



Optimizing Oncological Care in Patients with End-Stage Chronic Kidney Disease on Dialysis: Indian Scenario

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Ind J Med Paediatr Oncol 2025;46:409–417.

Abstract

Background In India, around 55,000 patients are on dialysis, with a 10–20% annual increase. With the growing dialysis population in India, cancer risk among end-stage renal disease (ESRD) patients is increasing. Managing chemotherapy in these patients is challenging due to limited data and guidelines, leading to treatment uncertainty.

Objectives This study provides real-world data from India on the clinical management and outcomes of cancer patients with ESRD undergoing dialysis while receiving chemotherapy.

Materials and Methods This prospective study analyzed data from five cancer patients with end-stage renal disease (ESRD) on hemodialysis prior to diagnosis of cancer treated at a tertiary oncology center in India. We analyzed the demographic details, cancer staging, treatment regimens, and dosage adjustments. Treatment modifications due to renal dysfunction, toxicities, and patient outcomes were also reviewed over a 12-month follow-up.

Results The cohort consisted of 80% (4/5 pts) females, with a median age of 57.8 years. Hypertensive and diabetic nephropathy were the leading causes of ESRD. Cancers included breast (3/5 pts), lung (1/5 pts), and ovarian (1/5 pts), with varying stages of diagnosis. 80% (4/5) of patients required tailored drug management. The Ovarian cancer patient experienced severe hypersensitivity to carboplatin, which was managed conservatively. No grade 3/4 immune-related adverse events occurred, and all patients were alive and disease-free at the one-year follow-up.

Conclusion Carefully tailored treatment strategies and a coordinated multidisciplinary approach allowed positive outcomes for cancer patients on dialysis, emphasizing the need for personalized approaches. These findings highlight the importance of refining treatment protocols for this complex group.

Keywords

- end-stage renal disease
- hemodialysis
- cancer
- immunotherapy
- targeted therapy

Introduction

Cancer and chronic kidney disease (CKD) often coexist, with studies indicating a prevalence of 12 to 53% at the time of cancer diagnosis, posing considerable therapeutic challenges.¹ Among patients with end-stage renal disease (ESRD) undergoing hemodialysis (HD), 3 to 5% are estimated to have a concurrent cancer diagnosis.¹ Despite this overlap, the overall incidence of cancer in ESRD patients remains relatively low. The approach to treating cancer in patients with ESRD on HD varies widely among physicians and across different countries. Unfortunately, the majority of published literature focuses on western populations, with limited research available on the feasibility and outcomes of these treatment recommendations in the Indian context.

The optimal anticancer treatment for this critical subset of patients remains an unresolved clinical issue, particularly concerning the necessary dosage adjustments based on pharmacokinetic (PK) and pharmacodynamic (PD) parameters and the timing of drug administration relative to HD sessions. The existing PK data on the interaction between dialysis and chemotherapeutic agents are limited, primarily derived from case reports and small case series.^{2,3}

Managing cancer in ESRD patients is complicated by altered PK and PD of chemotherapeutic drugs due to factors such as hypoalbuminemia, metabolic acidosis, and renal insufficiency.^{4–6} Additionally, HD could lead to the early elimination of drugs, potentially resulting in underdosage and reduced efficacy. This challenge is even more pronounced in HD patients receiving oral therapies multiple times a day.

CKD and cancer are interrelated, with cancer potentially leading to CKD through direct damage or treatment side effects. Conversely, CKD may elevate cancer risk due to chronic oxidative stress and immune system impairment.⁷ As more patients present with both ESRD and cancer, managing anticancer therapy becomes increasingly complex. Unfortunately, CKD patients on HD are often excluded from clinical trials, limiting insights into drug safety and efficacy and restricting access to effective treatments.⁸ This exclusion is particularly concerning, as it hampers the use of alternative therapies (immunotherapy, targeted therapy) to nephrotoxic chemotherapies. Notably, 85% of drug trials for the five most common cancers published in high-impact journals excluded most CKD patients.⁹

Given these challenges, our study aims to investigate the clinical management and outcomes of five Indian patients with cancer and ESRD on dialysis.

Materials and Methods

Study Design

This prospective observational study examined data from five patients with ESRD on HD diagnosed with cancer at a tertiary oncology center in India between April 2021 and December 2023. These patients were followed from the time of diagnosis through treatment and 12 months posttreatment to assess outcomes related to cancer management and dialysis.

