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RESEARCH

Assessment of characteristics and treatment patterns of adult patients with acquired aplastic anemia in Turkiye (PLANE-TR)

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Abstract

Acquired aplastic anemia (AA) is a rare blood disorder causing hypocellular bone marrow due to immune damage to hematopoietic stem cells, leading to low blood cell counts. This study investigates the demographics, treatment patterns, and clinical outcomes of AA in Turkiye. In this non-interventional, retrospective descriptive study, data of 274 patients (Female/Male: 4/5) diagnosed with AA between September 1, 2011, and September 1, 2021, were collected from 16 centers. Severe and very severe AA was diagnosed in 72% and 27.7% of patients, respectively. The mean time from diagnosis to first treatment was 119±287 days, while time to hematopoietic stem cell transplantation (HSCT) was 212±321 days, and to Anti-Thymocyte Globulin (ATG) was 87±242.5 days. The mean time to response after first-line and second-line treatment was 172.9±264.6 days and 191.9±211.9 days, respectively. The mean overall survival of patients with AA was 3.56±3.12 years, with a 5-year overall survival rate of 72.6%. HSCT and other initial treatments led to full or partial remission for most patients, improving survival rates for over half of them. The study observed comparable patterns to previous studies, providing vital insights into Turkiye's acquired AA treatment landscape.

Keywords Aplastic anemia · Blood disorder · Hematopoietic stem cell transplantation · Anti-T lymphocyte globulin

Introduction

Acquired aplastic anemia (AA) is a rare hematological disorder with high mortality rates due to bone marrow failure leading to impaired hematopoiesis and low blood cell counts. The pathophysiology of the disease is believed to be immune-mediated, with active destruction of hematopoietic stem and precursor cells by lymphocytes. The aberrant immune response may be triggered by environmental factors, such as chemicals and drugs or viral infections, and probably endogenous antigens generated by genetically altered bone marrow cells [1, 2]. The diagnosis of acquired AA is based on the exclusion of other disorders that can cause pancytopenia and on the well-known Camitta criteria [3].

There is limited information regarding the epidemiology of AA. Previous studies suggest the incidence to be 0.6 to 6.1 cases per million population [1, 4, 5]. A study published in 1997 from Turkiye reported the incidence of AA among hospitalized adult patients as 1.14 per 1,000 patients [6]. The male-to-female ratio is approximately 1:1. AA can affect individuals across all age groups, but it is most commonly diagnosed in those over 60 years old. Although a small peak in the incidence is observed in childhood, a second peak is found in the 20 to 25-year-old age group [7, 8]. Most cases of AA in the elderly are idiopathic, as genetic or viral causes are rarely identified in this group [8].

The mortality rate of severe AA is high, although the prognosis has dramatically improved owing to the advances in treatment over the last 25 years. Overall, more than 75% of AA patients now expected to survive long term [9]. Age, disease severity, initial therapy, and treatment response predict survival [7, 10]. The selection of first-line treatment for severe

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AA (SAA) depends on the patient's age and the availability of an Human leukocyte antigens (HLA)-matched sibling donor (MSD) [11]. The primary first-line treatments for newly diagnosed SAA patients include hematopoietic cell transplantation (HCT) from an HLA-identical sibling donor or immunosuppressive therapy (IST) [12]. IST is recommended as first-line therapy for non-severe AA patients requiring treatment, as well as for SAA or very severe AA (VSAA) patients under the age of 40 years without an MSD and for older SAA/VSAA patients. Both the European Society for Blood and Marrow Transplantation (EBMT) and the British Society for Haematology (BSH) published their updated guidelines in 2024 and include recommendation for triple therapy—horse Anti-Thymocyte Globulin (ATG), cyclosporine (CsA), and eltrombopag—as the preferred first-line treatment for IST [11, 12].

There is limited data from Turkiye on epidemiology, treatment patterns and patient characteristic in the real-world setting. The aim of this study is to investigate the demographics, treatment patterns, and clinical outcomes of AA in Turkiye.

