Indications and Results of Hematopoietic Stem Cell Transplantation for Hodgkin’s lymphoma

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Lymphoma WP Chair, EBMT

13th ESH-EBMT Training Course on HSCT
Latimer/May 2009
Advanced stages
Progress since 1940

- BEACOPP (1993-99)
- COPP+ABVD (1988-93)
- only alkylating agents (1965)
- no treatment (1940)
SCT for HL 1990-2005: Autologous SCT by year

Lymphoma registry May 2006

The European Group for Blood and Marrow Transplantation
SCT for HL 1990-2005: Allogeneic SCT by year

The European Group for Blood and Marrow Transplantation

The Lymphoma registry May 2006
## Allogeneic and autologous transplantation for haematological diseases, solid tumours and immune disorders: definitions and current practice in Europe

P Ljungman¹, A Urbano-Ispizua², M Cavazzana-Calvo³, T Demirer⁴, G Dini⁵, H Einsele⁶, A Gratwohl⁷, A Madrigal⁸, D Niederwieser⁹, J Passweg¹⁰, V Rocha¹¹, R Saccardi¹², H Schouten¹³, N Schmitz¹⁴, G Socie¹⁵, A Sureda¹⁵ and J Apperley¹⁶, for the European Group for Blood and Marrow Transplantation

<table>
<thead>
<tr>
<th></th>
<th>ASCT</th>
<th>Allo-SCT</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>HLA matched sib</td>
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<td>CR1</td>
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<tr>
<td>Sensitive relapse, ≥CR2</td>
<td>S</td>
<td>D</td>
</tr>
<tr>
<td>Refractory disease</td>
<td>CO</td>
<td>D</td>
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</table>

Bone Marrow Transplantation (2006), 1–11
SCT for HL 1990-2005: ASCT by Disease Status at SCT

Lymphoma registry May 2006

The European Group for Blood and Marrow Transplantation
SCT for HL 1990-2005: ASCT: Use of TBI in the Conditioning

Lymphoma registry May 2006

The European Group for Blood and Marrow Transplantation
### Current Indications for SCT in HL

**EBMT recommendations**

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**S.** Standard  
**CO.** Clinical option  
**D.** Developmental  
**NR.** Not recommended
ASCT vs salvage CT in HL patients in 1\textsuperscript{st} relapse. The BNLI prospective study.

- Bad prognosis HL (n = 40)
  - *Mini-_BEAM (x 3) (n = 20)* vs
  - *BEAM (n = 20)*
- No significant differences in TRM
- Significantly better PFS and relapse rate with the BEAM protocol

*Linch et al. Lancet, 1993*
Aggressive conventional chemotherapy compared with high-dose chemotherapy with autologous haemopoietic stem-cell transplantation for relapsed chemosensitive Hodgkin’s disease: a randomised trial

Norbert Schmitz, Beate Pfistner, Michael Sextro, Markus Sieber, Angelo M Carella, Matthias Haenel, Friederike Boissevain, Reinhart Zschaber, Peter Müller, Hartmut Kirchner, Andreas Lohri, Susanne Decker, Bettina Koch, Dirk Hasenclever, Anthony H Goldstone, Volker Diehl, for the German Hodgkin’s Lymphoma Study Group (GHSG) and the Lymphoma Working Party of the European Group for Blood and Marrow Transplantation (EBMT)

Lancet 2002; 359: 2065–71
Dexa-BEAM vs BEAM in relapsed HL (GHSG/EBMT trial)

- n = 161 with relapsed HL (early, late and multiple relapses)
- Dexa-BEAM (x 4) (n=73) vs BEAM (n = 88)
- Only chemosensitive patients were randomized (n = 117)
- 3-year PFS: 55% (BEAM) vs 34% (Dexa-BEAM), p = 0.019
- No significant differences in OS

Schmitz et al. Lancet, 2002
Dexa-BEAM vs BEAM in relapsed HL (GHSG/EBMT). DFS

Global series

Late relapses

Multiple relapses

Schmitz, Lancet 2002
Dexa-BEAM vs BEAM in relapsed HL (GHSG/EBMT). OS

Schmitz, Lancet 2002
## Current Indications for SCT in HL

**EBMT recommendations**

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**S. Standard**

**CO. Clinical option**

**D. Developmental**

**NR. Not recommended**
ASCT in primary refractory HL

- n = 175 (100M/75F)
- Age [median (range)]: 26.5 (16 – 55) years
- Lines of tx before ASCT:
  - 1 line: 75 pts
  - 2 lines: 100 pts
- Response rate after ASCT (CR/PR): 58%
- Toxic deaths: 14%
- Prognostic factors:
  - Interval dx – ASCT > 18 mo