The data collected included demographic information, cancer staging, histopathological examination (HPE), comprehensive treatment regimens, and any necessary dosage adjustments for anticancer drugs based on their pharmacokinetics. Additionally, modifications to standard treatment protocols due to renal dysfunction, toxicities, and patient outcomes were identified.

Sample Size

The sample size included five patients, given the rarity of cancer patients with ESRD on dialysis receiving oncological treatment.

Inclusion Criteria

- Patients older than 18 years with a diagnosis of cancer.
- Confirmed diagnoses of both cancer and CKD stage 5, as defined by the recent Kidney Diseases Improving Global Outcomes (KDIGO) classification,¹⁰ with an estimated glomerular filtration rate (eGFR) less than 15 mL/min/1.73 m² and undergoing HD.

Exclusion Criteria

- Patients unwilling to undergo cancer treatment.
- Those with poor compliance to dialysis or oncology treatment regimens.

Primary and Secondary Outcomes

Primary outcome: The 12-month disease-free survival rate following chemotherapy in ESRD patients on HD with cancer

Secondary outcomes: Feasibility of chemotherapy dose adjustments based on renal function in ESRD patients on HD and adverse event management

Statistical Analysis

The data were collected and compiled in Microsoft Excel. The data were analyzed using Statistical Package of Social Sciences (SPSS) version 29.0. Continuous variables were presented as mean \pm standard deviation or median (interquartile range). Categorical variables were expressed as frequencies and percentages.

Ethical Approval

The Army Hospital Research and Referral Institutional Ethics Committee (IEC Reg No.-11/2021, dated February 5, 2021) approval for the study was obtained. Written informed consent was taken from all the participants with precautions to maintain confidentiality. The procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation and with the Helsinki Declaration of 1964, as revised in 2013.

Results

Among the five patients analyzed, four were females (80%). The average age at cancer diagnosis was 57.8 years (ranging from 34 to 72 years). The mean duration between the initiation of dialysis and cancer diagnosis was 3 years. **Table 1** provides

Table 1 Summary of treatment protocols and outcomes in cancer patients with ESRD undergoing hemodialysis

Case	Age/sex	Initial symptoms	Comorbidities	Clinical examination	Relevant investigations (diagnostic imaging [mammogram/CT/MRI/PET-CT] and biopsy)	Diagnosis	Treatment (renal dose modification based on Cockcroft-Gault formula)	Toxicities and management	Follow-up (12 mo)
1	58/F	Progressive abdominal distension, pain, and significant weight gain over the past 3 mo	Hypertension and diabetes mellitus, leading to ESRD on HD for 5 y	Gross ascites, bilateral adnexal mass	Extensive peritoneal carcinomatosis, ascites, pleural effusion, and bilateral adnexal masses High-grade serous ovarian carcinoma CA-125: 860 IU/L BRCA/HRD: noncontributory	High-grade serous ovarian carcinoma, FIGO stage 4a	Three cycles of NACT with a regimen of paclitaxel (175 mg/m ²) and carboplatin (AUC 5) every 3 wk CA-125: 350 IU/L Interval debulking surgery with optimal cytoreduction Postoperative HPE for FIGO stage 2, with the presence of residual disease CA-125: 150 IU/L Three cycles of adjuvant chemotherapy with a regimen of paclitaxel (175 mg/m ²) and carboplatin (AUC 5) every 3 wk (carboplatin omitted in 6th cycle) CA-125: 50 IU/L	Severe hypersensitivity reaction to carboplatin during the fifth cycle: managed with adrenaline, corticosteroids, and antihistamines Carboplatin was omitted in the sixth cycle, and only paclitaxel was administered Renal function remained stable, and the patient continued twice-weekly dialysis	Alive and disease free CA-125: 45 IU/L
2	34/F	Lump in the left breast for 6 mo	ESRD secondary to lupus nephritis on HD for 1 y	6 × 5 cm left breast lump, with fixed axillary lymph node	6 × 4 cm, central quadrant mass at the 11 to 12 o'clock position with axillary node measuring 1 × 2 cm Invasive ductal carcinoma, ER/PR negative, Her2Neu 3+ Germline BRCA: noncontributory	Carcinoma of the left breast cT3N2M0: Her2Neu enriched	Six cycles of NACT with PTHC, three weekly regimens, docetaxel (75 mg/m ²), trastuzumab (loading dose of 8 mg/kg followed by 6 mg/kg every 3 wk), pertuzumab (loading dose of 840 mg/kg followed by 420 mg/kg every 3 wk) and carboplatin (AUC 5)	Grade 2 diarrhea, managed conservatively Cardiac monitoring with echocardiograms done every 3 mo remained stable throughout therapy	Alive and disease free

