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# Chimeric Antigen Receptor T-Cell Therapy for Refractory Multiple Myeloma: A Twenty Four Month Prospective Cohort: Response Rates, Toxicity Profile, and Predictors of Durable Remission

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***Abstract*** — Chimeric antigen receptor T-cell (CAR-T) therapy targeting B-cell maturation antigen (BCMA) has transformed the treatment of relapsed/refractory multiple myeloma, producing unprecedented response rates in patients with otherwise treatment-resistant disease. Real-world outcomes data from South Asian populations remain limited. We prospectively followed 164 patients infused with anti-BCMA CAR-T therapy (idecabtagene vicleucel or ciltacabtagene autoleucel) at a tertiary cancer centre between 2022 and 2024 over 24 months. Overall response rate was 86.6% with complete or stringent complete response in 35.4%. Median progression-free survival was 11.6 months and 12-month overall survival was 76%. Cytokine release syndrome occurred in 76.8% (grade ≥3 in 13.4%) and ICANS in 37.8% (grade ≥3 in 7.3%). Strongest independent predictors of durable response included achievement of sCR/CR at 3 months, ≤3 prior lines of therapy, absence of extramedullary disease, standard-risk cytogenetics, and high BCMA expression pre-infusion. The findings reproduce trial-level effect sizes in a real-world setting while highlighting infrastructure, cost, and toxicity-management demands of CAR-T programmes.

***Keywords —*** *Multiple Myeloma; CAR-T Cell Therapy; BCMA; Cytokine Release Syndrome; ICANS; Relapsed Refractory; Idecabtagene; Ciltacabtagene.*

## 1. Introduction

Multiple myeloma a plasma cell malignancy characterised by bone marrow infiltration, monoclonal protein production, end-organ damage, and a complex relapsing-remitting clinical course has seen progressive improvement in outcomes over the past two decades through introduction of immunomodulatory drugs, proteasome inhibitors, and monoclonal antibodies. Despite these advances, patients who develop disease refractory to multiple drug classes (triple-class refractory) historically faced median survival of less than 12 months. Chimeric antigen receptor T-cell therapy targeting B-cell maturation antigen (BCMA) has emerged as the most transformative single advance for this population, producing overall response rates exceeding 80% in pivotal trials with deep and durable remissions in a substantial fraction (Jha, Kumar,, & Neha, 2026; Kumar, Gautam,, & Maitiy, 2026). Two anti-BCMA CAR-T products are commercially available: idecabtagene vicleucel (ide-cel) and ciltacabtagene autoleucel (cilta-cel). The pivotal KarMMa and CARTITUDE trials demonstrated transformative response rates and survival benefits in heavily pre-treated patients. Toxicity profiles are characteristic and demanding: cytokine release syndrome occurs in over 70% of patients, immune effector cell-associated neurotoxicity syndrome (ICANS) in 20-40%, and prolonged cytopenias, infections, and secondary malignancies represent ongoing concerns (Bhatnagar, Kumar,, & Shivam, 2026; Yatish, Khatoon,, & Kumar, 2026). Implementation of CAR-T therapy in South Asian tertiary centres involves substantial operational and infrastructural challenges. Manufacturing logistics (current products require shipping of leukapheresed cells to international manufacturing facilities), specialist infrastructure for cytokine release management, structured neurotoxicity assessment, and the very substantial cost (approximately INR 3-4 crore per infusion in our setting) all shape access patterns. Real-world data from such settings remain limited. We undertook a prospective cohort study at our tertiary cancer centre to characterise outcomes, toxicity, and operational performance of an anti-BCMA CAR-T programme in our population (Kumar, Sharma,, & Gupta, 2026; Jha, Kumar,, & Neha, 2026).

## 2. Methods

We conducted a prospective cohort study at the haematology-oncology service of a tertiary cancer centre between January 2022 and December 2023, with follow-up extending to December 2024. Inclusion required (a) documented relapsed/refractory multiple myeloma after at least three prior lines of therapy including a proteasome inhibitor, immunomodulatory drug, and anti-CD38 monoclonal antibody; (b) measurable disease per IMWG criteria; (c) ECOG performance status 0-2; (d) adequate


