XX Congresso della Società GITMO

RIUNIONE NAZIONALE GITMO

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Strategie di desensibilizzazione nel paziente candidato a trapianto allogenico di CSE con DSA nel 2026: pro e contro

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Disclosures of Chiara Savignano

Company name	Research support	Employee	Consultant	Stockholder	Speakers bureau	Advisory board	Other

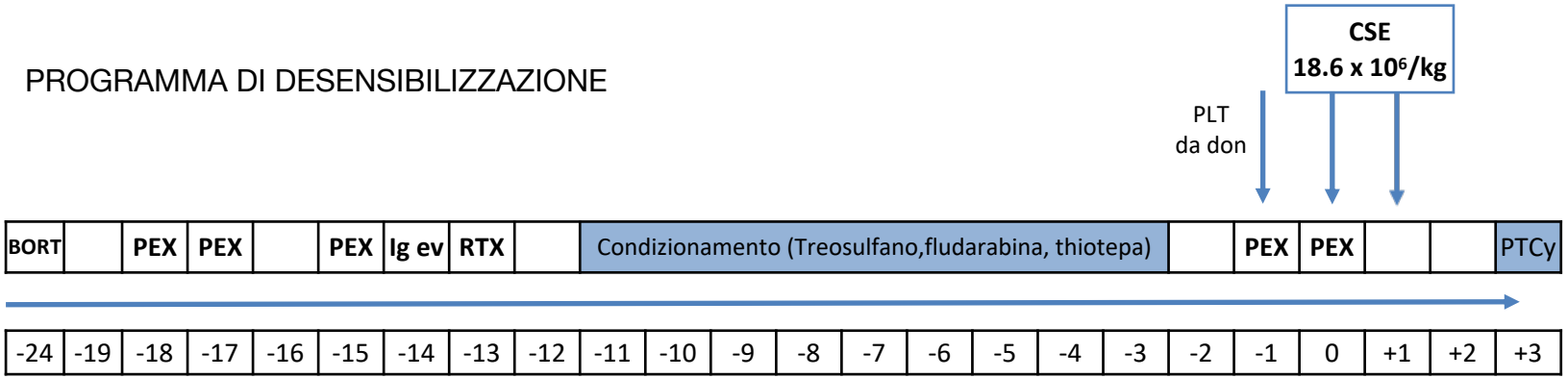
Nessun conflitto di interessi da dichiarare

Paziente 67 aa, candidata a trapianto allogenico di CSE
Diagnosi: Mielofibrosi idiopatica in fase blastica, CALR pos, TP53 mutata, WT1 iperespresso
Refrattaria a chemioterapia (2 cicli Azacitidina-Venetoclax)

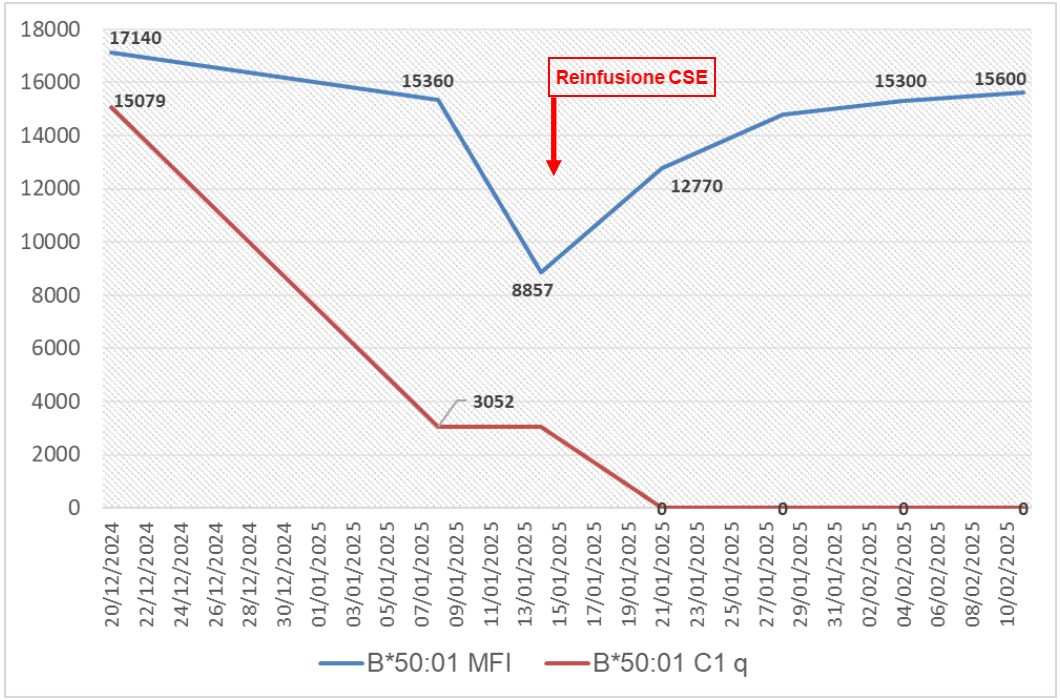
Work up pre-trapianto:
Presenza di Ab anti – HLA di classe I (SA 82%) e classe II (SA 74%)
Presenza di DSA classe I e/o II nei confronti di donatore MUD e dei 2 donatori APLO-id

Donatore selezionato:
Don familiare APLO-id (figlio, 34 aa), ABO incompat. maggiore (P 0 /D A),
DSA di classe I , B* 50:01 (MFI 20028)/ C1q positivo (MFI 15079)

PROGRAMMA DI DESENSIBILIZZAZIONE



MD Anderson Cancer Center: Desensitization approach for pts with DSA undergoing Haplo HSCT
Kongtim P et al, Advances in Hematology 2016



Evoluzione Clinica

primary graft failure
- PMN > 500 in + 33
- Piastrinopenia e anemia trasfusioni dipendenti