Methods

Patients and methods

This was a non-interventional, multicenter, retrospective descriptive study. Data was collected from medical charts of patients from 16 centers and 9 different provinces of Turkiye.

ICD (International Classification of Disease) codes were used to identify target population in the participating centers (Online Resource I). Additionally, inpatient/outpatient and hematopoietic stem cell transplantation (HSCT) registries as well as bone marrow biopsy reports at the participating centers were screened for patients with the diagnosis of AA. Antithymocyte globulin, used in the treatment protocols, included both rabbit ATG and horse ATG.

Inclusion criteria

All patients aged 18 and above diagnosed with acquired AA between September 1, 2011, and September 1, 2021, were included.

Outcomes

The primary aim of the study was to retrospectively define the characteristics of patients with AA in Turkiye and to determine their treatment patterns. Secondary endpoints included response rates, time to remission, relapse rates, time to relapse, complications and overall survival.

Severity of AA was defined by Camitta Criteria. Severe AA (SAA) is defined as marrow cellularity < 25% (or 25–50% with < 30% residual hematopoietic cells), plus at least 2 of: (i) neutrophils < 500/μL, (ii) platelets < 20.000/μL, (iii) reticulocyte count < 20.000/μL. Very Severe AA (VSAA) is defined as for SAA but neutrophils < 200/μL. Non-severe AA (NSAA) is defined as AA not fulfilling the criteria for SAA or VSAA.

Response to immune suppression was evaluated within 6 months after treatment and categorized into two groups: complete remission (hemoglobin > 10 g/dL, ANC > 1.5×10^9 /L, and platelet count > 100×10^9 /L) and partial remission (blood counts not meeting criteria for SAA and transfusion independent). Response was confirmed by two or more complete blood counts at least 4 weeks apart. Relapse was defined as the loss of one or more criteria for response, regardless of the need for transfusion of red blood cells and/or platelets.

Data sources

Individual patient records consisting of electronic health databases and patient files were considered as data sources. The first AA diagnosis date was determined as the index date. Patient records were tracked from the index date until the patient's death or the end of September 1, 2021. To address any inaccuracies in data entry, queries were systematically raised at each center.

Data analysis

Statistical analysis was conducted using MedCalc Statistical Software version 12.7.7 (MedCalc Software Bvba, Ostend, Belgium; http://www.medcalc.org; 2013). Descriptive stati stics are reported as mean and standard deviation for normally distributed variables. A smaller standard deviation than the mean indicated a narrow, likely symmetric distribution, suggesting minimal outliers, making the mean more appropriate than the median for interpreting times from diagnosis to treatment, response, and relapse. Categorical variables are described using frequencies (n) and percentages (%). The Kaplan Meier method was used to investigate time to relapse. Statistical significance was accepted when $p < 0.05$.

Results

A total of 274 patients (54% male and 46% female; Male/Female: 1.6:1) with acquired AA were included. Severe and very severe AA was diagnosed in 71.9% ($n = 197$) and 27.7% ($n = 76$) of patients, respectively. There was one patient with moderate AA. The mean age of the study population at the

time of diagnosis was 42 years and the median age was 38 (range:18–81) years, with a mean age of 44 years for female patients and 41 years for male patients. The incidence of acquired AA has a bimodal distribution peaking at 20 and 60 years of age. The mean time from diagnosis to treatment (for all treatments) was 119 ± 287 days.

Predisposing factors at the time of diagnosis included smoking (17.5%), alcohol consumption (2.9%). Exposure to chemotherapy and radiation were noted in 4% and 2.9% of the cases, respectively. Common comorbidities were hypertension (10.9%), diabetes (6.2%), rheumatological/autoimmune diseases (4.4%), coronary artery disease (4.4%), and hepatitis (2.9%). The most commonly used medicines prior to the diagnosis of AA were acetylsalicylic acid, metformin, rituximab, insulin, and methylprednisolone.