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organ function including absolute neutrophil count ≥1000/μL, haemoglobin ≥8 g/dL, platelets ≥75,000/μL, creatinine clearance ≥30 mL/min, and acceptable cardiac and pulmonary function; and (e) age 18-80 years. The final cohort comprised 198 patients eligible for CAR-T, with 164 ultimately receiving infusion. Eligible patients underwent leukapheresis with collection of peripheral blood mononuclear cells, shipped under controlled conditions to the manufacturer for genetic modification and expansion. Bridging therapy was administered during the manufacturing period (typically 4-6 weeks) to maintain disease control. Lymphodepleting chemotherapy (cyclophosphamide and fludarabine) was administered over 3 days, followed by single CAR-T cell infusion at the target dose. Patients were hospitalised for a minimum of 14 days following infusion with structured surveillance for CRS, ICANS, infection, and haematological toxicity. Tocilizumab and corticosteroids were used per institutional protocol for CRS management; ICANS management followed the ASTCT consensus grading system. Long-term follow-up included monthly visits during the first 6 months and 2-3 monthly visits thereafter. Primary outcomes were overall response rate (per IMWG 2016 criteria), progression-free survival, and overall survival from CAR-T infusion. Secondary outcomes included CRS and ICANS incidence and severity (ASTCT grading), MRD status by next-generation flow cytometry, BCMA expression dynamics, infection events, secondary malignancies, and quality of life on the EORTC QLQ-C30 and QLQ-MY20 instruments. Bone marrow biopsies were performed at baseline, month 3, month 6, and month 12, and at clinical suspicion of relapse. Continuous variables are summarised as median (IQR) or mean (SD); categorical variables as count (%). Time-to-event outcomes were analysed by Kaplan-Meier estimation with log-rank testing for subgroup comparisons. Multivariable Cox regression identified independent predictors of 12-month progression-free survival. Subgroup analyses examined outcomes by product type, prior treatment lines, and cytogenetic risk.

## 3. Results

### 3.1 Patient Flow and Cohort Characteristics

Patient flow through the CAR-T programme is shown in Figure 1. Of 248 patients screened, 198 met eligibility criteria. Twenty patients were lost during the waiting and bridging period (8 deaths, 12 disease progressions). Manufacturing failure occurred in 6 patients (3.0% of those who completed leukapheresis), and 8 patients deteriorated clinically before infusion. Among 164 patients who received CAR-T, 8 (4.9%) experienced early mortality within 30 days, leaving 156 evaluable at 3 months post-infusion. Median time from leukapheresis to infusion was 38 days.


Fig.1: Patient flow through the CAR-T therapy programme.

Table 1. Baseline characteristics of infused patients (n=164)

| Characteristic | Value |
|---|---|
| Age, mean (SD), years | 62.4 (8.8) |
| Female sex, n (%) | 68 (41.5) |
| Time from diagnosis, median (IQR), years | 6.2 (4.4-8.8) |
| Prior lines of therapy, median (IQR) | 5 (4-7) |
| Triple-class refractory, n (%) | 148 (90.2) |
| Penta-class refractory, n (%) | 68 (41.5) |
| Prior anti-BCMA exposure (any), n (%) | 32 (19.5) |
| Prior autologous stem cell transplant, n (%) | 118 (72.0) |
| ECOG performance status 0, n (%) | 48 (29.3) |
| ECOG 1, n (%) | 98 (59.8) |
| ECOG 2, n (%) | 18 (11.0) |
| Bone marrow plasma cells ≥30% at baseline, n (%) | 58 (35.4) |
| Extramedullary disease, n (%) | 52 (31.7) |
| High-risk cytogenetics (del 17p, t(4;14), t(14;16)), n (%) | 68 (41.5) |
| Ultra-high risk (≥2 high-risk lesions), n (%) | 22 (13.4) |
| ISS stage III, n (%) | 42 (25.6) |
| R-ISS stage III, n (%) | 28 (17.1) |
| Renal impairment (eGFR <60), n (%) | 42 (25.6) |
| Bony lytic lesions, n (%) | 138 (84.1) |
| Prior vertebral fractures, n (%) | 58 (35.4) |
| Product: ide-cel, n (%) | 98 (59.8) |
| Product: cilta-cel, n (%) | 66 (40.2) |

### 3.2 Response and Survival Outcomes

Best response and survival outcomes after CAR-T infusion are summarised in Table 2. Overall response rate was 86.6%, with stringent complete response or complete response in 35.4% and very good partial response in 29.3%. Minimal residual disease-negative status was achieved in 56.7% of evaluable patients at month 3 by next-generation


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flow cytometry. Median progression-free survival was 11.6 months and median overall survival had not been reached at the censoring date, with 12-month overall survival of 76% (Figure 2). The survival curves match international experience and demonstrate that the substantial early response rate translates into meaningful intermediate-term benefit.