(Continued)

Table 1 (Continued) Summary of treatment protocols and outcomes in cancer patients with ESRD undergoing hemodialysis

Case	Age/sex	Initial symptoms	Comorbidities	Clinical examination	Relevant investigations (diagnostic imaging [mammogram/CT/MRI/PET-CT] and biopsy)	Diagnosis	Treatment (renal dose modification done based on Cockcroft-Gault formula)	Toxicities and management	Follow-up (12 mo)
3	60/F	Lump in the right breast for 8 mo	Hypertensive nephrosclerosis leading to ESRD on HD for 2 y	7 × 4 cm right breast lump, with a mobile axillary lymph node	7 × 4 cm, central quadrant right breast mass at the 1 to 3 o'clock position with axillary node measuring 1 × 1 cm Invasive ductal carcinoma, ER/PR, Her2Neu negative Germline BRCA: noncontributory	Carcinoma of the right breast cT3N1M0: triple-negative.	Left modified radical mastectomy (MRM) Postoperative HPE: pathological complete response (pCR) Adjuvant chest wall radiation (RT), 40 Gy in 15 fractions through 3D-CRT technique and maintenance trastuzumab (loading dose of 8 mg/kg followed by 6 mg/kg every 3 wk) for 1 y	Grade 2 neutropenia Cardiac monitoring with echocardiograms done every 3 mo remained stable throughout therapy	Alive and disease free

Table 1 (Continued) Summary of treatment protocols and outcomes in cancer patients with ESRD undergoing hemodialysis

Case	Age/sex	Initial symptoms	Comorbidities	Clinical examination	Relevant investigations (diagnostic imaging [mammogram/CT/MRI/PET-CT] and biopsy)	Diagnosis	Treatment (renal dose modification done based on Cockcroft-Gault formula)	Toxicities and management	Follow-up (12 mo)
4	65/M	Dry cough for 1 y, 2 episodes of hemoptysis in the past 2 mo	Diabetic nephropathy leading to ESRD on HD for 6 y	Right second and third intercostal space dullness on percussion	5 × 4 cm, right upper lobe lung mass (SUVmax 15.5) with ipsilateral multiple hilar and mediastinal lymph nodes, largest measuring 1 × 1.5 cm with SUV max 13.5 Squamous cell carcinoma, CK7 positive, p40/p63 positive, CK20/TTF1/napsin/synaptophysin negative	Stage III B, T3N2M0 non-small cell lung cancer (NSCLC)-SCC	adjuvant pembrolizumab (200 mg) every three weekly Concurrent chemotherapy (CCRT) 60 Gy in 30 fractions through IMRT technique with weekly paclitaxel (50 mg/m ²) and carboplatin (AUC 2), followed by maintenance therapy with durvalumab (10 mg/kg) every two weekly for 1 y	Grade 2 esophagitis, managed conservatively	Alive and disease free
5	72/F	Lump in the left breast for 3 mo	Hypertension and diabetes mellitus, leading to ESRD on HD for 1 y	2 × 2 cm left breast lump with no nodes	11 × 20 mm BI-RADS 4B lesion, left breast upper inner quadrant Invasive ductal carcinoma, ER/PR strongly positive, Her2Neu negative	Carcinoma of the left breast cT1N0M0: hormone receptor positive	Breast conservation surgery (BCS + SLNB + level I oncoplasty) Postoperative HPE: tumor size 1 × 1.5 cm ER/PR: positive, Her2Neu negative Adjuvant chest wall RT, 40 Gy in 15 fractions through 3D-CRT technique Adjuvant hormonal therapy with letrozole	None	Alive and disease free