Supporto
- trasfusionale: 34 unità di EC , 65 AP
- G-CSF da + 7 a + 35

Complicanze infettivologiche:
infezione da Klebsiella pneumoniae ESBL
addensamento polmonare di ndd
Sindrome febbrile senza isolati
infezione da Clostridium difficile

Chimerismo:
- +30: 7.6% donatore (mo)
- +40: 3% donatore (sp)

Rivalutazione midollare:
+ 35 : presenza di blasti mieloidi pari al 18%

Fattori di rischio per sviluppo ab anti-HLA/DSA

Età, sesso F, parità, trasfusioni

Urgenza trapiantologica

Riscontro di DSA con elevato MFI per tutti i donatori testati

- MUD 7/8 (classe II)
- 2 donatori APLO (classe I)

Limitata efficacia terapia desensibilizzante per DSA con elevati MFI

Incidence of anti-HLA antibodies and DSA in allogeneic HSCT

Study	Donor type	N	MFI cutoff	Incidence of anti-HLA Ab	Incidence of DSA
Ciurea, et al. 2015	Haplo	122	> 500	NA	18%
Chang, et al. 2015	Haplo	345	> 500	25.2%	11.3%
Ma, et al. 2022	Haplo	3805	> 500	20.2%	NA
Gladstone, et al. 2013	Haplo	296	> 1000	23.0%	14.5%
Bramanti, et al. 2019	Haplo	135	> 1000	29.6%	14.1%
Carter, et al. 2022	Haplo	208	> 1000	32.7%	11.1%
Lima, et al. 2022	Haplo	59	> 1000	61.0%	18.6%
Liu, et al. 2023	Haplo	865	> 2000	NA	3,8%
Yoshihara, et al. 2012	Haplo	79	> 5000	20.2%	13,9%
Zhu, et al. 2023	Haplo	181	> 5000	NA	14.3%
Ciurea, et al. 2011	UD	516	> 500	19.0%	1.4%
Pan, et al. 2016	UD	123	> 500	37.4%	6.5%
Lima, et al. 2023	UD	303	> 1000	38.6%	3.6 %
Spellman, et al. 2010	UD	115	> 2000	37.0%	8.7%
Ruggeri, et al. 2013	CB	294	> 1000	21.0%	4.8%
Jo, et al. 2023	CB	567	> 1000	25.2%	3.5%

Haplo
DSA 11-18.6%

MUD
DSA 1.4-8.7 %

Impact of DSA on engraftement

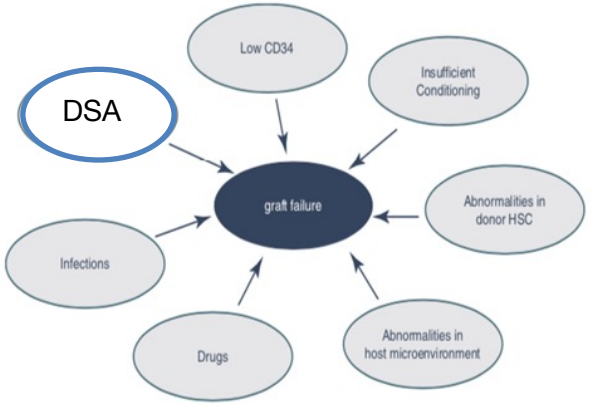


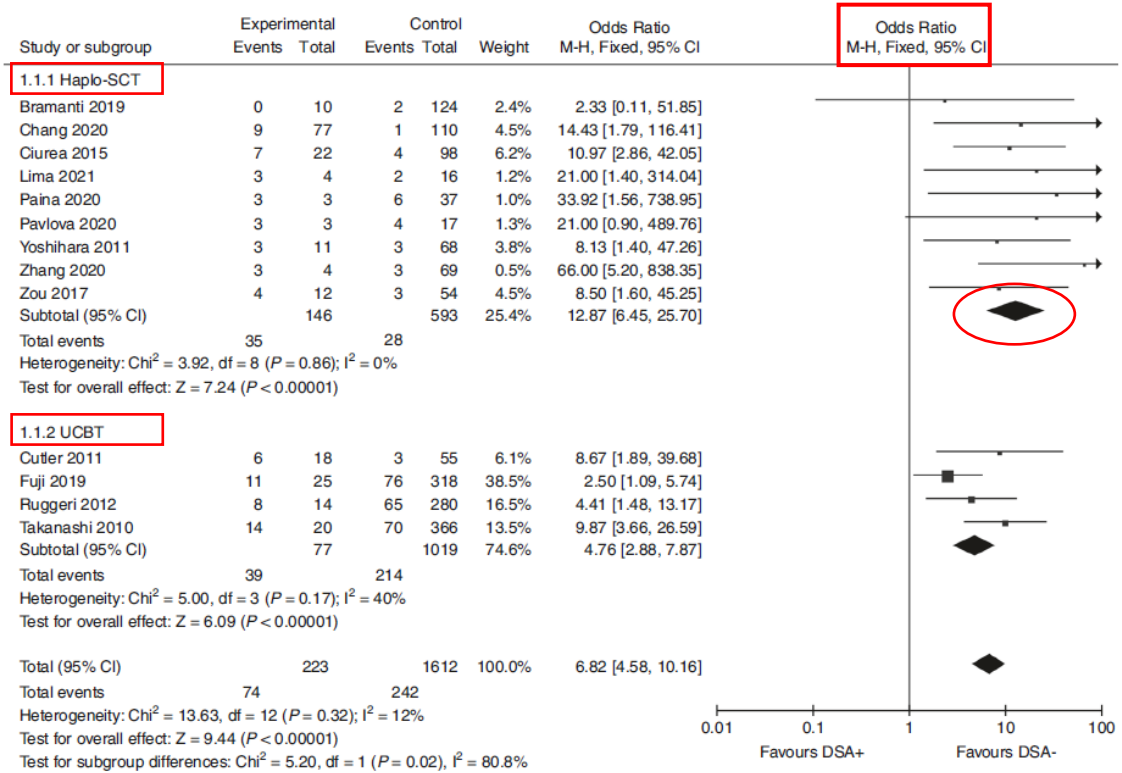
TABLE 1 | Studies of DSA impact in different settings in AHSCT.