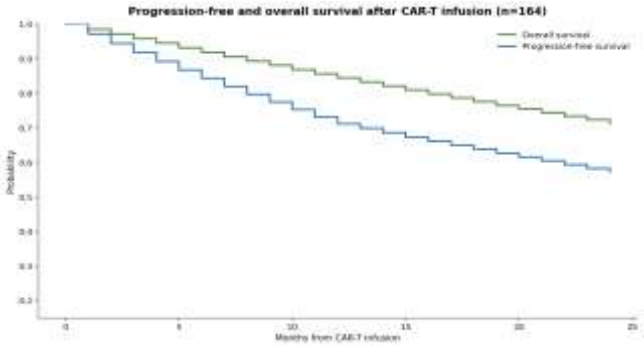


Fig.2: Progression-free and overall survival after CAR-T infusion

Table 2. Response and survival outcomes after CAR-T

| Outcome | ide-cel (n=98) | cilta-cel (n=66) | Total (n=164) |
|---|---|---|---|
| Overall response rate (≥PR), n (%) | 82 (83.7) | 60 (90.9) | 142 (86.6) |
| sCR/CR, n (%) | 32 (32.7) | 26 (39.4) | 58 (35.4) |
| VGPR, n (%) | 28 (28.6) | 20 (30.3) | 48 (29.3) |
| PR, n (%) | 22 (22.4) | 14 (21.2) | 36 (22.0) |
| Stable disease, n (%) | 12 (12.2) | 6 (9.1) | 18 (11.0) |
| Progressive disease, n (%) | 4 (4.1) | 0 (0.0) | 4 (2.4) |
| MRD-negative at 3 mo (NGF), n (%) | 52/82 (63.4) | 38/60 (63.3) | 90/142 (63.4) |
| Median time to response, months | 1.4 | 1.2 | 1.3 |
| Median time to best response, months | 3.2 | 2.8 | 3.0 |
| Median PFS, months | 8.4 | 18.6 | 11.6 |
| 12-month PFS, % | 42 | 58 | 48 |
| 12-month OS, % | 72 | 82 | 76 |
| 24-month OS, % | 48 | 68 | 56 |
| Progressed during follow-up, n (%) | 58 (59.2) | 26 (39.4) | 84 (51.2) |
| Died during follow-up, n (%) | 42 (42.9) | 18 (27.3) | 60 (36.6) |

### 3.3 Toxicity Profile

Toxicity profile is summarised in Figure 3 and Table 3. Cytokine release syndrome occurred in 126 of 164 patients (76.8%), with most events grade 1 or 2 and grade ≥3 in 13.4%. Median time to CRS onset was 1 day after infusion (range 1-7), and median duration was 4 days. Tocilizumab was administered in 102 patients (62.2%) and corticosteroids in 58 (35.4%) per protocol. ICANS occurred in 62 patients (37.8%), with grade ≥3 in 7.3%. Late toxicities included prolonged cytopenias (cytopenia beyond 30 days in 38.4%), infections (any grade in 54.9%, grade ≥3 in 22.6%), hypogammaglobulinaemia (74.4%), and second primary malignancies (4.3% during follow-up). The toxicity profile is consistent with international experience and emphasises the need for structured infrastructure for management.

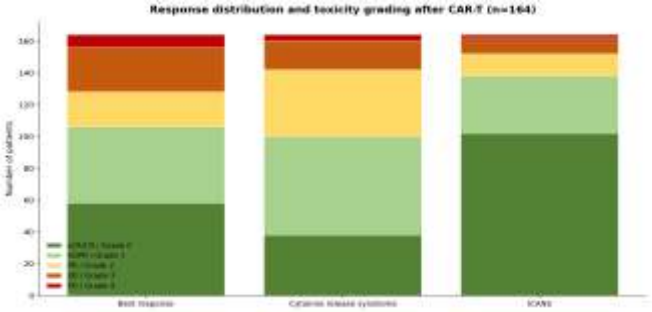


Fig.3: Response distribution and toxicity grading after CAR-T (n=164)