Overall, out of the total 274 patients, 18 patients (6.6%) did not receive a treatment while 256 (93.4%) were treated. Of the patients without treatment 56% were female and 44% were male, reflecting a higher proportion of females compared to the overall study population. The mean age at diagnosis was 42 years and the median age was 38 (range:18–81) years, closely aligning with the overall population. Similarly, the distribution of AA severity was comparable, with 72% of untreated patients having severe AA and 28% classified as very severe, consistent with the severity rates observed in the full study population.

Among treated patients, 60.9% ($n=167$), 30.7% ($n=84$), 7.3% ($n=20$) and 1.1% ($n=3$) received one, two, three, and four lines of treatment line, respectively.

The treatment response rates for first and second-line therapies are detailed in Table 1. Following first-line therapy, 20 patients (7.8%) relapsed, and 40 patients (15.6%) died, while after second-line therapy, 6 patients (7.1%) relapsed, and 22 patients (26.2%) died. During the study period, 7 patients receiving third-line therapy and 2 patients on fourth-line therapy did not survive. Among the 18 patients who received no treatment, 4 (22.2%) died.

The treatment response rates for patients treated with HSCT are detailed in Table 2. Following first-line therapy with HSCT, 3 patients (6%) relapsed, and 8 patients (16%) died, while after second-line therapy, 1 patient (3%) relapsed, and 13 patients (35%) died. The reported causes of death included sepsis, acute respiratory failure, cerebral toxoplasmosis and multiple organ failure. Complications developed in 18 out of 50 patients who received HSCT (36%), with most of them being reported as infection, sepsis, and GVHD in sequence.

Table 1 Treatment response rates of all patients ($n=274$)*

Response	First-line therapy ($n=256$)	Second-line therapy ($n=84$)
Complete Response	69 (27%)	28 (33.33%)
Partial Response	69 (27%)	19 (22.6%)
No Response	118 (46%)	37 (44%)

*18 of 274 patients were followed up without treatment

Table 2 Treatment response rates of patients treated with HSCT ($n=50$)

Response	First-line therapy with HSCT ($n=50$)	Second-line therapy with HSCT ($n=37$)
Complete Response	33 (66%)	20 (54%)
Partial Response	8 (16%)	7 (19%)
No Response	9 (18%)	10 (27%)

The treatment response rates for patients treated with ATG are detailed in Table 3. Following first-line therapy with ATG, 11 patients (22%) relapsed, and 28 patients (25%) died, while after second-line therapy, 0 patients (0%) relapsed, and 6 patients (38%) died. The most frequently reported causes of death are sepsis, septic shock, infection, and multiple organ failure, which are relevant to the to all patients included in the study. Complications developed in 36 out of 112 patients who received ATG (32.14%), with most of them being reported as infection, sepsis, and bleeding in sequence.

The mean overall survival (OS) of patients with AA was 3.56 ± 3.12 years, with a 5-year overall survival rate of 72.6% ($n=199$).

The first-line of treatment included ATG (40.9%), HSCT (18.2%), and other treatments (34.3%). The second line of treatment included ATG (19%), HSCT (44%), and other treatments (37%) (See Fig. 1). A detailed list of first-line and second-line treatments is presented in Table 4.

The treatment patterns observed for patients aged 40 years and younger for the first-line treatment predominantly included ATG, accounting for 39.6% of the cases, followed by HSCT (26.4%). For patients over 40 years old, the first-line treatment was evenly distributed between ATG and other treatments, each accounting for 42.3% of the cases and HSCT was used less frequently (9.2%). Although, ATG is the most common first-line treatment for patients < 40 years as well as over the age of 40, HSCT is the most common second-line treatment for patients < 40 years of age (see Fig. 2). Of the patients who received ATG in the first-line treatment, 11 also received ATG (reuse) in the second-line treatment. Furthermore, 1 patient who underwent HSCT in the first-line treatment underwent HSCT again in the second-line treatment.