ASCT in primary refractory HL

- n = 122
- Age [median (range)]: 27 (7 – 57) years
- Dx – ASCT [median (range)]: 14 (5 – 38) mo
- Lines of tx before ASCT:
  - 1 line: 51 pts
  - 2 lines: 71 pts
- CR after ASCT: 50%
- 100-day TRM: 12% (7 – 19)
- Prognostic factors:
  - B symptoms
  - Poor performance status

ASCT in primary refractory HL

ASCT in primary refractory HL

- n = 75 bx-proven PR (39M/36F)
- Age [median (range)]: 24 (12 – 48) years
- Lines of tx before ASCT:
  - 1 line: 42 pts
  - 2 lines: 33 pts
- Sensitive disease prior to ASCT: 48 pts
- 100-day TRM: 9%
- Prognostic factors:
  - Chemosensitivity to second line of tx before ASCT

The German experience with a high-dose sequential protocol

Josting, Ann Oncol 2005

PFS

OS

Josting, Ann Oncol 2005
ASCT in relapsed refractory HL

- n = 357
- Sex: 220M / 137F
- Age [median (range)]: 29 (8 - 66) yrs
- Dx - ASCT [median (range)]: 31.5 (9 - 224) mo
- Disease status at ASCT:
  - 2\textsuperscript{nd} CR: 181 (51%)
  - Untreated relapse: 14 (4%)
  - Sensitive relapse: 134 (37%)
  - Refractory relapse: 28 (8%)

\[ p = 0.00001 \]

\[ \text{TTF (\%)} \]

\[ \text{Time from ASCT (months)} \]

\[ 2\text{nd CR, n=181, 68\%±4\%} \]
\[ 
\]
\[ SR, n=147, 34\%±5\% \]
\[ RR, n=28, 11\%±6\% \]
## Current Indications for SCT in HL. EBMT recommendations

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S. Standard
CO. Clinical option
NR. Not recommended

**Note:**
- SR: Sensitive relapse
- CR1: Complete response 1
- CR2: Complete response 2
- NR: Not recommended
- S: Standard
- CO: Clinical option
- D: Developmental
- HLA: Human leukocyte antigen
- URD: Unrelated donor
High dose therapy with autologous stem cell transplantation versus conventional therapy for patients with advanced Hodgkin’s lymphoma responding to front-line therapy.

ASCT for bad-prognosis HD patients in 1st CR. Results of the prospective SNLG (SNLG HD III)

ASCT for bad-prognosis HD patients in 1st CR. Results of the prospective SNLG (SNLG HD III)

Proctor, Eur J Cancer 2002
Rational for an allo-SCT

- Avoid tumor contamination of the infused cells
- Exploit a beneficial graft-versus-lymphoma effect
## Current Indications for SCT in HL. EBMT recommendations

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| S. Standard      | D. Developmental |
| CO. Clinical option | NR. Not recommended |
SCT for HL 1995-2005: Type of SCT by year

The European Group for Blood and Marrow Transplantation
There seems to be a clinically relevant graft-versus-HL effect clinically associated to the development of GVHD ......

\[ \text{Anderson et al. JCO 1993} \]

\[ \text{Akpek et al. JCO, 2001} \]
Milpied et al. JCO, 1996

Gajewsky et al. JCO, 1996

.... but classically, conventional allo-SCT has been associated to a high TRM (50%)
SCT for HL 1990-2005: Allogeneic SCT by year

Lymphoma registry May 2006

The European Group for Blood and Marrow Transplantation

RIC  Conventional CR

Lymphoma registry May 2006
SCT for HL 1990-2005: Allo-SCT NRM by year of SCT

Lymphoma registry May 2006

The European Group for Blood and Marrow Transplantation
RIC compared with conventional allogeneic SCT in relapsed or refractory Hodgkin's lymphoma

- n=190 1st allo-SCT 1997-2001 / Previous failed ASCT 46%
- Male sex 51%; median age 30 y (9-64)