Reference	Patients (*n*)	Stem cell source	Conditioning	Anti-HLA%	DSA%	Graft failure with/without DSA
Spellman et al. (34) 2009	115	Mismatched unrelated	RIC	ND	9	24 versus 1%
Ciurea et al. (36) 2011	592	10/10 and 9/10 unrelated	MACorRIC	19.6	1.4	37.5 versus 2.7%
Yoshihara et al. (39) 2012	79	Haplo-identical	RIC	20.2	14	27 versus 3%
Ciurea et al. (36) 2009	24	Haplo-identical	RIC	ND	21	60 versus 5%
Chang et al. (40) 2015	345	Haplo-identical	MAC	25.2	11.3	61% (MFI>10,000) versus 3.2%
Ciurea et al. (36) 2015	122	Haplo-identical	Non-specified	ND	18	32 versus 4%
Takanashi et a (41) 2010	386	Single CBU	MAC	23.1	5	83 versus 32%
Cutler et al. (4 2011	73	Double CBU	MACorRIC	ND	24	57 versus 5.5%
Ruggeri et al. (43) 2013	294	Single and double CBU	RIC	23	5	81 versus 44%
Yamamoto et al. (44 2014	175	Single CBU	MACorRIC	39.4	ND	50% if anti-HLA-C, DP, DQ, DRB1/2/3 versus 16%

Morin-Zorman et al. Front Immun, 2016

Effects of donor-specific antibodies on engraftment and long-term survival after allogeneic hematopoietic stem cell transplantation—A systematic review and meta-analysis

Yarui Huang[1,2,4], Chengxin Luo[1,2,4], Guixian Wu[1,2], Xiangtao Huang[1,2], Yaqun Ding[1,2], Zhen Huang[1,2], Jieping Chen[1,2]✉, Xi Li[3]✉ and Shuangnian Xu[1,2]✉



17 eligible studies were included, involving 2169 patients receiving haplo-SCT or UCBT.

DSAs-positive pts are associated with significantly higher risk of:

- **Graft failure (OR = 12.87, P < 0.00001)**,
- **poorer neutrophil engraftment (HR = 2.20**; P = 0.04)
- **worse OS** (HR = 3.19, 95%CI, 1.85–5.50; P < 0.0001; HR = 1.68, 95%CI, 1.04–2.71; P =

Huang et al,Bone Marrow Transplant 2023

DSA desensitization in Haploidentical and MM related Allo HCT

Reference	Donor type (*N*)	Anti-HLA abs test	Desensitization method	MFI post-treatment	Graft outcome
Barge 1989 [69]	Haplo ($N=1$)	CDC	Plasmapheresis	NA	Graft failure
Maruta 1991 [84]	Mismatched related ($N=1$)	AHG-CDC	CyA, Methylprednisolone, Plasmapheresis, DLI	Negative XM	Engrafted
Braun 2000 [85]	Haplo ($N=1$)	FCXM	Staphylococcal protein A immunoadsorption	Negative XM	Engrafted
Ottinger 2002 [91]	Mismatched related ($N=2$)	DTT-CDC	Plasmapheresis, mismatched platelet transfusion	1 patient with negative XM, 1 patient with positive XM	Patient with negative XM post-treatment engrafted, while patients with positive XM had GF
Pollack 2004 [86]	Mismatched HLA-A68 related ($N=1$)	FCXM	Platelet transfusion, plasmapheresis, IVIg	Negative XM	Engrafted
Narimatsu 2005 [92]	Mismatched related ($N=1$)	AHG-LCT	Rituximab, platelet transfusion	Negative AHG-LCT	Engrafted
Ciurea 2009 [13]	Haplo ($N=4$)	Luminex MFI > 500	Plasmapheresis + rituximab	One negative, 1 low titer, 2 high titer	Patients with DSAs negative and low titer post-treatment engrafted, 2 patients with high titer had GF
Yoshihara 2012 [37]	Haplo ($N=5$)	Luminex MFI > 500	Plasmapheresis + rituximab ($N=2$), platelet transfusions ($N=2$), bortezomib + dexamethasone ($N=1$)	One patient had temporary DSA reduction and 1 patient had significant reduction post plasmapheresis, 2 patients had a significant reduction post platelet transfusion, 1 patient had moderate DSA reduction after bortezomib and dexa.	All 5 patients engrafted
Ciurea 2015 [34]	Haplo ($N=12$)	Luminex MFI > 500	Plasmapheresis + rituximab, + IVIg ($N=5$), PE + rituximab + IVIg + donor "buffy coat" infusion ($N=7$)	No significant change of MFI before transplant. All patients cleared DSA after transplant.	5 patients with C1q positive post treatment had GF while patients who became C1q negative engrafted.
Leffell 2015 [87]	Haplo ($N=13$) MMUD ($N=2$)	Luminex MFI > 1,000	Plasmapheresis + IVIg + Tacrolimus	Mean reduction of DSAs post-treatment was 64.4%. 1 patient failed to reduce DSAs to the level that was thought to be safe for transplant.	14/14 patients engrafted by Day +60 7 pts had relapsed disease

The European Society for Blood and Marrow Transplantation (EBMT) Consensus Guidelines for the Detection and Treatment of Donor Specific Anti-HLA Antibodies (DSA) in Haploidentical Hematopoietic Cell Transplantation

Screening of HLA antibodies as routine test in alloHSCT work up

How do we identify anti-HLA antibodies?

