

Steady-State Versus Chemotherapy-Based Stem Cell Mobilization in Multiple Myeloma: A Single-Center Study to Analyze Efficacy and Safety

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Abstract

Background: High-dose chemotherapy followed by autologous hematopoietic stem cell support is recommended in the treatment of eligible multiple myeloma (MM) patients. The aim of this study was to compare the efficacy and safety of steady-state versus chemotherapy-based stem cell mobilization in our Hungarian patient population.

Methods: The subjects were 210 MM patients who underwent stem cell mobilization procedure between 2018 and 2022. Solo granulocyte colony-stimulating factor (G-CSF) was administered in 104 cases, while 106 patients received chemotherapy which was followed by G-CSF administration. We evaluated the ratio of successful mobilizations, the amount of collected stem cells, the incidence of infections and cost-effectivity in the two groups.

Results: In the steady-state group, there was a significantly higher need for plerixafor (45% vs. 13%, $P < 0.001$), unsuccessful stem cell mobilization was more frequent (11% vs. 3%, $P = 0.024$) and the mean amount of collected stem cells was lower (6.9 vs. 9.8×10^6 , $P < 0.001$) than in the chemotherapy group. However, infections were less frequent (4% vs. 27%, $P < 0.001$) and the number of days spent in hospital was significantly lower (6 vs. 14 days, $P < 0.001$). Plerixafor was more frequently administered in those who had received lenalidomide or daratumumab than in those who had been treated with other regimens (41% vs. 23%, $P = 0.007$ and 78% vs. 23%, $P < 0.001$, respectively).

Conclusions: Steady-state mobilization is a safe method; however, the higher rate of plerixafor administration and unsuccessful attempts

may question its superiority to chemomobilization.

Keywords: Multiple myeloma; Stem cell; Mobilization; Chemotherapy; Granulocyte colony-stimulating factor; Plerixafor

Introduction

Multiple myeloma (MM) is a malignant lymphoproliferative disorder characterized by clonal plasma cell expansion. It represents 1-2% of all cancers and accounts for 17% of the hematological malignancies. It occurs mainly in elderly people. Major complications include the development of lytic bone lesions, hypercalcemia, bone marrow failure and renal impairment. MM is considered to be an incurable disease; however, there has been a significant improvement in patients' survival, due to the novel drugs that have been introduced recently [1]. The first-line therapy is usually a three- or four-drug combination regimen which includes a proteasome inhibitor, an immunomodulatory drug, steroid and daratumumab as an anti-CD38 monoclonal antibody. After the induction treatment, high-dose chemotherapy followed by autologous hematopoietic stem cell transplantation (AH SCT) should be considered in approximately half of the patients. Transplant eligibility is determined by the age and comorbidities [2, 3].

Stem cell mobilization procedure usually includes the administration of chemotherapy and granulocyte colony-stimulating factor (G-CSF). The gold standard is intermediate-dose ($2 - 4 \text{ g/m}^2$) cyclophosphamide, but other regimens, e.g., high-dose etoposide, cytosine-arabioside or combinations (bortezomib, thalidomide and dexamethasone-cisplatin, adriamycin, cyclophosphamide and etoposide (VTD-PACE), etoposide, dexamethasone, ara-C, and cisplatin (EDAP)), are also applied. Recently, steady-state mobilization method can also be considered. The administration of G-CSF may reduce chemotherapy-associated toxicities and infectious complications. The International Myeloma Working Group (IMWG) recommends collecting at least 4×10^6 CD34⁺ cells/body weight kilogram (bwkg) for each AH SCT, and a double amount is required if a tandem or a second transplantation is planned [4].

Our aim was to compare the efficacy and safety of solo G-

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CSF versus chemotherapy-based stem cell mobilization in our Hungarian MM patients.