Abbreviations: AUC, Area under the curve; BCS, Breast conservation surgery; CA 125, Cancer Antigen 125; CCRT, Concurrent Chemoradiotherapy; CT, Computed tomography; CK, Cytokeratin; ER, Estrogen receptor; ESRD, End stage renal disease; FIGO, Fédération Internationale de Gynécologie et d'Obstétrique; HD, Hemodialysis; HRD, Homologous recombination deficiency; MRI, Magnetic resonance imaging; MRM, Modified radical mastectomy; NACT, Neoadjuvant chemotherapy; NSCLC, Non small cell lung cancer; PR, Progesterone receptor; PCR, Pathologic complete response; SCC, Squamous cell carcinoma; SUV, Standardised uptake value; SLNB, Sentinel lymph node biopsy; TTF-1, Thyroid transcription factor -1; 3D CRT, Three-dimensional conformal radiation therapy.

Table 2 Prescribed anticancer drugs^{14,15,28}

Drug category with INN (international nonproprietary name)	Dose reduction required in ESRD patients on dialysis (yes/no/ND)	No. of times the drug was prescribed	Dialysable drug (yes/no/ND)
Chemotherapeutic agents			
Paclitaxel	No	13	No
Docetaxel	No	6	No
Doxorubicin	No	4	No
Carboplatin	Yes	18	Yes
Cyclophosphamide	Yes	4	Yes
Hormonal therapy			
Letrozole	No	18	ND
Targeted therapy			
Pertuzumab	ND	6	No
Trastuzumab	ND	23	No
Immune checkpoint inhibitors			
Pembrolizumab	No	17	No
Durvalumab	No	26	No

Abbreviation: ESRD, end-stage renal disease; ND, not determined.

the population characteristics along with a summary of treatment protocols and outcomes. The leading causes of ESRD were hypertensive and diabetic nephropathy, each accounting for 60% of cases. The primary cancer sites were the breast (3/5 patients), lung (1/5 patients), and ovaries (1/5 patients). Regarding nonsystemic treatments, 80% of the patients (4/5) underwent both surgery and radiotherapy.

The prescription comprised 10 different drugs (►Table 2), all of which were administered following dialysis sessions. Immunotherapeutic agents were cautiously administered without any renal adjustments during the first cycle. As the patient tolerated the treatment well and there was no decline in renal function, the same dosage was maintained in subsequent cycles.^{11–13} No dose adjustments were made for hormonal therapy. Among the five patients undergoing anti-cancer drug treatment, 80% (4/5 patients) required dosage adjustments or utilized medications lacking established data for dialysis patients. One patient with ovarian cancer experienced severe hypersensitivity to carboplatin during the fifth cycle, leading to its omission in the final cycle. The most commonly used drugs were targeted therapy (20%), immune checkpoint inhibitors (20%), alkylating agents (20%), mitotic spindle inhibitors (20%), antitumor antibiotics (10%), and hormonal therapy (10%; ►Table 2). No grade 3/4 immune-related adverse events (irAEs) were observed. Grade 2 adverse events, including diarrhea, esophagitis, and neutropenia, were managed conservatively. All patients were alive and disease free at the 1-year follow-up (►Table 1).

Discussion

Challenges and Considerations

In India, approximately 55,000 patients are on dialysis, with the number increasing by 10 to 20% annually.¹⁴ Improved

chronic renal replacement therapy has not only extended survival but also raised cancer risk compared with the general population.¹⁵ Patients with chronic renal insufficiency and dialysis experience chronic oxidative stress due to the buildup of reactive oxygen species, which can damage cellular structures and increase cancer risk. Additionally, patients with ESRD exhibit heightened genomic damage, which may contribute to cancer development.¹⁶

Administering chemotherapy to patients on HD presents several challenges, including altered pharmacokinetics due to drug clearance, complex dosing, and multidrug scheduling. Coordinating chemotherapy with HD sessions is crucial to optimize drug efficacy and minimize toxicity. HD can disrupt fluid and electrolyte balance, complicating the administration of chemotherapy, and the stress of HD may exacerbate chemotherapy side effects. Additionally, ESRD can cause dyskalemia, metabolic acidosis, and hyperphosphatemia, leading to severe complications such as muscle wasting, bone mineral disorders, vascular calcification, and increased mortality.¹⁷ Managing cancer in patients with end-stage CKD on dialysis requires careful adjustments to standard chemotherapy protocols, close monitoring for adverse effects, and effective collaboration between oncology and nephrology teams.³ In our study, 80% (4/5) of patients required tailored drug management concerning dosage and timing relative to their dialysis sessions.