- **Solid phase immunoassays (SPI**) performed on a conventional flow cytometer or a fluoroanalyzer **(Beads Based Immunoassay -Luminex**) enables the precise definition of anti- HLA antibodies and DSA and give semiquantitative value of antibody binding ability expressed as **MFI**
- **C1 q testing** is required for complement fixing DSA assessment
- DSA e C1q levels shoul be monitored before transplant , after desensibilization treatment and post infusion

Is there a DSA cutoff more detrimental to engraftment?

- MFI levels > 1000 : Positive for DSA
- **MFI levels > 5000 were associated with incresed incidence of Primary Graft Failure (aplo, MMUD)**
- MFI levels > 5000 correlate with the complement binding ability (C1q positivity)

Ciurea et al, Bone Marrow Transplant. 2018 May ; 53(5): 521–534

The European Society for Blood and Marrow Transplantation (EBMT) Consensus Guidelines for the Detection and Treatment of Donor Specific Anti-HLA Antibodies (DSA) in Haploidentical Hematopoietic Cell Transplantation

How do we treat patients with DSA before transplant?

Antibody removal

Plasmapheresis
Immunoadsorption

Inhibition of antibody production

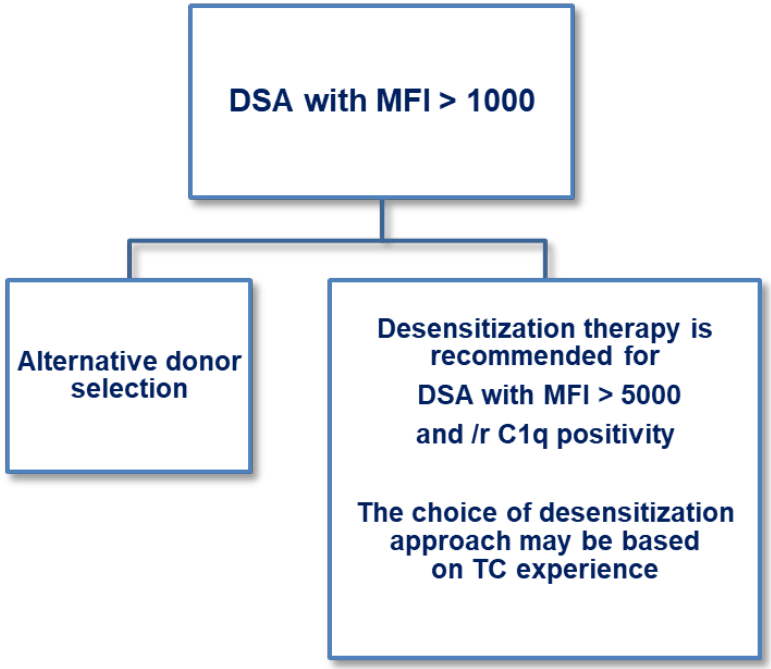
Rituximab
Bortezomib/Daratumumab
ISS therapy

Antibody neutralization

IV Ig
donor HLA antigens
(PLT , Buffy coat)

