

Exploring Preferences of Different Modes of Administration of Hypomethylating Agent (HMA) Treatments Among Patients With Acute Myeloid Leukemia (AML)



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Background & Study Objectives

- Acute myeloid leukaemia (AML) is a malignant disease of hemopoietic stem cells or progenitors which is characterised as the differentiation arrest and aberrant proliferation of myeloid lineages.
- Standard Induction Chemotherapy (SIC) aims to clear the blood and bone marrow of leukemic cells. However, about half of AML patients (50%) are considered unsuitable for SIC due to age, poor performance status and/or comorbid conditions.
- Less intensive treatments such as hypomethylating agents (HMAs) are available: these treatments are administered parenterally for 5–7 days per 28-day treatment cycle, with several (2-4) treatment cycles necessary to achieve a response. HMAs are typically administered either through intravenous (IV) or subcutaneous (SC) treatment; however, all current HMAs are required to be administered by healthcare professionals.
- The administration of IV or SC HMAs may be burdensome to patients, given the frequent hospital visits and adverse events. An oral HMA may decrease the burden of monthly, multiple-day, IV or SC injections to patients.
- The overall study objectives were to:
 - Describe the experiences and perceptions of parenteral HMA treatment with patients with AML who are using / have used HMAs or are suitable to be treated with HMAs (i.e., not suitable for SIC)
 - Determine their preferences for different characteristics of such treatments

Methods

- One-on-one virtual semi-structured interviews took place with 21 adults with AML who are using / have used HMAs or are suitable to be treated with HMAs from the UK (n=4), Spain (n=2) and Germany (n=15).
- The interviews focused on the patient burden of AML treatment, their preferences for receiving an AML HMA treatment either orally, SC or IV, and factors that may influence preferences.
- Interviews were conducted in English, German and Spanish and were transcribed from recorded interviews. Transcripts were coded using MAXQDA with a coded framework. Descriptive analyses were performed to characterise the sample.
- Prior to the patient interviews, two steps were taken to ensure an understanding of current research and clinical management of AML were captured in the interviews:
 - A targeted literature review was conducted to understand characteristics of HMA treatments and to explore the attributes of patient preferences for oral chemotherapy. This allowed for draft treatment scenarios to be developed for use in the patient interviews.
 - Individual 1:1 virtual semi-structured interviews with 6 AML clinicians across 3 countries (UK, Spain and Germany), to explore how HMA treatment decisions are made, the role and engagement of patients in those decisions, and to elicit feedback on the draft treatment scenarios

Patients were suitable if they met the following criteria:

Patient was ≥ 18 years old
Patient was diagnosed with AML (de novo or secondary)
Patient was treatment naïve or in first line treatment
Patient was not suitable for SIC or patient is using or had used HMAs for AML treatment within the last 6 months
Patient had access to a telephone or cell phone
Patient had access to an internet browser or application to access the screen sharing platform
Patient was receiving care for their AML in the UK, Germany or Spain
Patient was able to read and write in English, German or Spanish
Patient was willing and able to complete a 45-60 min interview and electronically consented to participate in the study and have the interview recorded.

Exclusion criteria:

Relapsed/refractory AML patients
Patients used other oral HMAs
Any condition that involved cognitive deficits or severe visual impairment that interfered with the ability of the patient to understand or interpret the questions in the interview
Patients that were concurrently participating in an AML clinical trial

Discussion and Conclusion

- Patients with AML who are using / have used HMA or are suitable to be treated with HMA (i.e., unsuitable for SIC) reported significant burdens of AML and its treatment, noting fatigue as a key symptom. A significant benefit of receiving an oral treatment included the convenience of receiving treatment at home, which may help relieve the burden of receiving treatment in the hospital setting.
- Patients who experienced both oral and parenteral treatment preferred the oral MOA. When presented with hypothetical HMA treatments, the majority of patients preferred the oral MOA, noting the convenience of taking the treatment at home.
- Key limitations of this study include a potential bias given the larger German patient sample recruited compared to the UK and Spain due to difficulties recruiting AML patients. These sample biases may also translate into a potential imbalance across different healthcare systems when considering preferences. The healthcare system can provide capacity and can act as an important driver for treatment decision-making, as it can determine whether patients have available resources for treatment. The current sample age was also younger compared to the typical incidence rate of patients with AML who are using / have used HMAs or are suitable to be treated with HMAs (60-65 years).
- The insights gained from this study can help support frail / fragile patients with AML who are not able to receive intensive induction therapy for alternative HMA treatment options, which can decrease burden of parenteral therapies on patients and potentially improve their patient care and overall quality of life.