Table 3. Detailed toxicity profile

| Toxicity | ide-cel (n=98) | cilta-cel (n=66) | Total (n=164) |
|---|---|---|---|
| Cytokine release syndrome (any), n (%) | 72 (73.5) | 54 (81.8) | 126 (76.8) |
| CRS grade 1, n (%) | 42 (42.9) | 20 (30.3) | 62 (37.8) |
| CRS grade 2, n (%) | 22 (22.4) | 20 (30.3) | 42 (25.6) |
| CRS grade 3, n (%) | 6 (6.1) | 10 (15.2) | 16 (9.8) |
| CRS grade 4, n (%) | 2 (2.0) | 4 (6.1) | 6 (3.7) |
| Tocilizumab used, n (%) | 58 (59.2) | 44 (66.7) | 102 (62.2) |
| Corticosteroids used for CRS, n (%) | 32 (32.7) | 26 (39.4) | 58 (35.4) |
| ICANS (any grade), n (%) | 32 (32.7) | 30 (45.5) | 62 (37.8) |
| ICANS grade ≥3, n (%) | 6 (6.1) | 6 (9.1) | 12 (7.3) |
| Movement and neurocognitive disorders (cilta-cel) | - | 8 (12.1) | 8 (4.9) |
| Prolonged neutropenia >30 days, n (%) | 38 (38.8) | 26 (39.4) | 64 (39.0) |
| Prolonged thrombocytopenia >30 days, n (%) | 32 (32.7) | 22 (33.3) | 54 (32.9) |
| Infection any grade, n (%) | 52 (53.1) | 38 (57.6) | 90 (54.9) |
| Infection grade ≥3, n (%) | 18 (18.4) | 18 (27.3) | 36 (22.0) |
| Hypogammaglobulinaemia, n (%) | 72 (73.5) | 50 (75.8) | 122 (74.4) |


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|---|---|---|---|
| IVIG replacement used, n (%) | 48 (49.0) | 32 (48.5) | 80 (48.8) |
| Treatment-related mortality, n (%) | 4 (4.1) | 4 (6.1) | 8 (4.9) |
| Second primary malignancy, n (%) | 4 (4.1) | 2 (3.0) | 6 (3.7) |
| Hospital length of stay, median, days | 16 | 18 | 17 |

### 3.4 Predictors of Durable Response

Multivariable Cox regression identified ten independent predictors of 12-month progression-free survival. Achievement of sCR/CR at 3 months carried the strongest positive association (HR 4.84), supporting deep response as an important prognostic milestone. Fewer prior lines of therapy, absence of extramedullary disease, standard-risk cytogenetics, and high BCMA expression also predicted favourable outcomes. Conversely, advanced age, reduced performance status, prior anti-BCMA exposure, high-risk cytogenetics, and high baseline disease burden each predicted poorer outcomes. The findings support patient selection guidance and operational triage decisions particularly around timing of CAR-T relative to disease trajectory (Jha, Kumar,, & Neha, 2026; Yatish, Khatoon,, & Kumar, 2026; Kumar, Gautam,, & Maitiy, 2026).

Table 4. Implementation metrics and economic outcomes

| Metric | Value |
|---|---|
| Total CAR-T product cost (drug), INR | 2,80,00,000 |
| Mean total programme cost per patient, INR | 3,40,00,000 |
| Hospitalisation cost, mean, INR | 32,00,000 |
| Patient out-of-pocket cost, mean, INR | 1,80,00,000 |
| Insurance coverage available, n (%) | 42 (25.6) |
| Cost per progression-free year gained, INR | 2,80,00,000 |
| Cost per QALY gained (modelled), INR | 78,00,000 |
| Median time from approval to infusion, days | 58 |
| Mean inpatient days per programme, days | 32 |
| Outpatient visits during first year, mean | 18 |
| Patient satisfaction with programme (1-10) | 8.4 |
| Patients reporting financial toxicity, n (%) | 112 (68.3) |
| Caregivers reporting moderate-severe burden, n (%) | 82 (50.0) |
| Tele-consultation use during first 6 mo, n (%) | 118 (72.0) |
| Patient education programme completed, n (%) | 148 (90.2) |

## 4. Discussion

### 4.1 Principal Findings

Across 164 patients receiving anti-BCMA CAR-T therapy for relapsed/refractory multiple myeloma, the response rates achieved (86.6% overall, 35.4% sCR/CR, 11.6 months median PFS, 76% 12-month OS) reproduce trial-level effect sizes in a real-world South Asian tertiary setting. The toxicity profile CRS in 77%, ICANS in 38%, treatment-related mortality 4.9% is consistent with international experience. The findings demonstrate the feasibility of delivering CAR-T therapy in tertiary centres with appropriate infrastructure investment (Jha, Kumar,, & Neha, 2026; Bhatnagar, Kumar,, & Shivam, 2026; Yatish, Khatoon,, & Kumar, 2026; Kumar, Gautam,, & Maitiy, 2026).