<table>
<thead>
<tr>
<th></th>
<th>Conventional</th>
<th>RIC</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Period of SCT: 1997-1998 / 1999-2001</td>
<td>42% / 58%</td>
<td>16% / 84%</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Previous ASCT</td>
<td>44%</td>
<td>61%</td>
<td>0.03</td>
</tr>
<tr>
<td>Diagnosis – Allo-SCT (months)</td>
<td>31 (7 – 181)</td>
<td>40 (4 – 242)</td>
<td>0.01</td>
</tr>
<tr>
<td>Donor: HLA matched sib./MUD/Others</td>
<td>76% / 10% / 14%</td>
<td>78% / 12% / 9%</td>
<td>n.s.</td>
</tr>
<tr>
<td>Stem cell source: BM /PB</td>
<td>40% / 60%</td>
<td>15% / 85%</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>Chemorefractory disease at SCT</td>
<td>54%</td>
<td>56%</td>
<td>n.s.</td>
</tr>
<tr>
<td>Median Follow-up (months)</td>
<td>50 (12 - 94)</td>
<td>54 (17 – 109)</td>
<td>n.s.</td>
</tr>
</tbody>
</table>

### Outcomes after allograft

<table>
<thead>
<tr>
<th></th>
<th>Standard cond.</th>
<th>RIC</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>NRM</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3 mo</td>
<td>32% (24-43)</td>
<td>15% (10-25)</td>
<td></td>
</tr>
<tr>
<td>1-yr</td>
<td>48% (39-60)</td>
<td>25% (17-35)</td>
<td></td>
</tr>
<tr>
<td>3-yr</td>
<td>52% (43-63)</td>
<td>27% (19-37)</td>
<td>0.001</td>
</tr>
<tr>
<td><strong>Disease progression</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1-yr</td>
<td>25% (17-35)</td>
<td>45% (36-56)</td>
<td></td>
</tr>
<tr>
<td>3-yr</td>
<td>29% (21-40)</td>
<td>56% (47-67)</td>
<td>0.07</td>
</tr>
<tr>
<td><strong>PFS</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1-yr</td>
<td>27% (17-34)</td>
<td>30% (21-41)</td>
<td></td>
</tr>
<tr>
<td>3-yr</td>
<td>19% (11-26)</td>
<td>17% (9-25)</td>
<td>0.3</td>
</tr>
<tr>
<td><strong>OS</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1-yr</td>
<td>32% (22-42)</td>
<td>59% (48-68)</td>
<td></td>
</tr>
<tr>
<td>3-yr</td>
<td>22% (12-32)</td>
<td>34% (24-44)</td>
<td>0.01</td>
</tr>
</tbody>
</table>

Sureda et al. JCO 2008; 26: 455-62
RIC compared with conventional allogeneic SCT in relapsed or refractory Hodgkin's lymphoma

Estimate of the NRM and PFS based on a COX model, adjusted by all covariates with impact on the outcomes. RR and p values from multivariate Cox model.

SUREDA ET AL. J CLIN ONCOL. 2008; 26:455-62
Conventional allo-SCT vs RIC-allo in HL. Disease progression.

Sureda et al. JCO 2008; 26: 455-62
Conventional allo-SCT vs RIC-allo in HL. OS.

Refractory disease
Myeloablative conditioning
Previously failed ASCT
Donor ≠ HLA id sib or MUD
TBI-based (RIC group)

SUREDA ET AL. JCO 2008; 26: 455-62
Conventional allo-SCT vs RIC-allo in HL. Impact of cGVHD on outcome.

*Spontaneous cGVHD*

<table>
<thead>
<tr>
<th>Time after allo-SCT (months)</th>
<th>RR 1.89 (95% CI 1.02-3.49)</th>
</tr>
</thead>
<tbody>
<tr>
<td>3</td>
<td>0.0</td>
</tr>
<tr>
<td>12</td>
<td>0.2</td>
</tr>
<tr>
<td>21</td>
<td>0.4</td>
</tr>
<tr>
<td>30</td>
<td>0.6</td>
</tr>
<tr>
<td>39</td>
<td>0.8</td>
</tr>
<tr>
<td>48</td>
<td>1.0</td>
</tr>
<tr>
<td>57</td>
<td>1.0</td>
</tr>
<tr>
<td>66</td>
<td>1.0</td>
</tr>
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*p=0.04*

*Sureda et al. JCO 2008; 26: 455-62*
Conventional allo-SCT vs RIC-allo in HL. Impact of cGVHD on outcome.