Table 3 Treatment response rates of patients treated with ATG ($n=112$)

Response	First-line therapy with ATG ($n=112$)	Second-line therapy with ATG ($n=16$)
Complete Response	21 (19%)	2 (13%)
Partial Response	37 (33%)	2 (13%)
No Response	54 (48%)	12 (75%)

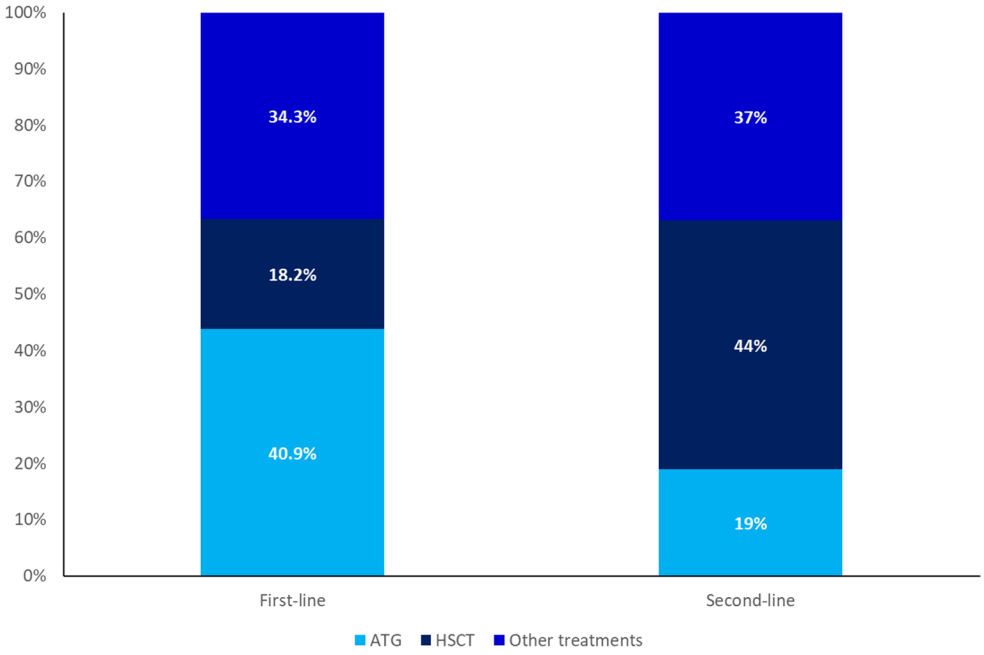


Fig. 1 Treatment pattern, by line

Table 4 First- and Second-Line treatments (n=274)*

Treatments	1st line (n=256)	2nd line (n=88)
ATG+Cyclosporine	107 (41.8%)	5 (4.8%)
HSCT	50 (19.5%)	37 (44%)
Cyclosporine (Monotherapy)	46 (17.9%)	4 (4.8%)
ATG (Monotherapy)	1 (0.3%)	10 (7.1%)
Cyclosporine+Eltrombopag	5 (2%)	2 (2.4%)
Anabolic Steroids (Monotherapy)	14 (5.5%)	5 (6%)
Cyclosporine+Anabolic Steroids	10 (3.9%)	1 (1.2%)
Eltrombopag (Monotherapy)	2 (0.8%)	13 (15.5%)
ATG+Cyclosporine+ Eltrombopag	14 (2.7%)	1 (1.2%)
Other	7 (5.5%)	11 (13.1%)

*18 of 274 patients were followed up without treatment

Table 5 Source of stem cells

Source of stem cells	N (%)	Donor type	N (%)	Matching status	N (%)
Bone marrow	58 (66.66)	Related	67 (77.01)	Haplo, Mismatched	24 (27.59)
Peripheral blood	29 (33.33)	Unrelated	20 (22.99)	Matched	63 (72.41)
Total	87 (100)	Total	87 (100)	Total	87 (100)

The source of stem cells, donor type, and matching status for the total number of patients treated with HSCT is presented in Table 5. The distribution of stem cell sources used in first-line and second-line HSCT is shown in Fig. 3.