The cumulative costs of resources used in HD and chemotherapy impose a significant financial burden on patients. Clinical data and established guidelines for using many chemotherapy agents in patients with HD are limited,^{3,18} resulting in uncertainty in decision-making and suboptimal care for cancer patients with ESRD. To address these challenges, we present a real-world study from the Indian subcontinent, where data are scarce and this study

shows that cancer patients with ESRD undergoing dialysis can be effectively managed with customized treatment approaches.

Chemotherapy Dosing Adjustments

Drugs that are primarily eliminated by the kidneys, such as cisplatin, carboplatin, and cyclophosphamide, require dose adjustments in patients with renal impairment. Chemotherapeutic agents with minimal or no renal excretion, such as taxanes and anthracyclines, can be administered at full doses in patients with ESRD.

In patients with renal impairment, the carboplatin dose is reduced to achieve the target area under the curve (AUC), with the reduction based on the creatinine clearance rate (CrCl).^{19,20} In our study, all patients had their chemotherapy regimens tailored to their renal function, with carboplatin dosing adjusted for each cycle according to eGFR. CrCl was calculated using the Cockcroft–Gault formula and was measured at baseline and before each therapy cycle. Similarly, the dose of cyclophosphamide was reduced for patients with severe renal dysfunction on HD. Haubitz et al²¹ studied the administration of cyclophosphamide at a dose of 0.5 to 1 g/m² in HD patients, finding that 22% of the drug was eliminated within 3 hours after dialysis began, with an overall clearance lower than in patients with normal renal function. Consequently, a 30% dose reduction is recommended.

The immune checkpoint inhibitors were cautiously administered without any renal adjustments during the first cycle. Given the patient's tolerance and stable renal parameters, the same dose was continued in subsequent cycles.^{11,12} No dose modifications were made for hormonal therapy.

Which Equation Should Be Used for eGFR Estimation?

The Chronic Kidney Disease Epidemiology Collaboration (CKD-EPI) equation is considered the best tool for estimating GFR, as it provides more accurate estimates in individuals with normal or mildly reduced GFR compared with other equations.²² Although the CKD-EPI, 4-variable Modification of Diet in Renal Disease (MDRD), and Cockcroft–Gault formulas may yield slightly different GFR estimates, they generally align when it comes to dosing renally excreted cancer drugs.²³ It is advisable to consistently use the same formula to monitor renal function throughout treatment. We utilized the Cockcroft–Gault formula in our study.

Timing of Dialysis

The timing of dialysis in relation to chemotherapy was crucial. Chemotherapy was administered after dialysis to minimize drug clearance, optimize exposure, and ensure maximum therapeutic benefit while reducing the risk of premature drug removal.^{24,25} Renal parameters were monitored twice weekly before dialysis, with all five patients maintaining a twice-weekly dialysis schedule. This timing was carefully chosen, considering the dialyzability of carboplatin and cyclophosphamide. Coordinating dialysis schedules with the nephrologist to ensure uninterrupted cancer treatment is vital for achieving positive outcomes, especially in a resource-constrained country like India.

Pharmacokinetics and Pharmacodynamics

The altered pharmacokinetics and pharmacodynamics in patients with CKD necessitated close monitoring of drug levels and adjustments to dosing intervals. As a result, these patients had to undergo comprehensive blood tests, including renal function, electrolytes, and liver parameters, twice weekly to optimize dosing strategies, mitigate toxicities, and address any electrolyte imbalances. All patients tolerated the modified treatment regimens well, with no evidence of disease recurrence at the 12-month follow-up (► Table 1).

Guidelines for the Use of Erythropoiesis-Stimulating Agents

Nephrologists commonly use erythropoiesis-stimulating agents (ESAs) to maintain hemoglobin levels in CKD patients.⁶ However, evidence for ESA use in the context of ESRD with cancer is inconclusive. Studies suggest ESAs may worsen malignancy outcomes and increase thrombosis risk,²⁶ complicating management for CKD/ESRD patients with cancer. Guidelines provide limited clarity,²⁷ emphasizing the need for individualized treatment by balancing the risks and benefits of ESA therapy in such complex cases. Epoetin injections were utilized in all two of our patients; however, no thrombosis-related complications were noted.