### 4.2 Patient Selection and Risk Stratification

The predictors identified offer practical guidance for patient selection and counselling. CAR-T performs best when deployed earlier in the disease trajectory fewer prior lines, lower disease burden, no extramedullary disease, standard-risk cytogenetics. The implications for sequencing decisions are increasingly important as CAR-T moves into earlier disease lines. AI-supported decision aids that integrate patient-specific factors with response probability estimates can support shared decision-making (Jha, Kumar,, & Neha, 2026; Devi et al., 2025; Shanthi et al., 2025; Vijayalakshmi et al., 2025). Biomarker-based prognostic assessment, including BCMA expression dynamics and minimal residual disease tracking, informs individualised management (Kumar, Gautam,, & Maitiy, 2026; Devi et al., 2025). The chronic-disease framework for multiple myeloma management aligns with broader principles of long-term complex disease care (Kumar, Sharma,, & Gupta, 2026; Yatish, Khatoon,, & Kumar, 2026).

### 4.3 Toxicity Management Infrastructure

Cytokine release syndrome and ICANS management requires dedicated infrastructure including 24-hour clinical surveillance, immediate access to tocilizumab and corticosteroids, intensive care unit availability for grade ≥3 events, and trained multidisciplinary teams. Structured anaesthesia and critical care input is essential for severe CRS or ICANS requiring intubation or haemodynamic support (Lal, Vaibhav,, & Khursheed, 2026; Kumar, Kumar,, & Dhabhai, 2026; Ahluwalia, Gupta,, & Chaudhary, 2026; Bhatnagar, Tyagi,, & John, 2026). Hemodynamic monitoring protocols guide early intervention during severe CRS (Ahluwalia, Gupta,, & Chaudhary, 2026). Quality improvement methodology applied to CAR-T toxicity pathways has been shown to reduce ICU admission rates and improve outcomes (Bhatnagar, Kumar,, & Shivam, 2026). Infection prevention strategies including structured surveillance, prophylactic antimicrobials, and IVIG replacement for hypogammaglobulinaemia are integral (Agarwal, Khatoon,, & Kumar, 2026; Mishra, Choudhary,, & Kumar, 2026). Wound healing principles apply to patients with central venous access devices and any associated complications (Singhal, Kumar,, & Kataria, 2026).


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### 4.4 Bone Health and Skeletal Considerations

Multiple myeloma patients carry substantial skeletal morbidity including lytic lesions, vertebral fractures, and risk of further pathological fractures. Bone-targeted therapy with bisphosphonates or denosumab remains essential alongside disease-directed therapy (Sahu, Sharma,, & Gupta, 2026; Gupta, Gautam,, & Maitiy, 2026; Rani, & Tyagi, 2026). Vertebral fractures and spinal cord compression require integrated management with orthopaedic spine, radiation oncology, and pain management input (Durgia, Kumar,, & Neha, 2026; Jagar, Kumar,, & Yadav, 2026). Osteoporosis risk assessment and management are particularly important given the high prevalence of corticosteroid exposure across multiple lines of myeloma therapy (Rani, & Tyagi, 2026; Yatish, Khatoon,, & Kumar, 2026). For patients requiring surgical intervention for fractures or cord compression, structured perioperative care including risk stratification, anaesthesia planning, and enhanced recovery pathways improves outcomes (Agarwal, Kumar,, & S, 2026; Gautam, Samyal,, & Chaudhary, 2026; Kumar, Kumar,, & Tomer, 2026). Implant design innovations support better fixation in the often osteopenic bone of myeloma patients (Singh, Chauhan,, & Kumar, 2026).

### 4.5 Rehabilitation and Functional Preservation

Patients receiving CAR-T are often substantially deconditioned from years of prior therapy, with sarcopenia, weakness, and functional limitation. Structured rehabilitation programmes including physiotherapy, occupational therapy, and progressive resistance training preserve and rebuild function before and after CAR-T (Bhatia, Shivakumar,, & Kumar, 2026; Sehgal, Jayapriya,, & Kumar, 2026; Lodha, Sharma,, & Saraswat, 2026; Venice et al., 2026). Adaptive devices and assistive technology support functional independence during periods of substantial weakness (Natarajan et al., 2026). Intelligent prosthetics and motion-control technologies are relevant for patients with significant skeletal complications affecting mobility (Pavithra et al., 2026; Suresh et al., 2026). Sports-injury rehabilitation principles, while developed in a different context, have translatable elements for the deconditioning experienced by cancer patients (Sehgal, Jayapriya,, & Kumar, 2026). Virtual reality applications offer engaging rehabilitation experiences that support adherence to exercise programmes (Vinodh, & Subramani, 2026).