Materials and Methods

We collected data retrospectively from MM patients who underwent stem cell mobilization procedure in our institute between January 2018 and December 2022. Patients with plasma cell leukemia, solitary plasmacytoma and amyloidosis were excluded from the analysis. The clinical files were reviewed with particular reference to age, sex, clinical stage, previous treatment and response achieved, mobilization strategy, length of hospital stay, infectious complications and the amount of harvested stem cells. The International Staging System (ISS) and revised ISS (R-ISS) stages were determined using the IMWG criteria, if the relevant data were available. The way how fluorescence *in situ* hybridization (FISH) testing was performed varied, there was no consensus regarding the probes used, but those specific for 17p deletion, translocations (11;14), (4;14) and (14;16) and 1q amplification were generally part of the set. FISH results of unfavorable prognosis included t(4;14), t(14;16) and del(17p).

Response criteria (complete response (CR), very good partial response (VGPR), partial response (PR), no response (NR), and progressive disease (PD)) were also determined via the IMWG criteria.

All patients had undergone central venous catheter insertion before the stem cell mobilization process was initiated. Chemotherapy-based treatment included the administration of intermediate-dose cyclophosphamide (3 - 4 g/m²) or combination regimens (PACE). Filgrastim stimulation at the dose of 10 µg/kg/day was started if the patients' absolute neutrophil count dropped off below 1,000/µL. Peripheral CD34⁺ cell counts were evaluated by flow cytometry method if leukocyte counts began to increase, and their number exceeded 5,000/µL. In terms of steady-state mobilization, patients received generic G-CSF 10 µg/kg/day subcutaneously for 4 days. On the fifth day, flow cytometry was performed to determine the peripheral stem cell count in the patients' blood sample. In both groups, patients were administered plerixafor 24 mg/day subcutaneously if leukocyte count exceeded 5,000/µL and peripheral CD34⁺ cell count was in the 5 - 20/µL range. Stem cell harvesting procedure was launched if peripheral CD34⁺ stem cell count exceeded 20/µL. All collections were performed using the MNC program of the Spectra Optia apheresis system. The goal was to harvest at least 4 × 10⁶ stem cells per bwkg for each autologous transplantation.

Categorical variables were given as their frequencies and percentages, while continuous variables with medians and ranges. The Kolmogorov-Smirnov test was used for evaluation of data normality. Discrete variables were compared using a Chi-square test, while analysis of variance (ANOVA) was used for the measurement of associations between patient characteristics and outcomes. Pearson's correlation and *t*-test were used to assess whether the difference in the means of two variables reaches statistical significance. Binary logistic regression and multivariable logistic regression was used to determine which

factors were significant in determining outcomes. The level of statistical significance was considered at $P < 0.05$. *Post-hoc* power analysis was used to assess statistical power. Statistical analyses were performed using SPSS26.0 (IBM Corp., Armonk, NY, USA).

Ethical issues

All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. The research project was approved by the Regional Ethical Committee of the University of Debrecen (permission number: DEKK/RKEB/IKEB 6548-2023). Written informed consent for participation was not required for this study in accordance with the national legislation and the institutional requirements.

Results

Patient characteristics

In that 5 years' period, 210 patients underwent stem cell mobilization procedure. Their demographics were generally balanced. A moderate male predominance was observed (51.1%), while the average age was 61 years (range 32 - 75). One-hundred and six patients received chemotherapy-based protocols for stem cell mobilization, while 104 patients were administered G-CSF alone. The most commonly used chemotherapeutic mobilization protocol was cyclophosphamide monotherapy (84.9%) in patients also receiving MM-specific, PACE-based combination therapies (15.1%). There was no difference in the epidemiological, disease-related or treatment parameters between the two groups with different mobilization strategies. Patients' main clinical features and induction therapies as well as their results are presented in Table 1.

Efficacy of stem cell mobilization

In the solo G-CSF group, there was a significantly higher need for plerixafor administration (45% vs. 13%, $P < 0.001$), unsuccessful stem cell mobilization was more frequent (11% vs. 3%, $P = 0.024$) and the mean amount of collected stem cells was significantly lower (6.9 vs. 9.8 × 10⁶/bwkg, $P < 0.001$) than in the chemotherapy group. On the other hand, infections were less frequent (4% vs. 27%, $P < 0.001$) and the number of days spent in hospital was significantly lower (6 vs. 14 days, $P < 0.001$). There was no significant difference between the median days of apheresis (Table 1). Multivariable analysis identified chemotherapy + G-CSF stem cell collection protocol as a sole and independent risk factor for infectious complications ($P = 0.001$), while the solo G-CSF protocol ($P < 0.001$) and daratumumab exposure ($P = 0.003$) predicted requirement for subsequent plerixafor therapy (Table 2). No independent prognostic