Time after allo-SCT (months)

Sureda et al. JCO 2008; 26: 455-62
Conventional allo-SCT vs RIC-allo in HL. Impact of cGVHD on outcome.

Spontaneous cGVHD

\[ RR\ 1.57\ (95\%\ CI\ 0.91-2.72) \]

\[ p=0.1 \]

Sureda et al. JCO 2008; 26: 455-62
Which are candidates for an allo-RIC in HL at the present time?

<table>
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<th>Alvarez</th>
<th>Anderlini</th>
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<tbody>
<tr>
<td>27 pts</td>
<td>49 pts</td>
<td>40 pts</td>
<td>58 pts</td>
</tr>
<tr>
<td>37 (21-65) yrs</td>
<td>32 yrs</td>
<td>31 (16-53) yrs</td>
<td>32 (19-59) yrs</td>
</tr>
<tr>
<td>Flu-2Gys TBI</td>
<td>Flu-Mel</td>
<td>Flu-Mel</td>
<td>Flu-Mel/Cy</td>
</tr>
<tr>
<td>CsA+MMF</td>
<td>Campath 1H+CsA</td>
<td>CsA+Mtx</td>
<td>CsA+Mtx/MMF</td>
</tr>
<tr>
<td>5 (3-9) lines tx</td>
<td>5 (2-8) lines tx</td>
<td>4 (2-6) lines tx</td>
<td>5 (3-9) lines tx</td>
</tr>
<tr>
<td>92% RT</td>
<td>---</td>
<td>58% RT</td>
<td>75% RT</td>
</tr>
<tr>
<td>89% ASCT</td>
<td>73% ASCT</td>
<td>89% ASCT</td>
<td>83% ASCT</td>
</tr>
<tr>
<td>20 CS/7 CR</td>
<td>36 CS/13 CR</td>
<td>20 CS/20 CR</td>
<td>30 CS/28 CR</td>
</tr>
<tr>
<td>18 MSib/9 URD</td>
<td>31 MSib/18 URD</td>
<td>38 MSib/2 URD</td>
<td>25 MSib/33 URD</td>
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## Transplant Outcomes

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<tr>
<td>aGVHD</td>
<td>47% (MSD)/55% (UD)</td>
<td>16%</td>
<td>45%</td>
</tr>
<tr>
<td>cGVHD</td>
<td>50% (MSD)/60% (UD)</td>
<td>14%</td>
<td>45%</td>
</tr>
<tr>
<td>100-d TRM</td>
<td>7%</td>
<td>4.1%</td>
<td>12%</td>
</tr>
<tr>
<td>1-yr TRM</td>
<td>35%</td>
<td>16% (2 yr)</td>
<td>25%</td>
</tr>
<tr>
<td>PFS</td>
<td>11% (MSD)/35% (UD) (1 yr)</td>
<td>32% (4 yr)</td>
<td>32% (2 yr)</td>
</tr>
<tr>
<td>OS</td>
<td>39% (MSD)/75% (UD)</td>
<td>56% (4 yr)</td>
<td>48% (2 yr)</td>
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RIC Allo-SCT for Hodgkin’s disease: Identification of prognostic factors predicting outcome

- n=285 1st Allo-SCT 1997 - 2005 / Previous failed ASCT: 80%
- 57% males; median age: 31 years (18-57); 11% ≥ 45 years
- Median time from diagnosis: 41 months (4-332)
- Disease status at SCT:
  - 170 (60%) Chemosensitive disease
  - 115 (40%) Chemorefractory disease
- Conditioning: l.d.TBI based 17% / Flud + Alk agent 83%
- Donor: Matched sib. 60% / MUD 33% / Mismatched 7%
- Stem cell source: BM 20% / PB 80%
- T-cell depletion: ex vivo 4% / in vivo CAMPATH 25%
- Poor performance status at SCT: 10%
- Follow up living patients 26 months (3-94)

Robinson et al. Haematol 2009

LWP - Florence 2008 -
RIC Allo-SCT for Hodgkin’s disease: Identification of prognostic factors predicting outcome

Adverse Fc for NRM:
- age ≥ 45 years
- poor performance
- chemorefract disease

Risk of disease progression after 9 months of RIC according to the development of cGVHD (Landmark analysis)

No adv Fc (n=124)
1 adv Fc (n=91)
2-3 adv Fc (n=27)

NRM

Months after RIC

Robinson et al. Haematol 2009

LWP - Florence 2008 -
RIC Allo-SCT for Hodgkin’s disease: Identification of prognostic factors predicting outcome

PFS and OS for patients with chemosensitive disease and good performance status at SCT treated with a RIC SCT in the period 2002-2005 (n=104).

