluate pediatric patients who received OPAT over a five-year period in a tertiary care hospital in Türkiye. Additionally, OPAT-related complications and hospital readmission rates were examined to assess the safety profile of this treatment approach.

MATERIALS and METHODS

This single-center descriptive study was conducted at an education and research hospital that serves as a referral center for pediatric patients in the Aegean region of Türkiye. Pediatric patients aged between 1 month and 18 years who received outpatient parenteral antimicrobial treatment under the p-OPAT program at University of Health Sciences Türkiye, İzmir Faculty of Medicine, Dr. Behçet Uz Pediatric Diseases and Surgery Training and Research Hospital between January 2020 and January 2025 were included in the study. The study was conducted following approval granted from the Local Research Ethics Committee of University of Health Sciences Türkiye, İzmir Faculty of Medicine, Dr. Behçet Uz Pediatric Diseases and Surgery Training and Research Hospital (decision no: 2024/18-09, date: 26.12.2024) and in accordance with the World Medical Association Declaration of Helsinki Medical Research Involving Human Participants. Written informed consent was obtained from the parents of all patients.

At our institution, the p-OPAT program is coordinated by the pediatric infectious diseases team in collaboration with the ward nursing staff. Clinically stable patients who did not require ongoing inpatient hospitalization, and needed short-term parenteral antimicrobial therapy that could not be safely or effectively administered via oral route were eligible candidates for p-OPAT program. In addition, patients without severe comorbid conditions and with reliable caregivers capable of ensuring daily hospital visits and treatment follow-up were considered suitable for p-OPAT. Parenteral antimicrobial therapies were administered via peripheral intravenous catheters in all patients. Intravenous access was evaluated by nursing staff prior to each administration for patency and signs of infiltration, phlebitis, and local infection (if any). The frequency of intravenous catheterization was determined based on its functionality and clinical indication.

Patients were clinically assessed before each p-OPAT administration and were regularly monitored for intravenous access-related and other potential complications. After termination of p-OPAT, patients were observed for at least 30-60 minutes, particularly for infusion-related adverse reactions. OPAT was discontinued upon completion of the planned course of antimicrobial treatment, after achievement of sufficient clinical improvement allowing transition to oral therapy, development of p-OPAT-related complications, or the emergence of a need for hospital admission due to clinical deterioration.

In this study, clinical improvement was defined as resolution or marked improvement of infection-related clinical signs and symptoms during or at the end of the p-OPAT course, with successful completion of the planned p-OPAT without the need for additional intravenous therapy or hospital admission. Insufficient clinical improvement was defined as failure to achieve the expected clinical response during p-OPAT, persistence or worsening of symptoms, requirement for modification of antimicrobial therapy, or the need for hospital admission due to clinical deterioration. The number of inpatient hospital days saved due to the implementation of p-OPAT were also calculated.

Data obtained from medical records included demographic characteristics, diagnoses, bacteriological culture results, duration of p-OPAT, antimicrobial therapies

used, hospital days saved due to p-OPAT, p-OPAT-related complications, and readmission rates.

Statistical Analysis

Statistical analyses were performed using SPSS version 25.0 (IBM Corp., Armonk, NY, USA). Numerical and categorical variables were analyzed using descriptive statistical methods. Continuous variables were expressed as medians and interquartile ranges (IQR), while categorical variables as frequencies and percentages.

RESULTS

The study population of 21 cases consisted of 12 (57.1%) female, and 9 (41.9%) male pediatric patients with a median age of 85 months (IQR: 23-150.5 months).Two patients were infants, aged 6 and 11 months.

All patients included in the study received p-OPAT in the outpatient units of the hospital. The primary diagnoses of patients enrolled in the p-OPAT program were as follows: leishmaniasis [33.3% (n=7)], pneumonia [23.8% (n=5)], soft tissue abscesses [19.0% (n=4)], upper respiratory tract infections [14.3% (n=3)], osteomyelitis [4.8% (n=1)] and a urinary tract infection [4.8% (n=1)]. Methicillin-resistant *Staphylococcus aureus* (*MRSA*) was isolated in 14.3% (n=3) of patients, including two cases with soft tissue abscesses and one with osteomyelitis. The demographic and clinical characteristics of the patients are detailed in Table 1.