Table 1. Patient Characteristics and Comparison of Different Stem Cell Mobilization Approaches

Characteristics	All patients (n = 210)	Chemotherapy + G-CSF group (n = 106)	Solo G-CSF group (n = 104)	P-value
Age, median (range)	61 (32 - 75)	59 (38 - 75)	63 (32 - 75)	ns
Sex, male/female (%)	107/103 (51/49)	55/51 (52/48)	52/52 (50/50)	ns
M-protein type, n (%)				ns
IgG	128 (61)	60 (58)	68 (65)	
IgA	39 (19)	19 (18)	20 (19)	
IgM	1 (0.5)	1 (1)	0	
IgD	2 (1)	1 (1)	1 (1)	
LCD	37 (18)	22 (21)	15 (15)	
NS	1 (0.5)	1 (1)	0	
R-ISS, n (%)				ns
I	34 (16)	17 (16)	17 (16)	
II	58 (27)	27 (25)	31 (30)	
III	77 (37)	38 (36)	39 (38)	
n/a	41 (20)	24 (23)	17 (16)	
FISH risk, n (%)				ns
Standard	69 (33)	34 (32)	37 (36)	
High	92 (44)	46 (43)	47 (45)	
n/a	49 (23)	26 (25)	20 (19)	
Previous lines of therapy, median (range)	1 (1 - 6)	1 (1 - 6)	1 (1 - 3)	ns
Number of previous lines, n (%)				ns
1	152 (73)	73 (69)	83 (80)	
2	45 (22)	27 (25)	18 (17)	
≥ 3	9 (5)	6 (6)	3 (3)	
First-line therapy				ns
VTD	119 (57)	63 (59)	56 (54)	
VRD	37 (18)	14 (13)	24 (23)	
VCD	42 (20)	23 (22)	19 (18)	
Other	12 (5)	6 (6)	5 (5)	
Previous exposure of, n (%)				ns
Lenalidomid	71 (34)	30 (28)	41 (39)	
Daratumumab	18 (9)	7 (7)	11 (11)	
Venetoclax	10 (5)	5 (5)	5 (5)	
Time from dg. to mobilization, months, median (range)	5.5 (2.6 - 107.2)	5.5 (0.6 - 107.2)	5.4 (2.6 - 23.2)	ns
Disease status before mobilization, n (%)				ns
CR	51 (24)	24 (23)	27 (26)	
VGPR	91 (43)	45 (42)	46 (44)	
PR	66 (32)	35 (33)	31 (30)	
SD	2 (1)	2 (2)	0	
Karnofsky status before AHSCT, %, median (range)	90 (60 - 100)	90 (60 - 100)	90 (70 - 100)	ns
Mobilization failure, n (%)	5 (2)	3 (3)	11 (11)	0.024
Plerixafor usage, n (%)	61 (29)	14 (13)	47 (45)	< 0.001
Days of apheresis, median (range)	2 (0 - 4)	2 (0 - 4)	2 (1 - 4)	ns
Total CD34 ⁺ stem cells, n, × 10 ⁶ , median (range)	7.8 (0.5 - 29)	8.9 (1.8 - 29)	6.8 (0.5 - 21)	< 0.001
Infectious complications, n (%)	33 (16)	29 (27)	4 (4)	< 0.001
Hospital stay, days, median (range)	11 (2 - 27)	14 (9 - 27)	6 (2 - 11)	< 0.001

G-CSF: granulocyte colony-stimulating factor; Ig: immunoglobulin; LCD: light chain disease; NS: non-secretory; R-ISS: revised International Scoring System; FISH: fluorescence *in situ* hybridization; VTD: bortezomib, thalidomide and dexamethasone; VRD: bortezomib, lenalidomide and dexamethasone; VCD: bortezomib, cyclophosphamide and dexamethasone; dg.: diagnosis; CR: complete response; VGPR: very good partial response; PR: partial response; SD: stable disease; AHSCT: autologous hematopoietic stem cell transplantation; ns: not significant.