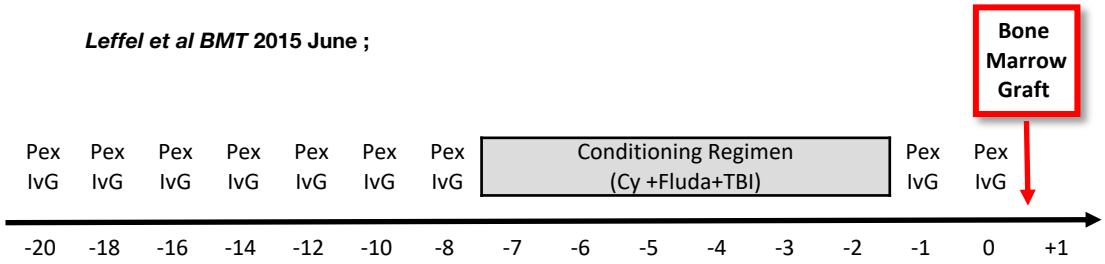
Complement cascade blockage

IV Ig
inhibition of complement cascade

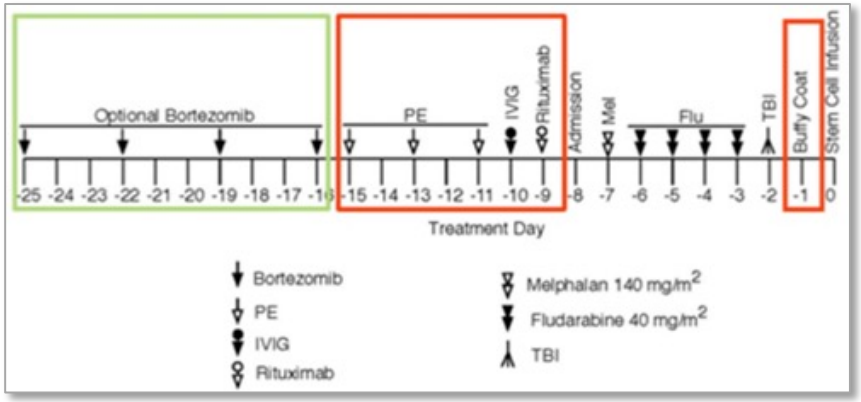


Ciurea et al, Bone Marrow Transplant. 2018 May ; 53(5): 521–534

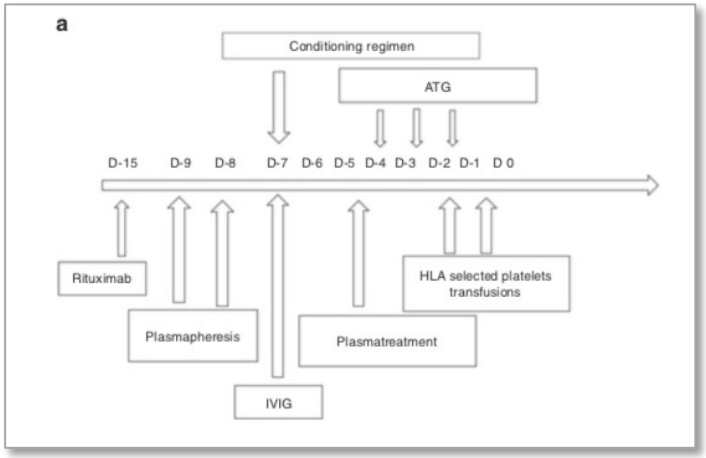
***Leffel et al BMT* 2015 June ;**



IVIG (100 mg/kg)
TAC 1 mg, i.v./day, MMF1gx2/day



Kongtim P, et al. Advances in hematology.2016



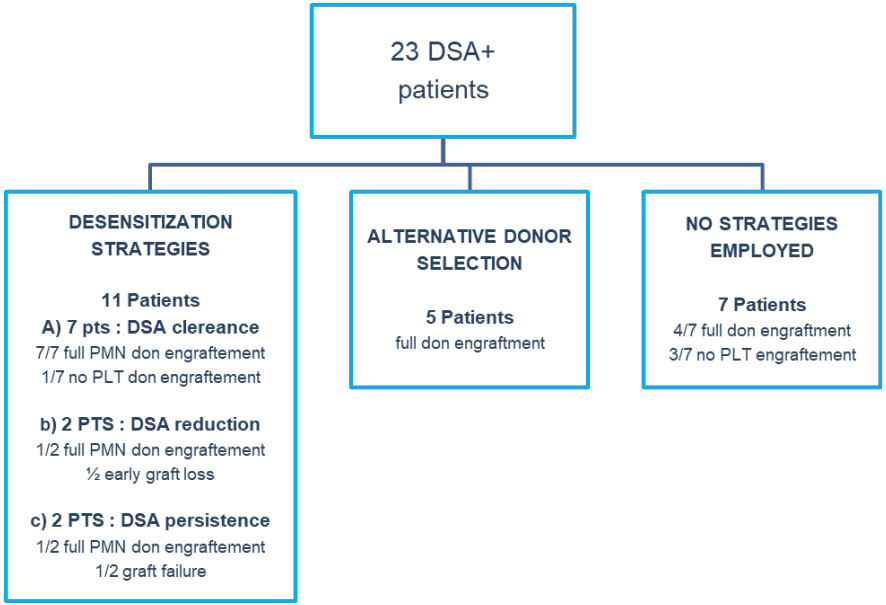
La Rocca U et al, BMT, 2019

Donor-specific anti-HLA antibodies (DSAs) in patients undergoing allogeneic hematopoietic stem cell transplantation from mismatched donors on behalf of GITMO and AIBT

Ursula La Rocca[1,*], Roberto Ricci[2], Alfonso Piciocchi[3], Walter Barberi[1], Elena Oldani[4], Alida Dominietto[5], Raffaella Cerretti[6], Alessandra Picardi[7,8], Francesca Bonifazi[9], Riccardo Saccardi[10], Maura Faraci[11], Giovanni Grillo[12], Lucia Farina[13], Benedetto Bruno[14], Anna Grassi[4], Anna Proia[15], Elena Tagliaferri[16], Giuseppina De Simone[17], Michele Malagola[18], Michela Cerno[19], Simone Cesaro[20], Paolo Bernasconi[21], Lucia Prezioso[22], Paola Carluccio[23], Nicola Mordini[24], Matteo Pelosini[25], Attilio Olivieri[26], Patrizia Chiusolo[27], Stella Santarone[28], Michele Cimminiello[29], Roberto Crocchiolo[22], Franco Papola[30], Gianni Rombolà[31], Nicoletta Sacchi[32], Valeria Miotti[33], Lia Mele[34], Benedetta Mazzi[35], Fabio Ciceri[36], Massimo Martino[37], Anna Paola Iori[1,*]

Desensitization Strategies

- RTX (-15), PEX (-9-8), IVIG-7, don Plt transfusion -1
- PEX (-10,-8.-1)
- Immunoadsorbtion
- RTX + PEX weekly x 4
- RTX + IVIG
- IVIG + Pts



Different MFI cut-offs were considered for desensitization therapy (MFI 1000-5000) according to the different Kit employed

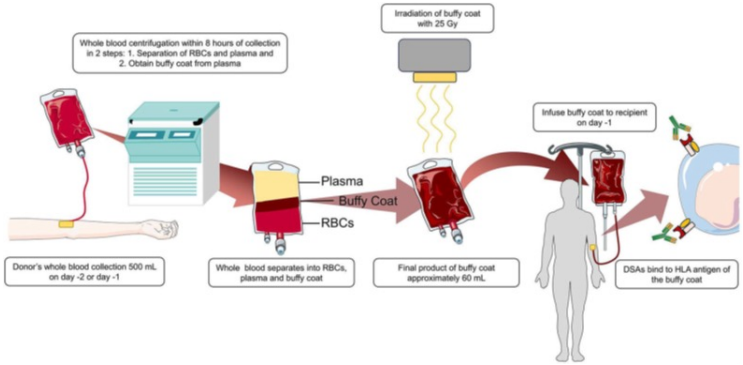
REGULAR ARTICLE

blood advances

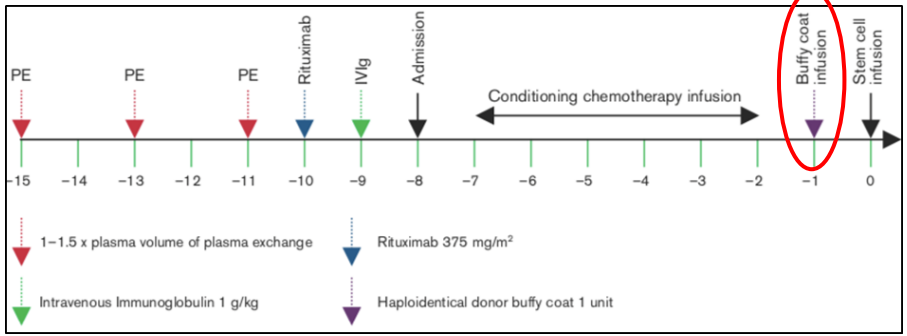
Treatment of allosensitized patients receiving allogeneic transplantation