Two infants included in the study were diagnosed with *MRSA*-related soft tissue abscesses. Teicoplanin was administered intravenously via a peripheral venous

Table 1. Demographic and clinical characteristics of the patients

Characteristics	n	%
Age (months), median (IQR)	85.0 (23.0-150.5)	
Female gender	12	57.1
Underlying disease		
Autism	1	4.8
Type of infection		
Skin and soft tissue: abscess	4	19.0
Respiratory: pneumonia	5	23.8
: upper respiratory tract infection	3	14.3
Musculoskeletal: osteomyelitis	1	4.8
Urinary tract infection	1	4.8
Leishmaniasis: visceral leishmaniasis	6	28.6
: cutaneous leishmaniasis	1	4.8
Positive culture from a sterile site		
Methicillin-resistant *S. aureus*	3	14.3
Type of intravenous access		
Peripheral venous catheter	21	100.0
Duration p-OPAT (days), median (IQR), min-max	2 (1-5), 1-21	
Bed-days saved, median (IQR)	6 (2-12.5)	
Hospital readmission	3	14.3

IQR: Interquartile range, p-OPAT: pediatric outpatient parenteral antimicrobial therapy, *S. aureus*: *Staphylococcus aureus*

catheter in both infants, with a p-OPAT duration of 2 days in the 6-month-old infant and for 1 day in the 11-month-old infant. Neither infant required hospital readmission during or after p-OPAT.

Three patients aged 23, 83, and 211 months categorized under upper respiratory tract infections had p-OPAT for a duration of 1-5 days received the diagnosis of acute otitis. OPAT was initiated due to a more severe clinical course and the unsuitability or insufficiency of oral antibiotic therapy. These patients received short-course intravenous ceftriaxone administered via peripheral venous catheters.

In most cases, p-OPAT was initiated after a period of inpatient treatment and clinical stabilization. The median number of 8 (IQR: 0-15 days) inpatient days have passed before initiation of p-OPAT. Six patients were not hospitalized prior to initiation of p-OPAT. Among these cases, only one patient completed the entire p-OPAT course exclusively.

The median duration of p-OPAT was 2 days (1-IQR: 1-5 days) ranging between minimum 1, and maximum 21 days. All patients received p-OPAT through a peripheral venous catheter. Antimicrobial therapies received by the patients were as follows: liposomal amphotericin B (L-AmB) [33.3% (n=7], ertapenem [14.3% (n=3)], ceftriaxone [28.6% (n=6)] teicoplanin [28.6% (n=6)], and combination of ceftriaxone and teicoplanin [4.8% (n=1)]. The distribution of antimicrobial treatments by diagnoses is presented in Figure 1.

Reduced hospital length of stay, duration of p-OPAT, and clinical improvement rates according to diagnosis are summarized in Table 2. Overall, clinical improvement was achieved in 85.7% (18/21)of patients, who completed the planned p-OPAT course without the need for hospital readmission. OPAT reduced hospital length of stay for a median of 6 days (IQR: 2-12.5) per case. However, 14.3% (n=3) of the patients required hospital readmissions. One of these patients, who was being treated with ceftriaxone

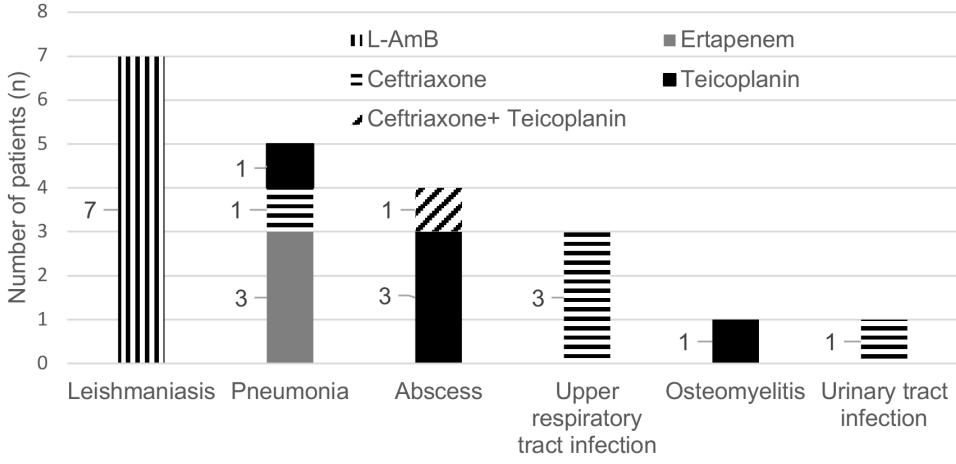

Figure 1. Distribution of antimicrobial therapies among patients with different infectious