The mean time to response after the first-line and second-line treatment was 172.9 ± 264.6 days and 191.9 ± 211.9 days, respectively (Table 6). The mean time to relapse after the first-line treatment was 822.2 ± 1044.6 days and 202.8 ± 129.8 days after second line treatment (Table 6). A total of 31% (n = 86) patients developed complications during the study and accounted for 111 complications. Among all complications, infections accounted for 38% (n = 42), followed by sepsis (18%; n = 20), graft-versus-host disease (GVHD;

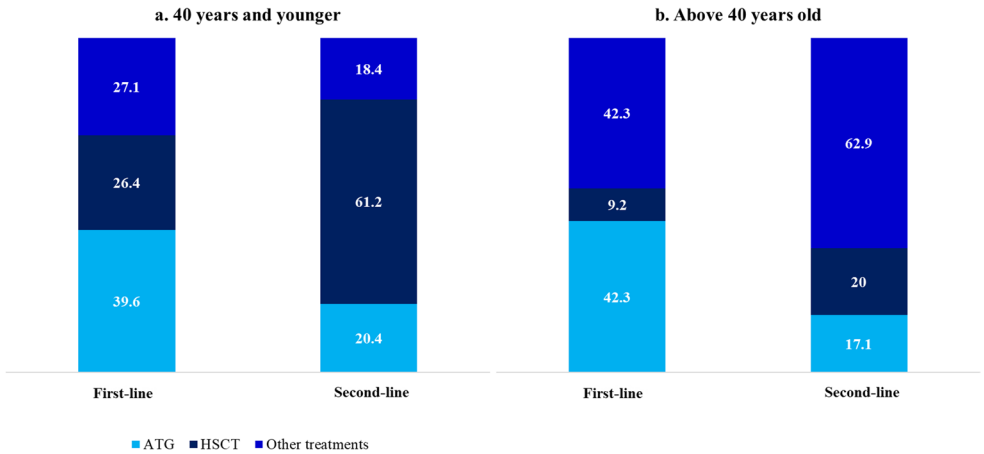


Fig. 2 Treatment pattern, by age

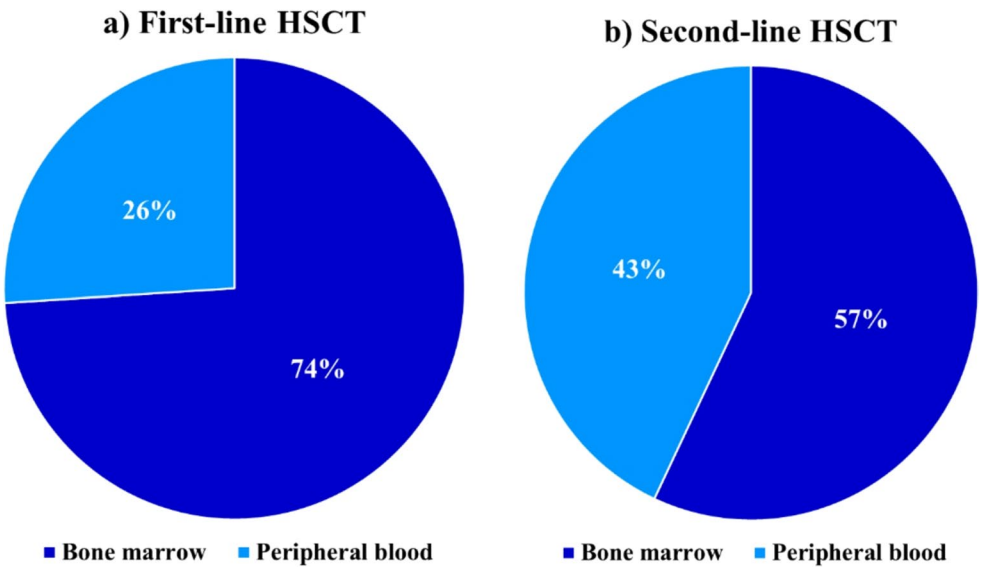


Fig. 3 Stem cell source distribution

Table 6 Mean time to evaluate the response

	Mean	S.D.
Mean time to respond (in days)		
First-line HSCT	110.1	76.7
Second-line HSCT	135	133
First-line ATG	229	375
Second-line ATG	152	46
First-line - other treatments	138	107
Second-line - other treatments	288	303

8%; $n = 9$), bleeding (7%; $n = 8$), avascular necrosis (3%; $n = 3$), and other complications (26%; $n = 29$).