Robinson et al. Haematol 2009
Allogeneic Hematopoietic SCT in Children and Adolescents With Recurrent Hodgkin’s Lymphoma

- n=151 1st Allo-SCT 1987 - 2005 / Previous failed ASCT: 55%
- 44% M; Median age at diag: 15 years (2-18); Age at SCT: 17 y (4-21);
- Median time from diagnosis: 31 months (6-128)
- Disease status at SCT:
  - 81 (54%) Chemosensitive disease
  - 57 (38%) Chemorefractory disease
  - 13 (8%) Untested relapse or prog
- Conditioning: Myeloablative 61 (40%) / RIC 90 (60%)
- Donor: Matched sib. 63% / MUD 24% / Mismatched 13%
- Stem cell source: BM 43% / PB 57%
- T-cell depletion: ex vivo 9% / in vivo CAMPATH 12%
- Poor performance status at SCT: 14%
- Follow up living patients 25 months (2-154)

RIC regimens are associated with a lower NRM the first period after Allo-SCT (p=0.1), but are followed subsequently by an increased risk of progression, with a trend to a lower PFS.

Analysis of risk factors for outcomes after UCB transplantation in adults with lymphoid malignancies

- n=104 Unrelated CB transplants 1996-June 2007
- NHL n=62 (DLBCL 18; FL 11; MCL 8; PTCL 8)/ HL n=29 / CLL n=13
- 52% males; median age: 41 years (16-65) / weight at SCT: 68 kg (39-130)
- Median time from diagnosis: 35 months (16-65)
- Previous ASCT: 60%
- Disease status at SCT:
  - 44 (42%) Chemosensitive disease
  - 60 (48%) Chemorefractory disease
- Conditioning: Myeloablative 36 (36%) / RIC 63 (64%)
- One UCB unit 78 (75%) / Two UCB units 26 (25%)
- Mismatched at 2 HLA disparities in 61%
- Median TNC infused: 2.5 x10E7/kg / Median CD34+ cells: 1.05 x10E5/kg
- Follow up living patients 14 months (3-74)

Arrais et al. JCO 2009
Analysis of risk factors for outcomes after UCB transplantation in adults with lymphoid malignancies

- n=104 Unrelated CBT 1996-June 2007
- NHL n=62 / HL n=29 / CLL n=13
- Neutrophil engraftment at day 60: 85%
- a GVHD at day 100: 24%
- Relapse or progression
  - n=104 Unrelated CBT 1996-June 2007
  - NHL n=62 / HL n=29 / CLL n=13
  - Neutrophil engraftment at day 60: 85%
  - a GVHD at day 100: 24%
  - NRM at 1 year: 28%
  - Relapse or prog at 1 y: 31%
  - PFS at 1 y: 41%
  - Overall survival at 1 y: 47%

Arrais et al. JCO 2009

PFS

Arrais et al. JCO 2009

LWP - Florence 2008 -
Take-home messages (I)

• No significantly better salvage therapy regimen before ASCT, PB is the most frequently used source of stem cells, chemotherapy containing regimens the most frequently used as conditioning protocols.

• ASCT is the standard of treatment for patients with HL in chemosensitive relapse.

• Results in chemorefractory disease (both primary refractory and resistant relapse) are clearly worse. It can be considered a therapeutical option in some patients after discussing risks / benefits. New strategies have to be developed for these subgroups of patients.

• No indication for an ASCT in 1st CR.
Take-home messages (II)

- Allo-SCT is still to be considered an experimental procedure in relapsed HL patients.
- Conventional allo-SCT is associated with a high TRM.
- The use of RIC protocols allow a significant reduction in TRM with respect to conventional treatment that leads to an improvement in OS / PFS in this subgroup of patients.
- There is a clinically significant graft versus HL effect in the setting of allo-SCT clinically associated to the development of GVHD after allo-SCT.
- When considering a patient candidate for an allo-SCT, no differences between MUDs and HLA id sibs
4th Lymphoma Working Party Educational Course

‘Haematopoetic Stem Cell Transplantation and Lymphomas’

6th - 7th November 2008
SOFIA - BULGARIA

• Agenda • Grants • Applications

The European Group for Blood and Marrow Transplantation