L-AmB: liposomal amphotericin B

Table 2. outcomes of p-OPAT according to diagnoses

Diagnosis	n	Duration of p-OPAT (days), median (IQR)	Saved hospital days, median (IQR)	Clinical improvement, n (%)
Leishmaniasis	7	2 (1-2)	10 (7-15)	6/7 (85.7)
Pneumonia	5	5 (3-10)	5 (3-10)	5/5 (100.0)
Abscess	4	2 (1.3-14.0)	2 (1.3-14.0)	3/4 (75.0)
Upper respiratory tract infection	3	1 (1-1)	1 (1-1)	3/3 (100.0)
Osteomyelitis	1	21 (-)	21 (-)	1/1 (100.0)
Urinary tract infection	1	1 (-)	1 (-)	0/1 (0.0)

IQR: Interquartile range, p-OPAT: pediatric outpatient parenteral antimicrobial therapy

and teicoplanin for a soft tissue abscess under the p-OPAT program, was hospitalized due to insufficient clinical improvement and the need for further monitoring on day 2 of p- OPAT. Another patient receiving L-AmB for the treatment of leishmaniasis developed elevated transaminase levels during follow-up, necessitating hospitalization for treatment and observation on day 1 of p-OPAT. Additionally, a patient treated with ceftriaxone under p-OPAT protocol for a urinary tract infection was rehospitalized due to abdominal pain and fever on day 1 of p-OPAT. No infusion-related adverse events were observed in any of the patients included in the p-OPAT program.

DISCUSSION

Our study focused on examining the clinical and microbiological characteristics of patients receiving p-OPAT, the antimicrobial therapies used, p-OPAT-related complications, and readmission rates in a children's hospital. Clinical improvement was observed in 85.7% of cases in our p-OPAT cohort, with no need for readmissions. The median duration of p-OPAT was 2 days, and the most commonly used antimicrobial therapy was L-AmB. In patients receiving antimicrobial treatment under the p-OPAT program, length of hospital stay was relatively reduced for a median of 6 inpatient days. Our youngest two patients, aged 6 and 11 months, completed p-OPAT without developing any complications.

The notably short median p-OPAT duration of 2 days observed in our cohort may reflect the predominant use of p-OPAT as a step-down strategy following inpatient treatment and clinical stabilization. Indeed, a considerable proportion of patients had varying lengths of hospitalization prior to initiation of p-OPAT. Guidelines of p-OPAT and pediatric good-practice recommendations emphasize that eligibility for p-OPAT should be decided based on a combined assessment of clinical stability, the absence of a requirement for continued inpatient care, the feasibility of using safe outpatient parenteral therapy, and the availability of reliable caregiver support and follow-up. Indeed, our patient selection criteria strictly adhered to these broadly recommended principles[7,8].

The most common diagnosis in our study was leishmaniasis, accounting for 33.3% (n=7) of cases, and these patients were treated with L-AmB. The most frequently used antimicrobial therapies for p-OPAT are antibiotics, while antifungal agents are rarely preferred[9]. The main reason for this preference is the presence of underlying comorbidities such as hematological diseases or immune deficiencies in these patients. In an OPAT study conducted in adults and published by Gil-Navarro et al.[2], although no significant difference was found between the effectiveness and safety of antifungal treatment and antibiotic use; it was observed that the rate of comorbidities was higher in patients receiving antifungal treatment. Therefore, certain criteria have been recommended for the safe and effective use of antifungal treatment for OPAT including microbiological confirmation of the diagnosis, control of the source of infection, administration of initial antifungal treatment in a hospital setting, ensuring the patient's hemodynamic stability, and regular follow-up by an infectious diseases specialist[2]. Studies evaluating p-OPAT for leishmaniasis are limited. However, a study reporting a saving of 14.2 bed-days per case emphasized that p-OPAT could be an effective alternative to hospitalization for leishmaniasis and other tropical diseases[10]. The recommended regimen for the treatment of leishmaniasis is the administration of 3 mg/kg L-AmB on days 1-5, 14, and 21, with a total dose of 21 mg/kg[11]. The patients in our cohort received their initial L-AmB treatment during hospitalization, and after their clinical condition stabilized, they were discharged. Three of these patients received p-OPAT on day 21, and four received p-OPAT on days 14 and 21. Only one patient in our study required readmission due to elevated transaminases, but discontinuation of the antimicrobial used was not required.

Ertapenem is an important option for the management of p-OPAT due to its once-daily dosing regimen for the treatment of intra-abdominal infections, complicated skin and soft tissue infections, community-acquired pneumonia, and complicated urinary tract infections[12]. Ertapenem is effective against both Gram-negative and Gram-positive bacteria, as well as anaerobic bacteria, due to its broad-spectrum activity; however, it is not effective against *Enterococcus species (Enterococcus spp.)*, *Pseudomonas aeruginosa*, or *Acinetobacter spp.*[13]. Although past experience is limited, previous studies have shown that patients with complicated urinary tract infections, intra-abdominal infections, and community-acquired pneumonia have been successfully treated using ertapenem in cases with p-OPAT[13-15]. In our cohort, ertapenem was successfully administered to three patients diagnosed with complicated community-acquired pneumonia, and no p-OPAT-related complications or readmissions were observed.