Table 2. Univariate and Multivariable Logistic Regression Analyses of Disease Parameters, Associated With Infectious Complications, Plerixafor Use and Mobilization Failure

Variable	Univariate analysis			Multivariable analysis		
	OR	95% CI	P-value	OR	95% CI	P-value
Infectious complications						
Male sex	1.372	0.648 - 2.907	0.407			
High-risk FISH	1.541	0.642 - 3.696	0.330			
> 1 lines of therapy	2.156	0.988 - 4.707	0.050			
Lenalidomide exposure	0.383	0.150 - 0.976	0.039	1.677	0.539 - 5.219	0.372
Daratumumab exposure	0.294	0.038 - 2.290	0.216			
Below VGPR disease status	1.235	0.568 - 2.685	0.594			
Chemomobilization	9.416	3.176 - 27.915	< 0.001	7.392	2.366 - 23.090	0.001
Plerixafor use						
Male sex	1.582	0.866 - 2.890	0.135			
High-risk FISH	1.061	0.546 - 2.062	0.862			
> 1 lines of therapy	1.473	0.761 - 2.854	0.249			
Lenalidomide exposure	2.309	1.247 - 4.276	0.007	0.673	0.294 - 1.542	0.349
Daratumumab exposure	10.798	3.389 - 34.406	< 0.001	0.077	0.014 - 0.431	0.003
Below VGPR disease status	1.548	0.830 - 2.885	0.168			
Chemomobilization	0.185	0.093 - 0.365	< 0.001	0.176	0.076 - 0.407	< 0.001
Mobilization failure						
Male sex	1.953	0.166 - 1.583	0.278			
High-risk FISH	1.154	0.235 - 3.191	1.000			
> 1 lines of therapy	1.168	0.257 - 2.852	0.759			
Lenalidomide exposure	2.817	0.937 - 8.475	0.056			
Daratumumab exposure	1.876	0.386 - 9.091	0.429			
Below VGPR disease status	1.212	0.366 - 4.014	0.753			
Chemomobilization	0.246	0.067 - 0.910	0.024	4.55	0.850 - 24.357	0.077

CI: confidence interval; FISH: fluorescence *in situ* hybridization; OR: odds ratio; VGPR: very good partial response.

factor for mobilization failure was found.

We also investigated the impact of induction treatment to stem cell mobilization. Most patients received bortezomib-based triplets: VTD, bortezomib, lenalidomide and dexamethasone (VRD) or bortezomib, cyclophosphamide and dexamethasone (VCD). The amount of harvested stem cells was significantly lower in those patients who received lenalidomide-containing regimens than in those who were given lenalidomide-free induction therapy (6.6 vs. 9.3×10^6 /bwkg, $P < 0.001$). Besides, plerixafor was more frequently used in the lenalidomide group (40.8% vs. 23%, $P = 0.007$). Also, there was a marked, but not significant difference in the ratio of unsuccessful mobilization attempts (11.3% vs. 4.3%, $P = 0.056$) (Fig. 1). However, lenalidomide exposure alone does not predispose to either plerixafor use or mobilization failure (Table 2). Eighteen patients were exposed to daratumumab before stem cell collection, which is only a relatively small portion of the whole population. Nevertheless, our preliminary data showed that daratumumab did not influence the efficacy of the stem cell harvesting procedure; however, the need for plerixa-

for administration was higher (77.8% vs. 24.5%, $P < 0.001$) (Fig. 1 and Table 2).

Discussion

The incorporation of novel drugs to the induction treatment may question the necessity of autologous stem cell transplantation even in young and fit MM patients. However, recent studies have reported that AHSCT significantly improves progression-free survival in patients who undergo the treatment compared to those who do not [5]. Therefore, international guidelines still recommend the administration of high-dose melphalan followed by autologous stem cell transplantation in the eligible population [6].