Venous Access

Venous access among these ESRD patients on HD who were concurrently diagnosed with cancer was managed using a variety of approaches. These included arteriovenous fistulas, chemoports, and HD catheters, each selected based on the patient's unique clinical circumstances and cancer treatment requirements.

Peritoneal versus HD: Is There a Difference?

Peritoneal dialysis (PD) and HD are two dialysis options for patients with ESRD who are not candidates for preemptive kidney transplantation. In our study, all five patients were receiving HD for ESRD. Although PD is less commonly used, the choice of dialysis can affect the dosage and dosing interval of chemotherapy drugs. Current PK data on the interaction between dialysis type and chemotherapeutic agents are scarce. HD removes carboplatin at 25% of the rate of renal clearance, while PD is ineffective in eliminating carboplatin. Cyclophosphamide can be cleared by both HD and PD. Information regarding the effects of targeted therapy and immune checkpoint inhibitors remains unknown.²⁸ This impacts the selection of alternative drug regimens as well as dose modifications.

Management of Adverse Events

The life-threatening delayed hypersensitivity reaction to carboplatin observed in the first patient underscores the necessity for preparedness in managing severe adverse events. Quick intervention and adjustments to the treatment plan were crucial in reducing risks and ensuring the patient's safety. Up to 16% of ovarian cancer patients treated with carboplatin-containing regimens experienced

hypersensitivity reactions. The cumulative incidence of these reactions rises with the number of carboplatin cycles and higher doses, particularly after more than eight cycles or a total dose exceeding 3,500 mg, and the reason being unknown.²⁹ Therefore, experiencing this reaction during the fifth cycle is not considered a rare occurrence.

Patients with CKD undergoing dialysis are at a higher risk of infections due to immunosuppression and the presence of dialysis catheters. To prevent neutropenia, patients on dose-dense regimens were administered prophylactic Peg-filgrastim 6 mg subcutaneously 24 hours after completing chemotherapy. Additionally, prophylactic antibiotics were used in neutropenic patients while adhering to strict aseptic techniques.^{3,25}

In a large meta-analysis covering various cancer types, the frequency of irAEs was estimated to be around 56%.³⁰ Most of these adverse events were classified as grades 1 and 2. The most frequently reported adverse events were hematologic, followed by gastrointestinal issues, which aligns with our study's observations as well.³⁰

Multidisciplinary Approach between Oncology, Nephrology, and Palliative Team

Through the development of detailed, individualized treatment plans that incorporated a multidisciplinary approach, our careful planning and collaboration with the nephrologist led to successful oncological and renal outcomes (►Table 1). Supportive care, encompassing nutritional support, pain management, and psychological assistance, played a vital role in enhancing the quality of life for patients with cancer and CKD. Additionally, palliative care services were instrumental in symptom management and offering emotional support to both patients and their families.

Considering the limitations of our study (small sample size, single institution), we recommend conducting further research with a larger cohort, longer follow-up, and participation in prospective studies to more accurately evaluate outcomes, especially for specific cancer types in CKD patients.

Conclusion

Managing anticancer drugs in dialysis patients is challenging due to limited data, as current recommendations rely on case reports and series, with high-level evidence lacking. However, ESRD is not an absolute contraindication for anticancer therapy. We successfully treated cancer patients on HD by addressing the complexities of their dual conditions. Our findings advocate for inclusive clinical trials considering renal impairment, emphasizing individualized care and multidisciplinary collaboration to optimize outcomes.

Declaration of GenAI Use

During the preparation of this work, the authors used Chat-GPT to improve language and readability. After using this tool/service, the authors reviewed and edited the content as needed and take full responsibility for the content of the publication.

Authors' Contributions

N.D.S. performed the initial manuscript write-up, data collection, literature review, and manuscript editing. N.K.K. assisted with the final write-up, data collection, literature review, and editing of the manuscript. K.M.R. and R.G. assisted in data collection and literature review.

Patient's Consent

Written informed consent was obtained from the patients.

Funding

None.

Conflict of Interest

None declared.

Acknowledgments

The authors are deeply appreciative of the patients and their families who participated in this study for their cooperation and trust.

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