Staphylococci and *streptococci* are the most common causative agents of osteomyelitis, complicated skin and soft tissue infections, and endocarditis[16]. This group of diseases typically requires prolonged intravenous therapy

lasting approximately six weeks. Teicoplanin is effective against *staphylococci* (including methicillin-resistant strains), *streptococci*, and *Enterococcus spp*[17]. In our study, teicoplanin was used within the p-OPAT program for the management of soft tissue abscesses, osteomyelitis, and pneumonia, while *MRSA* was identified in three of these patients. One of the patients receiving teicoplanin was also on combination therapy with ceftriaxone. This patient required readmission for monitoring purposes due to insufficient clinical improvement; however, no changes to the treatment regimen were necessary. The patients in our study received teicoplanin once daily. Although studies investigating the use of teicoplanin three times a week in osteomyelitis and soft tissue infections have shown successful outcomes, these findings need to be validated with new data[16,18].

Ceftriaxone is the most frequently prescribed antibiotic within the p-OPAT program[19]. Its primary indications include skin and soft tissue infections, bone and joint infections, and Lyme disease; however, it has been also successfully used in the treatment of other infectious diseases, such as pneumonia, upper respiratory tract infections, and urinary tract infections[19-21]. In our clinic, ceftriaxone was used within the p-OPAT program for upper respiratory tract infections, pneumonia, urinary tract infections, and soft tissue abscesses. One patient treated for a urinary tract infection required readmission to the hospital due to fever and abdominal pain during follow-up. None of the patients receiving ceftriaxone through p-OPAT protocol experienced infusion-related side effects.

In pediatric OPAT studies, adverse event rates of up to approximately 30% have been reported, with intravenous access–related problems being the most common complications[6]. In previous studies evaluating the safety of using central venous catheters during OPAT in children, complication rates ranged between 29% and 33%, whereas a study in which most patients were managed with peripheral cannulas reported an overall complication rate of 11%[3]. The absence of peripheral venous catheter–related complications in our study is noteworthy and may be explained by several factors: (i) the predominantly short duration of p-OPAT in our cohort, (ii) the use of peripheral venous access rather than central catheters, and (iii) routine nursing assessment of intravenous access prior to each administration and post-infusion observation. Nevertheless, although p-OPAT-related complications were routinely recorded during clinical follow-up, given the retrospective design of the study, it should be considered that minor events such as mild infiltration or irritation may not always have been reflected in the medical records. In contrast, 14.3% of the patients in our cohort required hospital readmission. Our readmission rates for various reasons have been reported to range between 11% and 17% in consistent with those previously reported[3,6].

Study Limitations

The study has several limitations. First of all, the diagnosis and indications, as well as the antimicrobial drugs used, showed a heterogeneous distribution, which might be a confounding factor. In addition, the sample size was relatively small. To our knowledge, data on use of OPAT in pediatric patients from Turkey are limited, and this study provides insights that may inform future research. The single-center and retrospective design of the study, along with the relatively small sample size, limited the generalizability of the results obtained.

CONCLUSION

In conclusion, our data suggest that p-OPAT may be a good choice for selected pediatric patients. Pediatric OPAT programs should be further investigated, expanded, and structural frameworks should be developed to promote wider implementation of OPAT in children.

Ethics

Ethics Committee Approval: The study was conducted following approval granted from the Local Research Ethics Committee of University of Health Sciences Türkiye, İzmir Faculty of Medicine, Dr. Behçet Uz Pediatric Diseases and Surgery Training and Research Hospital Hospital (decision no: 2024/18-09, date: 26.12.2024) and in accordance with the World Medical Association Declaration of Helsinki Medical Research Involving Human Participants.

Informed Consent: This is a retrospective study.

Footnotes

Author Contributions

Concept: H.Ö, D.E., P.K., N.B., Design: H.Ö, D.E., A.A.K., Data Collection or Processing: H.Ö, D.E., B.K.Ç., Ç.Ö., Analysis or Interpretation: H.Ö., A.Ö., G.G.Ö., A.A.K., D.O., N.B., İ.D., Literature Search: H.Ö, A.Ö., G.G.Ö., Ç.Ö., Writing: H.Ö, D.E., P.K., B.K.Ç., A.Ö., Ç.Ö., G.G.Ö., A.A.K., D.O., N.B., İ.D.

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