The method of stem cell mobilization depends on several factors, such as disease activity, the number of transplantations planned and the presence of risk factors that may predict poor mobilization potential [7]. Chemotherapy-based regimens include the administration of intermediate-dose cyclophospha-

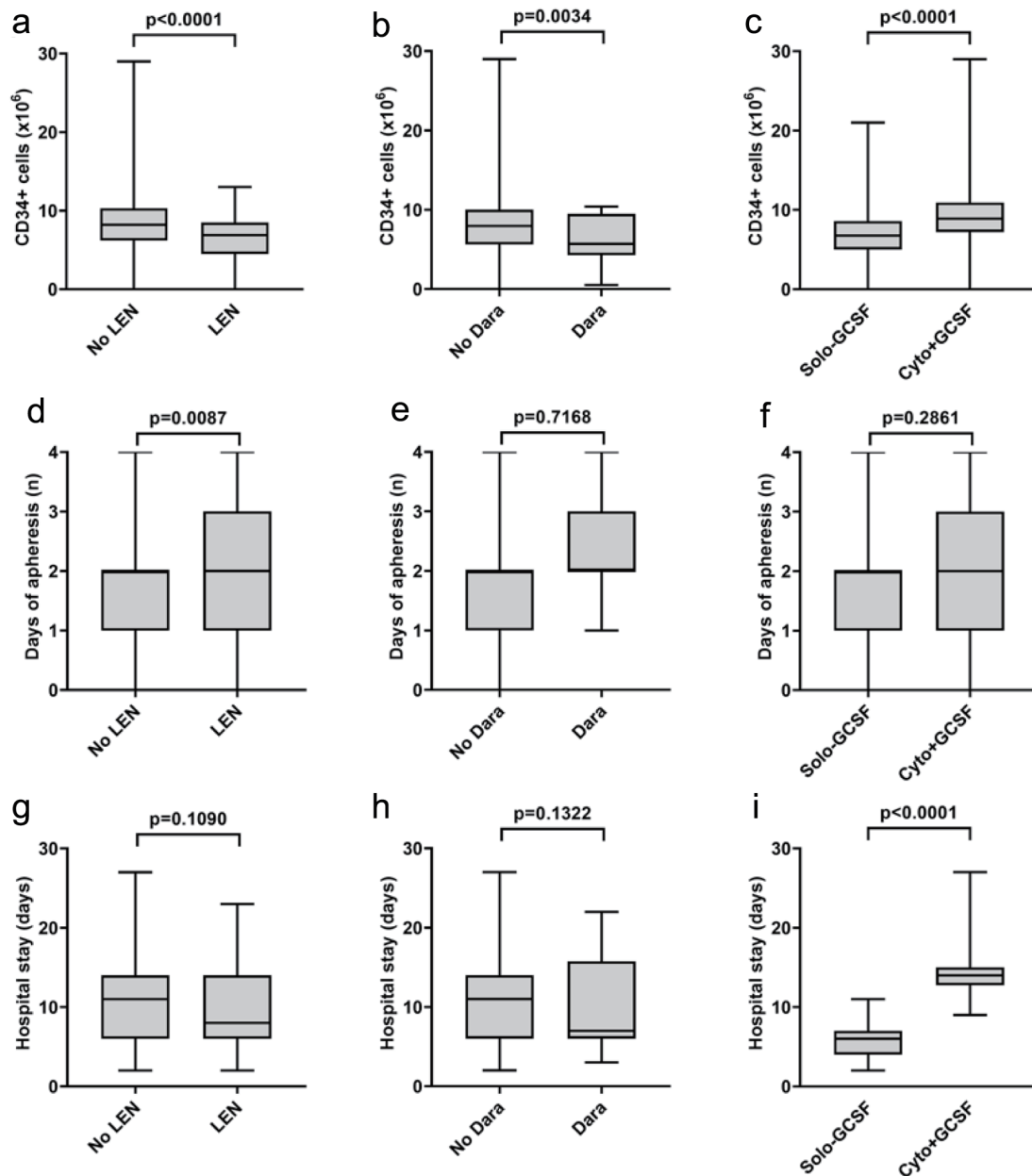


Figure 1. The effect of LEN, Dara and mobilization strategy on the amount of bone marrow stem cells collected (a-c), the number of days of apheresis (d-f) and the length of hospital stay (g-i). LEN: lenalidomide; Dara: daratumumab; G-CSF: granulocyte colony-stimulating factor.