The overall survival rate of all AA patients was found to be 72.6% (See Fig. 4), while for those who received any treatment, it was 71.9%. The most frequently reported causes of death included sepsis, septic shock, infection, and multiple organ failure.

Discussion

The present study reviewed the medical records of 274 patients (46% female and 54% male) diagnosed with acquired AA. A significant portion (71.9%) had severe AA, while 27.7% had very severe AA. There was a singular patient with moderate AA and was assessed as a part of the cohort, representing a minority of the sample. Conclusions about this subset should be cautious due to its underrepresentation, likely from sampling issues, underreporting, or chance. The mean diagnosis age was 42 years, with women at 44 years and men at 41 years. A higher incidence of AA diagnoses was noted between ages 20–60.

Baslar et al. (1997) reported an incidence of 1.14 per 1000 of total new admissions for AA in Turkiye. The male-to-female ratio of these cases was 1.6:1, which was similar to the ratio noted in the current study. The median age was 30 years overall, 25 for females, and 30 for males. Females showed peaks in the 20–24, 35–39, and 55–59 age groups, while males had peaks at 30–34 and 55–59 years. Severe AA accounted for 89% of cases, consistent over the study years, with similar severity in both genders. Non-severe cases were generally older than the overall group, and within both severe and non-severe groups, females were younger than males [6].

In the Spanish study conducted by Vallejo et al. (2024), the incidence of AA was calculated to be 2.83 per million inhabitants per year. The median age at diagnosis was 61 years, with a comparable distribution between males and females. At the time of diagnosis, 30.5% of cases were classified as very severe AA (VSAA), 25.3% as severe AA (SAA), and 35.8% as moderate AA (MAA) [5]. In another previous Barcelona-based study, an overall incidence of 2.34 per million inhabitants per year was reported. A biphasic age distribution was observed, with peaks at 15–24 years (2.16 per million per year) and ≥ 65 years (5.33 per million per year). Of the 235 cases, 197 met the criteria for severe or very severe AA. The highest proportions of very SAA were found among patients aged 45 to 64 years, and those aged 2 to 14 years (59.3% and 48.3%, respectively). The proportion of cases with very SAA at the time of diagnosis decreased throughout the study period [9]. Additionally, as compared to these studies [5, 9], there was a higher proportion of cases with SAA and VSAA in our study. Like Montane et al. (2008) [9], the incidence of acquired AA in the current study also has a bimodal distribution but peaking at 20 and 60 years of age.

The most frequently used first-line treatment was ATG followed by HSCT, while in second-line treatment, HSCT and other treatments were favored over ATG. For patients