Stefan O. Ciurea,[1,2,*] Monzr M. Al Malki,[3,*] Piyanuch Kongtim,[2] Jun Zou,[4] Fleur M. Aung,[4] Gabriela Rondon,[1] Julianne Chen,[1] Michiko Taniguchi,[5] Salman Otoukesh,[3] Auayporn Nademanee,[3] Stephen J. Forman,[3] Richard Champlin,[1] Ketevan Gendzekhadze,[5,†] and Kai Cao[4,†]

[1]Department of Stem Cell Transplantation and Cellular Therapy, The University of Texas MD Anderson Cancer Center, Houston, TX; [2]Hematopoietic Cell Transplantation and Cellular Therapy Program, Division of Hematology-Oncology, The University of California Irvine, Irvine, CA; [3]Department of Hematology and Hematopoietic Cell Transplantation, City of Hope, Duarte, CA; [4]Department of Pathology, The University of Texas MD Anderson Cancer Center, Houston, TX; and [5]HLA Laboratory, City of Hope, Duarte, CA



Study group: 37 pts with hematologic malignancy that received desensitization therapy prior to HaploSCT for DSA (years 2010-2019)
Control group: 345 pts without DSA who received a HaploSCT



Study group DSA	**37 pts**
DSA :	
Classe I	14 (37,8%)
Classe II	12 (32,4%)
Classe I e II	11 (29,7%)
Pre desensization DSA level MFI media (SD)	**10.198,2 (8618,6)**
Pts with MFI <10.000	21 (56,8%)
Pts with MFI 10.000-20.000	10 (27,0%)
Pts with MFI >20.000	6 (16,2%)
Pre desensization C1q positive pts	14 (46,7%)
Post desensitization DSA level MFI media (DS)	**5.937,2 (8.336,0)**
Post desensitization C1q positive pts	8 (27,6%)

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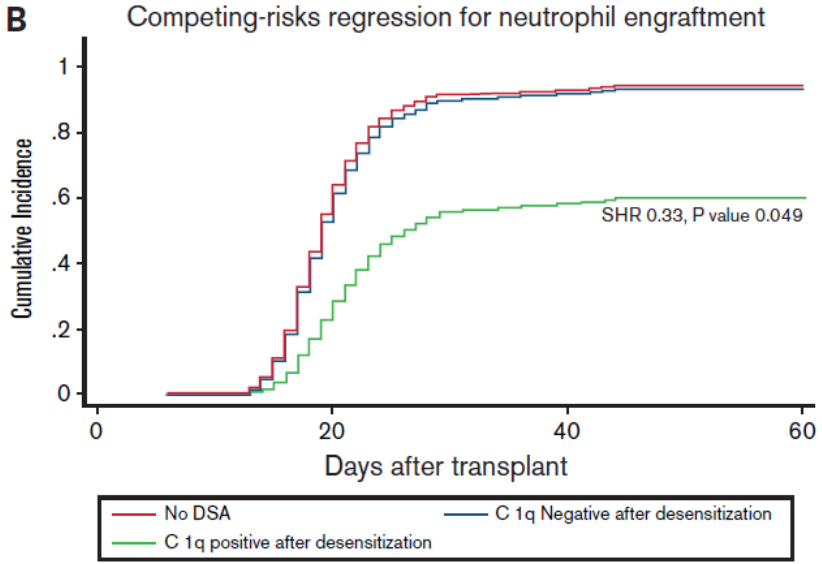
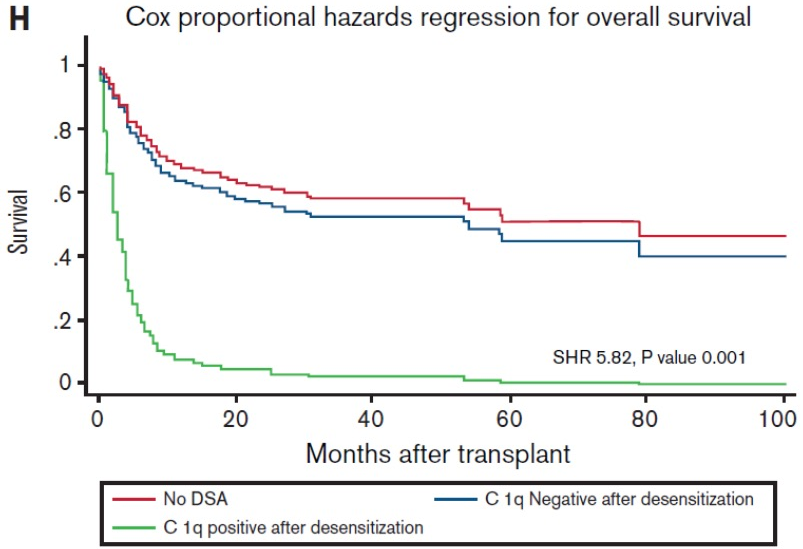
- **patients with DSA range < 20 000 MFI and negative C1q** after desensitization had rates of neutrophil engraftment comparable with controls
- **Patients with DSA levels > 20 000 MFI and persistent C1q** positivity at transplant have a higher risk of engraftment failure and poor survival.