mide, etoposide, cytarabine or combination therapies (e.g., PACE). This strategy can be recommended for heavily pre-treated patients with active disease, as more potent mobilizing effects can be achieved. The beneficial effect of chemotherapy on the underlying disease during stem cell collection for patients with MM is a matter of debate [8]. Steady-state mobilization is accompanied with lower toxicities as only G-CSF is administered. Plerixafor, a selective and reversible CXCR4 inhibitor, can be added to the therapy if the primary mobilization seems to be ineffective [9]. However, several studies reported the superiority of chemotherapy-based mobilizations

in terms of the harvested stem cell amounts and the number of successful attempts [10]. Formerly, intermediate-dose cyclophosphamide treatment followed by G-CSF was our first choice when we indicated stem cell mobilization in our MM patients. However, coronavirus disease 2019 (COVID-19) pandemic forced us to change our strategy, as the avoidance of therapies associated with possible infectious complications and long-term hospital stays were crucial. Therefore, we began to prefer steady-state mobilization from 2020. Our goal was to compare the efficacy and cost-effectivity of the two mobilization strategies in a retrospective way.

Half of our patient population received chemotherapy-based treatment, while the other half was administered G-CSF alone. In the chemotherapy group, the harvesting procedure was more effective considering the number of collected stem cells and the ratio of unsuccessful attempts. Our results indicate that chemotherapy produced a significantly higher harvest of the amount of stem cells than solo G-CSF. Both approaches provided a conveniently sufficient amount of product to store. Also, with both approaches, we were able to collect multiple times the minimum number of stem cells required for AHSCT by the IMWG guidelines [4]. Not surprisingly, hospitalization was significantly longer, and infectious complications were more frequent with chemomobilization. However, only 13% of the patients required plerixafor administration, while this ratio was 45% in the G-CSF group. These results are in line with what reported in previous studies [11, 12]. On the other hand, financing issues can be also taken into account. An Italian study has recently reported on 50 patients who underwent stem cell mobilization, and found that chemo-free strategy was associated with lower costs [13]. On the other hand, a Chinese group found no significant difference between the efficiency of steady-state and chemotherapy-based mobilization approaches, while the more frequent plerixafor use resulted in a high financial burden when no chemotherapy was administered [14].

We also investigated the impact of induction therapies administered before the stem cell harvesting procedures. Lenalidomide is known to have a negative effect on stem cell mobilization, and our results are also in accordance with this finding. Daratumumab administration has been recently approved in the first-line therapy of transplant-eligible patients [15]. Results from pivotal studies confirmed that patients who received daratumumab-containing triplets are more likely to require plerixafor support upon the stem cell collection [15, 16]. Our preliminary data also showed that previous daratumumab treatment did not influence the success rate of stem cell harvesting procedure; however, the need for plerixafor administration was significantly higher and the amount of collected stem cells was significantly lower than in those patients who were daratumumab-naive.

The main limitation of this work is the patients included in the study were recruited from only one hematological center. Moreover, daratumumab is still not widely available in the first-line therapy of MM; therefore, a relatively low number of patients could receive it as part of the induction treatment. We think that adding data of other centers as well as including more patients treated with daratumumab may make our results more remarkable.

Conclusions

Our study is the first that highlights the negative impact of daratumumab pretreatment on the efficacy of stem cell collection. Our results support that chemotherapy-based mobilization strategies are still cost-effective, despite the higher rate of infectious complications and longer hospital stays. The results presented here also suggest that the reduced potential for mobilization expected both with lenalidomide and daratumumab

pretreatment and with solo G-CSF can be overcome by the administration of plerixafor. This recognition may motivate caretakers to choose a chemotherapy-free strategy with a lower risk of infections for the frail population, thereby bringing personalized medicine closer to MM patients.

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Conflict of Interest

None of the authors had any conflict of interest.

Informed Consent

No informed consent was required for retrospective data collection.

Author Contributions

Conceptualization, formal analysis, data curation, visualization, and writing original draft preparation: NOA, KF and LV; treatment of the patients, investigation and resources: NOA, KF, LIP, GK, AI and LV; supervision: LV; writing review and editing: NOA, KF, LIP and LV. All authors have read and agreed to the published version of the manuscript.

Data Availability

The authors declare that data supporting the findings of this study are available within the article.

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