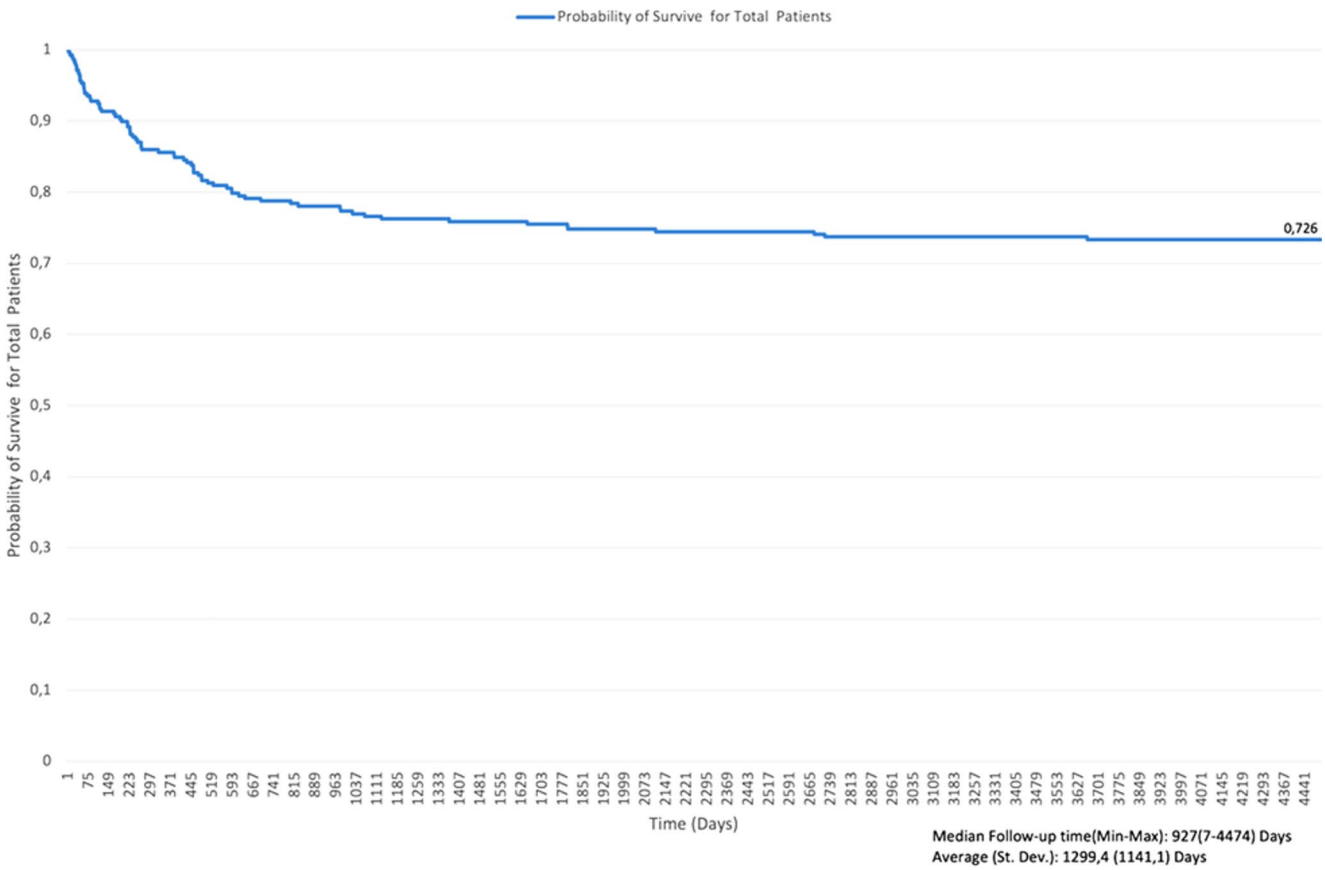


Fig. 4 Overall survival curves

aged 40 years and younger, first-line treatments were primarily ATG (39.6%), followed by HSCT (26.4%) and other treatments (27.1%). For those over the age of 40, first-line treatments included ATG and other therapies (42.3% each), HSCT (9.2%), and 6.2% received no treatment. In second-line therapy, HSCT was most common in patients aged 40 years and younger (61.2%), while for those over the age of 40, other therapies dominated (62.9%). The treatment approach for acquired AA in Turkiye varied by age, with older patients mostly receiving ATG initially, and younger patients mostly receiving HSCT in second-line therapy. In the study by Vallejo et al. (2024), the first-line treatment most commonly utilized was a combination of ATG and CsA (44.2%), followed by other CsA-based regimens (46.3%). HSCT was rarely employed. The majority of patients over 60 years of age received IST with either ATG/CsA or CsA alone as initial treatments. The increased use of ATG in Turkiye may be attributed to the challenges in obtaining unrelated donors and the prolonged confirmation testing process, leading to its routine initiation in the absence of an identical sibling, in line with recommendations to simultaneously search for unrelated donors while administering ATG and CsA [13]. Additionally, these two therapies were combined with Eltrombopag in a few patients towards the conclusion of the study [5] The limited administration of Eltrombopag therapy during that period in Turkiye can be associated with reimbursement challenges in addition to triple therapy (ATG combined with CsA and Eltrombopag) being recommended as standard of care post-RACE (Randomized, Multicenter Trial Comparing Horse ATG plus Cyclosporine with or without Eltrombopag as First-Line) study publication in 2022 [14]. A cohort registry study in 22 AA treatment centers in China examined the characteristics and treatment patterns of 340 newly diagnosed AA patients. At baseline, most received IST, followed by traditional Chinese medicine, and HSCT; only 22.2% of IST-treated patients initially received guideline-recommended ATG with CsA. Most patients received supportive care such as blood transfusions, antibiotics, and hematopoietic growth factors. In China, most AA patients start with IST, often as CsA alone or with androgen, but only 1 in 5 receive the recommended IST regimen of ATG with CsA [13]. In our study, compared to Zhu et al. (2019), majority of patients received ATG along with CsA.