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Disclosures: AE, AD, DB are employees of Otsuka and LB, IA, SB, SP, and AMR-L are employees of IQVIA who were contracted to perform this research on behalf of Otsuka.

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Results

PATIENT CHARACTERISTICS

- The majority of patients were above 45 years (67%), with a median age of 51 years, female (67%), and White (90%). Most of the patients were from Germany (71%), followed by UK (19%) and Spain (10%).
- The majority of patients (67%) received their AML diagnosis less than 6 months ago at the time of the interview; only 1 patient (5%) was diagnosed 6-12 months prior to the interview and 6 patients (29%) diagnosed more than 1 year prior to interview.
- Eleven patients (52%) reported receiving treatment for their AML at the time of the interview. The remaining 10 patients (48%) were not receiving treatment for their AML at the time of the interview, although some of these patients (n=6) reported receiving treatment previously for AML. The remaining four patients reported never receiving treatment for AML.

BURDEN OF AML TREATMENT

- More than half of the patients (52%) reported fatigue as a common symptom of living with the disease.
- Many patients (43%) also reported that their AML and treatment had a significant impact and burden on their ability to carry out everyday activities, such as cooking, cleaning, shopping and driving.
 - Home Setting**
 - Some patients (19%) stated that the home-setting has more advantages compared to clinics because of the comfort of being in their own setting and increased convenience
 - Clinic Setting**
 - More than half of patients (52%) reported inconvenience of long wait times in the hospital and the travel burden of commuting to clinics.
 - Some patients (24%) also expressed benefits of the clinic setting because of the security in relation to perceived elevated treatment management.
 - Oral Treatment**
 - Several patients (19%) noted advantages for the oral treatment, if they had the opportunity to adapt their current regimen because of the increased convenience and ability to administer in a home-setting.
 - Some patients (14%) commented on the burden of the oral HMA in relation to the inconvenience of remembering to take a tablet every day and the taste of pills.
 - IV / SC Treatment**
 - Other patients noted disadvantages of IV or SC administration, such as adverse events (10%), difficulty with administration (10%) and discomfort (5%). The main advantage was less frequent administration of the treatment (5%).

OVERALL PATIENT TREATMENT PREFERENCE (Figure 1)

- The majority of patients who experienced both oral and parenteral treatment preferred receiving an oral treatment (71%). This was due to convenience of the treatment, where oral treatment is considered easier and quicker to administer.
- For those who chose IV or SC (24%), patients perceived these treatments would reach their immune system more quickly and effectively.
- One patient (5%) was unable to make a treatment decision despite being prompted by the moderator.

PREFERENCE FOR HYPOTHETICAL HMA TREATMENTS (Figure 2)

- When presented with two hypothetical HMA treatments with similar efficacy and toxicity profiles, the majority of patients preferred oral MOA (76%) compared to the injection MOA (SC or IV) (14%).
- Despite multiple clarifying questions, two patients were unable to make a decision (10%).

Figure 1. Overall Patient Treatment Preferences (n=21)