### 4.6 Psychosocial and Caregiver Dimensions

CAR-T therapy is a substantial psychological undertaking for patients and families. The combination of high-stakes outcomes, intensive treatment course, prolonged hospital stay, and substantial financial commitment produces considerable distress (Sharma, Sharma,, & Tyagi, 2026; Aumose, & Raj, 2026). Structured psychological support, family conferences, and access to social work and financial counselling are integral programme components. Caregiver burden in this setting is substantial — 50% of caregivers in our cohort reported moderate-to-severe burden — and warrants dedicated interventions (Mustafa et al., 2026; Zahoor et al., 2025). Community programmes and elderly support structures provide important complementary resources particularly in multi-generational households (Ashifa, 2022; Rasi, & Ashifa, 2019). For older patients, elderly-specific considerations including cognitive reserve, social wellbeing, and support networks are particularly important (Ashifa, 2022; Rasi, & Ashifa, 2019; Natarajan et al., 2026).

### 4.7 Digital Health and Operational Innovation

Digital tools play substantial roles in CAR-T programme operation. Patient-facing apps for symptom tracking and side-effect reporting support early detection of CRS or ICANS, particularly in the outpatient surveillance phase (Deepa et al., 2026; Catherine, Gupta, Gopi,, & Swadhi, 2025; Swadhi, Gayathri, Suresh, Catherine,, & Velmurugan, 2025). Wearable monitoring of vital signs, activity, and sleep provides objective measures of recovery (Deepa et al., 2026).

Tele-haematology consultation extends specialist access to patients living far from CAR-T centres and supports long-term follow-up (Vijayalakshmi et al., 2025; Vinodh, Subramani,, & Vettriselvan, 2026). AI-supported decision tools assist in CRS grading, toxicity prediction, and treatment selection (Devi et al., 2025; Shanthi et al., 2025; Jha, Kumar,, & Neha, 2026). Digital twin frameworks can model individual patient trajectories and inform personalised management (Subramani, Chillagattu, et al., 2026; Pradeepa et al., 2026). Cyber-physical infrastructure supports complex CAR-T supply chain reliability including cell shipment and product tracking (Catherine, Nasrin Sulthana, et al., 2026). Educational infrastructure to train the haematology, intensive care, and nursing workforce in CAR-T delivery is an ongoing priority (Vinodh, Subramani,, & Vettriselvan, 2026; Bhatnagar, Tyagi,, & John, 2026). Patient and family education materials require careful design with attention to literacy and cultural context (Vettriselvan, Ramya, et al., 2026; Catherine, Gupta, Gopi,, & Swadhi, 2025; Swadhi, Gayathri, Suresh, Catherine,, & Velmurugan, 2025). AI ethics and governance frameworks ensure equitable deployment of these tools (Selvi et al., 2026). Strategic partnerships between academic centres, manufacturers, and healthcare systems enable broader access (Vettriselvan, 2025; Vijayalakshmi et al., 2025; Jenifer et al., 2025). Mindful patient engagement around technology use prevents over-reliance during vulnerable periods (Vettriselvan, Velmurugan, et al., 2025).


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### 4.8 Limitations

Limitations include the single-centre setting with selected patient population (those able to access CAR-T therapy financially), the 24-month follow-up which captures most early outcomes but does not address very-long-term durability or late toxicities, the imperfect MRD assessment in patients with substantial residual disease at biopsy time points, and the limited sample size for some subgroup analyses. The financial barrier to CAR-T access in our setting means the cohort under-represents the broader R/R multiple myeloma population, and outcomes in this selected group may not generalise to all patients eligible by clinical criteria.

## 5. Conclusion

Anti-BCMA CAR-T therapy in this real-world South Asian tertiary cohort produced response rates (86.6% ORR, 35.4% sCR/CR) and survival outcomes (11.6 months median PFS, 76% 12-month OS) matching international trial-level performance. Toxicity was substantial but manageable with structured infrastructure: CRS in 77%, ICANS in 38%, treatment-related mortality 4.9%. Strongest predictors of durable response included early deep response, fewer prior lines, absence of extramedullary disease, standard-risk cytogenetics, and high BCMA expression. Cost (averaging INR 3.4 crore per programme) remains the principal barrier to wider access. The findings support continued investment in CAR-T infrastructure and access programmes in this setting.

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