Treatment for acquired AA depends on factors like patient age, matched sibling donor availability, and disease severity. HSCT is recommended for younger patients with a matched sibling donor, as it is curative. Without a

matched donor, IST, including ATG and cyclosporine, can restore hematopoiesis in about two-thirds of patients. However, some may not respond, risk late clonal disorders such as myelodysplasia, or have incomplete blood cell recovery, requiring retreatment for recurrent pancytopenia [2]. The choice of treatment is also influenced by the patient's comorbidities, access to therapies, and institutional protocols. For instance, HSCT is preferred for younger patients due to its curative potential, but it is less accessible for older patients or those with significant comorbidities [15]. Age plays a crucial role in treating acquired AA. Patients under 40 have better engraftment success and fewer complications, while those over 60 face higher risks with HSCT and often receive IST instead [16]. The type of HSCT donor also impacts outcomes. Donor selection typically prioritizes: [1] HLA-identical sibling [2], HLA-matched unrelated donor, and [3] HLA-haploidentical donor if no matched unrelated donor is available [17]. This hierarchy considers compatibility and GVHD risks. For example, one study found that HLA-haploidentical HSCT with post-transplant cyclophosphamide results in high survival rates and low morbidity, making it an option for patients without fully matched donors [18]. In comparison to these general donor selection practices, our study found that among HSCT patients, 66.66% used bone marrow stem cells and 33.33% used peripheral blood. Most donors were related (77.01%), with fewer being unrelated (22.99%). Additionally, 72.41% of patients had fully matched donors, while 27.59% had haploidentical or mismatched transplants. These findings largely align with established donor selection practices.

The overall survival rate for all AA patients was 72.6%. Montane et al. (2008) found nearly one death per million per year over two years. Survival rates were 73% at three months, 57% at two and five years, and 51% at fifteen years. Prognosis improved over 23 years, with better outcomes linked to younger age and milder disease at diagnosis. Bone marrow transplantation showed a trend towards better survival at two years [9]. In Vallejo et al. (2024), the study reported an overall fatality rate of 43.5% at six months post-diagnosis, which increased to 69.6% within the first year after diagnosis [5].

Limitations

The retrospective nature of this study may have introduced biases and has resulted in missing information. Extreme outlier values are present and reflect actual recorded values, not data errors. The study included patients from 11 cities across 16 centers, enhancing its generalizability for Turkiye. A robust data management process also strengthened the study.

Conclusion

PLANE-TR offers an extensive retrospective epidemiological analysis of AA cases, therapeutic approaches, and patient outcomes in Turkiye. The study implored that initial treatment of AA leads to full or partial remission for most patients, improving survival rates for over half of them. Future prospective studies are needed for a better understanding of the outcome differences associated with treatment strategies in different parts of the world.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s00277-026-06871-y.

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Data availability The data will be shared upon reasonable request.

Declarations

Ethics approval and consent to participate The study was approved by the Clinical Research Ethics Committee of Eskisehir Osmangazi University (Approval number: 42/, date: 04 October 2022) and was carried out in accordance with the legal and regulatory requirements, the principles of Good Clinical Practice and Declaration of Helsinki. This study was conducted as a retrospective analysis of previously collected data. Therefore, informed consent was not applicable, as no new patient interventions or identifiable personal data were involved.

Consent to publication Not applicable.

Competing interests S. Sener and S.S. Calika are employees of Pfizer. Other authors declare no conflict of interest related to this work.

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