Esperienza monocentrica CT Udine

Analisi retrospettiva: Gennaio 2016-Aprile 2022

- 11 Pz sottoposti a terapia di desensibilizzazione per alto titolo DSA pre allo_HSCT (7% pz sottoposti a aplo/mmMUD HSCT)
- 1M/10F, età mediana 60aa (55-68)
- Metodo rilevazione DSA: Luminex single antigen (Cut off di positività: 1.000 MFI)

DSA MFI (medio)

- Pre-desensibilizzazione 12.458 (2.795-24.200)
- Post-desensibilizzazione 6.608 (0-22.100)
- Engraftment 1012 (0-6200)

DSA Post desensibilizzazione

- Riduzione DSA >50% 6/11 (55%)
- DSA negativi 4/11 (36%)

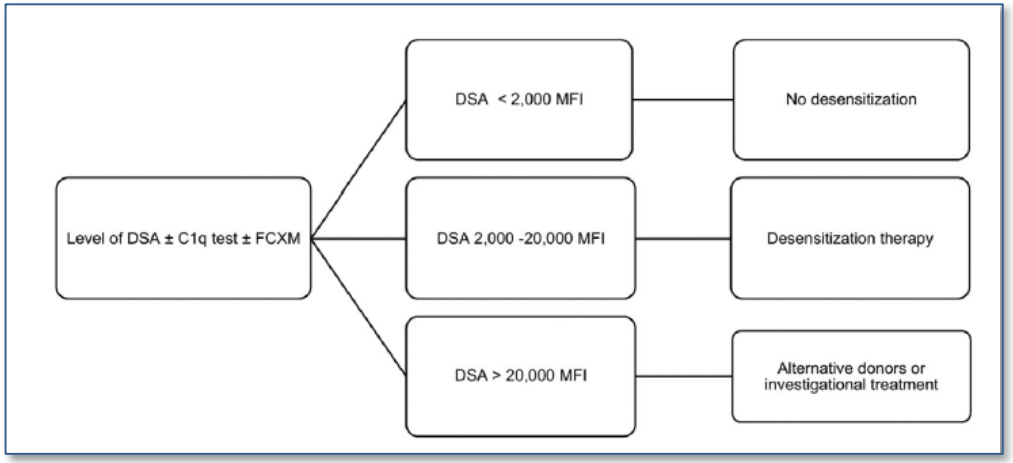
	Sesso	Tipologia trapianto	DSA	MFI pre	MFI post (infusione)	Engraftment
1	F	Aplo	Classe I (B)	9600	10500	si
2	F	Aplo	Classe I (A)	3700	650	si
3	F	Aplo	Classe I (A) Classe II (DRB1 DQB1)	**24200** (A) 10000 (DRB1) 16000(DQB1)	0 (A) 0 (DRB1) 10100(DQB1)	si
4	F	MUD (mmA)	Classe I (A)	3400	1100	si
5	M	Aplo	Classe II (DQB1 -DPB1)	2795(DQB1) 1047(DPB1)	0 (DQB1) 1100 (DPB1)	si
6	F	Aplo	Classe I (A- B)	17200(A) **22500**(B)	15900(B) 12100(A)	si
7	F	MUD (mmA)	Classe IA Classe II (DPB1)	9000(A) 3900(DPB1)	4600(A) 0 (DPB1)	si
8	F	Aplo	Classe I C	14390	10980	si
9	F	Aplo	Classe II (DRB1 DQB1)	**22700 (DRB1)** **13250(DQB1)**	16650(DRB1) 3050(DQB1)	no
10	F	MUD (mmA)	Classe I (A)	10800	0	si
11	F	Aplo	Classe II DR13 DQ6	**21900 (DR13)** **6450 (DQ6)**	22100(DRB1) 4600(DQB1)	no

Authors	N° of pts	Donor Type	Conditioning Regimen	GVHD prophyl.	HLA loci targeted	DSA level	Desensitization protocol	Outcomes
Choe et al. (2019)	14	Haplo-CBT	Flu + Mel + ATG ± TBI	CSA + MP	A/B/C/ DRB1/DPB 1	>2000	Bort (1.2 cycles) + IVIG*	All patients achieved initial hematopoietic recovery. The median time to engraftment for patients with successful desensitization was 11 days.
Ciurea et al. (2021)	37	Haplo-SCT	Flu-Mel (± TBI, thiotep) (70.3%) Flu-Bu (± TBI, thiotepa) (13.5%) Others (16.2%)	PT/Cy + Tac + MMF	NA	Median DSA level: 10,198	PEX (3 proced) + Rituximab + IVIG +donor buffy coat	100% engraftment for MFI < 5000 97% engraftment for MFI < 10000 95% engraftment for MFI < 20000 **50% engraftment for MFI > 20000**
Zhu et al. (2023)	19	Haplo-SCT	Bu/Cy or Bu/Flu plus ATG	CSA + stM TX + MMF	NA	>5000	Varied IVIG Ritux + IVIG + PLT trasfusion	Neutrophil engraftment was achieved in all patients. Survival rates were comparable in patients with and without DSAs.
Bailen et al. (2023)	63	Haplo-SCT	MAC (n = 32); RIC (n = 37)	PT/Cy + MMF + Tac or CSA	A/B/C/DRB1/ DQB1	>5000	Ritux+ IVIG + PE PLT trasfusion	**8 pts had primary GF despite desensitization**. **Baseline MFI > 20,000 was an independent risk factor for survival**, an increased titer after infusion was an independent risk factor for GF.
Liu et al. (2024)	155	Haplo-SCT	Bu/cy + ATG*	CSA + stM TX + MMF	A/B/DRB1	>2000	Ritux + UCB	T**he incidence of primary PGF and GR after desensitization was 6.5% and 0.6%, respectively**. DSA levels >5000 had an impact on efficiency of rituximab-based desensitization
Cochran et al. (2024)	14	Haplo-SCT	MAC	PT/Cy + MMF + Tac	A/B/C/DR/ DP/DQ	>2000	PE + IvIgG + R	**Desensitization before haplo-SCT produced similar outcomes to patients without DSAs.**

Guideline

ASTCT Consensus Recommendations on Testing and Treatment of Patients with Donor-specific Anti-HLA Antibodies