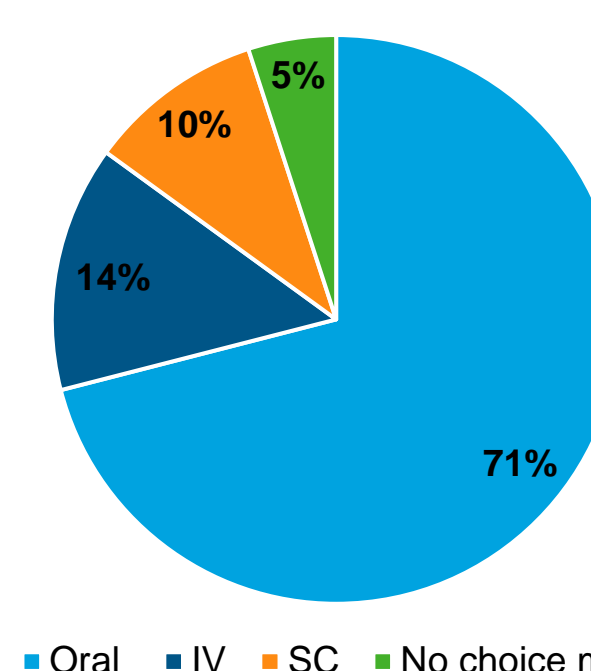
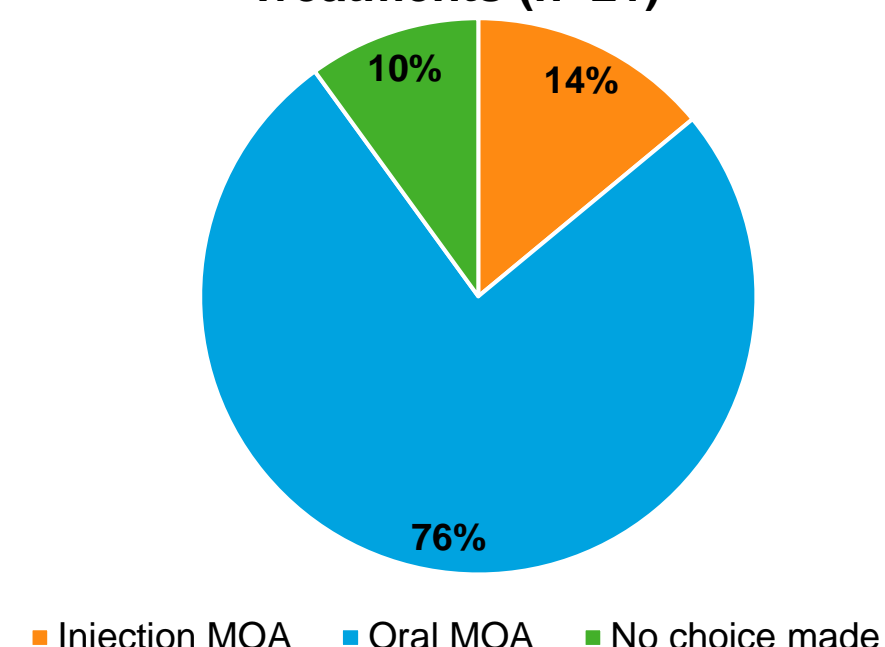


Figure 2. Overall Patient Treatment Preference for Hypothetical HMA Treatments (n=21)



REASON FOR PREFERENCE (Figure 3)

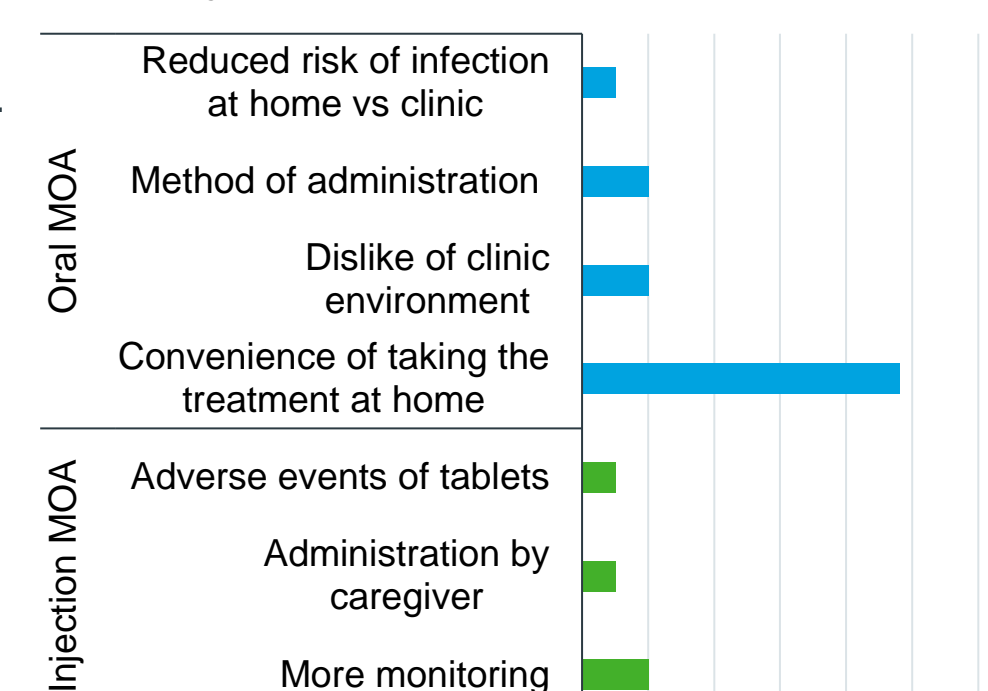
Oral MOA

- Nearly half of patients (48%) mentioned convenience of being able to take the treatment at home as the reason for selecting the oral treatment.
- Dislike of the clinical environment where injection treatments are administered and MOA were also mentioned by 10% of patients. Reduced risk of infection at home was reported by 5% of patients.

Injection MOA

- More monitoring by a nurse or clinician was mentioned for selecting the injection MOA by 10% of patients.

Figure 3. Reasons for Oral or Injection MOA Preference (n=21)



0% 10% 20% 30% 40% 50% 60%