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HAPLOIDENTICAL HSCT WITH FLUDARABINE, MELPHALAN 75MG/M2 AND 400 CGY TBI : A TOLERABLE CONDITIONING REGIMEN WITH LOW TOXICITY AND GOOD ANTI-LEUKEMIC ACTIVITY

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INTRODUCTION

- **Long-term data of haplo-HSCT from India has shown that day-100 non-relapse-mortality(NRM) is very high and its around 45% mainly due to multi-drug resistant(MDR) gram-negative infections and acute GVHD.**
- Fludarabine(160mg/m2), melphalan(75mg/m2) and total-body-irradiation(TBI) 400cGy (FluMelTBI400) have been previously shown to be effective RIC regimen for matched-related-donor(MRD) allogeneic SCT. This regimen was also associated with significantly less mucositis and infections.
- However, there is no data of this regimen in the setting of haploidentical HSCT.

AIM

To study the utility of **FluMelTBI400/PTCy50** as a conditioning regimen for haploidentical HSCT in the treatment of various hematologic malignancies.

METHOD

Design: Retrospective analysis.

Patients: Patients with Hematologic malignancies like ALL, AML, T-LBL, MPAL etc undergoing haploidentical HSCT.
Six (75%) patients were transplanted in CR1 and 2(25%) patients were in CR2

Main outcome measures: Overall survival (OS), event-free-survival(EFS), incidence of GVHD, and complications post HSCT.

RESULTS

- The study comprised of eight patients (three males and five females)
- The median age was 35yrs(range:19-50)
- There were three patients of AML, one Ph-positive ALL, one T-LBL, one MDS-EB2, one CML blast crisis and one B/myeloid MPAL.
- The median CD34 stem cell dose was 5.9 x 10-6/kg (range:3.4-7).
- All patients developed mucositis and grade 3-4 mucositis was seen 3(37.5%) patients.
- The median time to neutrophil engraftment was 16 days(range:12-21) and platelet engraftment was 17 days (range:12-26).
- No patient developed chronic GVHD to date.
- Two(25%) patients relapsed and are receiving salvage therapy.
- **Overall survival at a median follow-up of 20 months is 100% and EFS is 75%.**
- No patient developed graft failure, thrombotic-microangiopathy(TMA), or any other regimen-related-toxicity(RRT).

Patient	CIBMTR DRI	Bacterial infections	Chimerism at D+28	CMV reactivation	Other viruses	GVHD
Patient 1	High	-	100%	Day+25	-	Acute Grade II
Patient 2	Intermediate	*Pseudomonas aeruginosa*	100%	Day +30	-	-
Patient 3	High	CRK	100%	Day +60	-	-
Patient 4	High	*Elizabeth kingae*	99.40%	Day+ 28	-	-
Patient 5	-	-	100%	Day+41	HHV6	-
Patient 6	Very high	CRE	100%	Day+60	-	-
Patient 7	Intermediate	*E.coli, C.diffcile*	99.82%	No	-	-
Patient 8	High	Nil	99.61%	No	-	-

CRK- carbapenem resistant Klebsiella pneumoniae, CRE- carbapenem resistant E.coli
CIBMTR DRI- Center for International Blood and Marrow Transplant Research Disease risk index

CONCLUSIONS

- Flu/Mel/TBI400 is a safe and effective conditioning regimen for haploidentical HSCT, particularly **suited for limited-resources settings** due to **mild mucositis** and resultant low rates of gram-negative sepsis.
- It has a very low incidence of GVHD and relapse, hence **striking a fine balance between GVHD and Graft-versus-leukemia(GVL) effect**
- Needs further validation in a large cohort of patients

REFERENCES

Chen GL, Hahn T, Wilding GE, Groman A, Hutson A, Zhang Y, et al. Reduced-Intensity Conditioning with Fludarabine, Melphalan, and Total Body Irradiation for Allogeneic Hematopoietic Cell Transplantation: The Effect of Increasing Melphalan Dose on Underlying Disease and Toxicity. Biol Blood Marrow Transplant [Internet]. 2019 Apr 1;25(4):689–98

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