Piyanuch Kongtim[1], Pongthep Vittayawacharin[1], Jun Zou[2], Samer Srour[3], Brian Shaffer[4], Roman M. Shapiro[5], Ankur Varma[6], Joseph McGuirk[7], Bhagirathbhai R. Dholaria[8], Shannon R. McCurdy[9], Amy E. DeZern[10], Nelli Bejanyan[11], Asad Bashey[12], Sabine Furst[13], Luca Castagna[14], Jacopo Mariotti[15], Annalisa Ruggeri[16], Rebeca Bailen[17], Takanori Teshima[18], Huang Xiao-Jun[19], Carmen Bonfim[20], Fleur Aung[21], Kai Cao[21], Paul A. Carpenter[22], Mehdi Hamadani[23], Medhat Askar[24,25], Marcelo Fernandez-Vina[26], Alin Girnita[27], Stefan O. Ciurea[1,*]



Current evidence suggests that :

For DSA <2,000 MFI in haplo HSCT and <1,000 MFI in single CBT desensitization is not required.
(Levels of evidence

For DSA up to 20,000 MFI
plasmapheresis, rituximab, IVIG and infusion of donor-derived HLA antigen (donor irradiated buffy coat/ or platelet transfusions) are recommended

For DSA 2,000-10,000 MFI in haplo HSCT
or 1,000- 10,000 MFI in CBT,
additional data are needed to determine that patients can be treated with a lower intensity desensitization protocol (rituximab with IVIG)

For DSA >20,000 MFI,
an alternative donor without corresponding HLA should be selected, or else should be used an investigational approach.

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REVIEW

Desensitization Strategies for Donor-Specific Antibodies in HLA-Mismatched Stem Cell Transplan[illegible] and What

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TABLE 1 Reported use of daratumumab for DSA desensitization.

Study	Sex, age, diagnosis	Desensitization regimens	DSA MFI (range)	Graft source	Conditioning	Time to neutrophil engraftment (days)	Donor chimerism
Lipsitt et al.[4]	Female, 21 years Severe aplastic anaemia	*First course (Day −147 to 107)*: Bortezomib (6 doses) Rituximab (4 doses) TPE (5 sessions) *Second course (Day −93 to −10)*: Daratumumab (6 doses) Rituximab (2 doses), TPE with IVIg (8 sessions)	*Baseline*: 8000–25 000 *Pretransplant*: <1000–8000 *Post-transplant*: <2000	Haploidentical (related)	RIC (ATG, FLU, CY, TBI)	14	Day +28 100%
Li et al.[14]	Female, 36 years B-cell acute lymphoblastic leukaemia	Leukaemia therapy included 2 cycles of daratumumab combined with etoposide and venetoclax *Desensitization post daratumumab*: Prednisone (Day −7 to day 0) IVIg (0.5 g/kg, on day −2, −1)	*Baseline*: 14 776–19 606 *Post 2 cycles*: 6366–10 649 *Day 0*: 6141–12 144 *Day +7*: All negative	Haploidentical (related)	MAC (TBI, CY, FLU, ARA-C)	17	Day +28 100%
Ibrahim et al.[15]	Female, 60 years JAK2-mutated post essential thrombocythaemia myelofibrosis	*First course*: Rituximab TPE (3 sessions) *Second course*: Daratumumab (8 doses) *Third course*: Daratumumab (9 doses) Bortezomib (8 doses) Followed by TPE (7 sessions) with IVIg, and tacrolimus and MMF (Day −15 to −1)	*Baseline*: 18 600 *Post first course*: 7069 *Post second course*: 248 *12-week rebound*: 11 786 *Post third course*: 4921 *Day −1*: 534	9/10 HLA-matched unrelated donor	MAC (TT, BU, FLU)	25	Day +30, CD33 100% Day +60, CD3 100%

- La definizione e il perfezionamento dei protocolli di desensibilizzazione sono frutto di un lavoro multidisciplinare cui hanno partecipato ematologi, trapiantologici, immunogenetisti e trasfusionisti .

- Sono stati fissati i cut off di MFI associati a un incrementato rischio immunologico (>5000 MFI)
- Le esperienze pubblicate hanno evidenziato che per valori di MFI < 20000 **le strategie di desensibilizzazione sono in grado di ridurre il rischio di graft failure**
- Sulla base del razionale eziopatogenetico sono potenzialmente disponibili differenti categorie di farmaci da inserire nei programmi di desensibilizzazione

- Permangono dei limiti metodologici e di confrontabilità inter laboratorio dei risultati dei test impiegati per la determinazione dei DSA (Luminex)
- Non sono definiti precisi target di desensibilizzazione (DSA MFI)
- L' estrema variabilità dei protocolli in parte legata alle preferenze dei CT e alle caratteristiche del DSA (specificità, classe I -II, livello di MFI , capacità di fissare il complemento) rende difficilmente confrontabili i risultati dei vari studi clinici.

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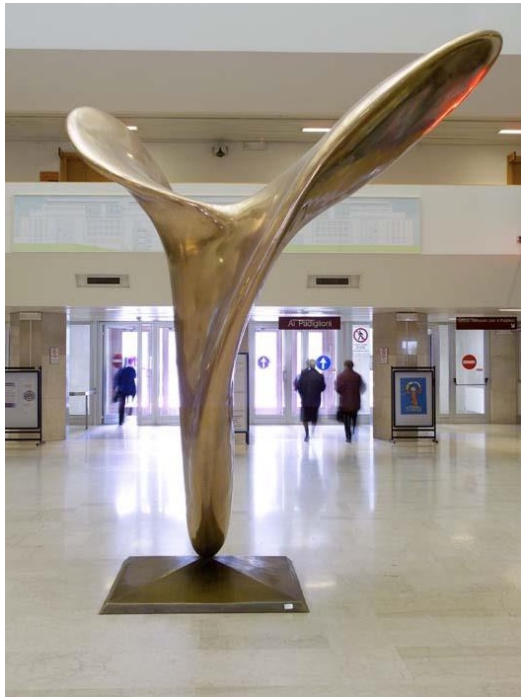

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