Plerixafor in Stem Cell Mobilization – Slovenian Experience

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SLOHEM Podčetrtek
April 12, 2013

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Mobilization in Hematology

High dose chemotherapy +/- radiation therapy in NHL, MM, HL require subsequent SCT,

Classical source of SCT is peripheral blood,

Single agent (G-CSF) or chemomobilization fails in 5-40% cases,

Plerixafor is a novel CXCR4 chemokine-receptor antagonist for autologous HSC mobilization,

FDA 2008, EMEA 2009 approval.
Mobilization aims

Minimum CD34+ yield is $2 \times 10^6$ CD34+ cells/kg,

Higher doses lead to faster neutrophil and platelet recovery,

Risk factors for suboptimal HSC mobilization:

- Progressive disease,
- Older age >60,
- Previous chemotherapy and radiotherapy,
- Previous failed mobilization,
- Fludarabine, melphalan, lenalidomide previous therapy,
- Platelet count $< 100 \times 10^9$/L,
- Neutropenic fever during mobilization.
Mobilization strategies

Single agent G-CSF:
- Disrupts adhesion molecules (c-kit, CXCR4, SDF-1),
- Dose 10 $\mu$g s.c. daily five days,
- Mild toxicity profile,
- NHL/HL/MM – 26.8/26.4/6.6% failures, respectively.

Chemotherapy +/- G-CSF:

Compensatory neutrophil production after myelosuppression,
Reduces tumor burden and enhances stem cell mobilization.
Plerixafor

Small bicyclam molecule,
Reversibly and selectively antagonizes the CXCR4 chemokine receptor,
Blocks binding of SDF-1 (stromal cell-derived factor-1-a),
Peak concentration 30-60 min, dose 240 μg/kg,
Combined with G-CSF mobilization is enhanced,
Peak CD34+ cell concentration following 10-14 h,
Safe and well tolerated.
Dosing and reconstitution

The recommended dose of Mozobil (plerixafor) is 0.24 mg/kg body weight/day. It should be administered by subcutaneous injection 6 to 11 hours prior to initiation of apheresis following 4 days pre-treatment with G-CSF. In clinical trials, Mozobil has been commonly used for 2 to 4 (and up to 7) consecutive days. Based on increased exposure with increased body weight, the Mozobil dose should not exceed 40 mg/day.

Method of administration:
- Mozobil is administered by subcutaneous injection
- Each vial of Mozobil is intended for single use only
Mozobil + G-CSF increases predictability of apheresis yield and timing\textsuperscript{18,25,26}

In a pharmacodynamic study in healthy volunteers (n=3) of Mozobil + G-CSF administered at identical dose regimen to that in patient studies, a sustained elevation in the peripheral blood CD34+ count was observed from 4 to 18 hours after Mozobil administration with peak response between 10 and 14 hours\textsuperscript{26}.

\textit{Figure: Mobilisation of Peripheral Blood CD34+ Cells After Administration of Mozobil + G-CSF\textsuperscript{26}}

[Adapted from Liles WC et al, 2003]
Stem cell mobilisation in Non-Hodgkin’s Lymphoma (NHL)

- Enhanced stem cell mobilisation with Mozobil + G-CSF vs G-CSF alone\(^{18}\)
- Prompt and durable engraftment

Figure: Kaplan Meier Estimate of the Percentage of NHL Patients Who Achieved ≥ 5 × 10^6 CD34+ Cells/kg by Apheresis Day\(^{17}\)
[Adapted from DiPersio JF et al, 2009]

Multicentre, double-blind, placebo-controlled, comparative study randomised 298 subjects with NHL, 150 to Mozobil + G-CSF and 148 to placebo + G-CSF.
Stem cell mobilisation in Multiple Myeloma (MM)

• Significantly enhanced stem cell mobilisation with Mozobil + G-CSF versus G-CSF alone\textsuperscript{18}

• Prompt and durable engraftment

Figure: Kaplan-Meier Estimate of the Percentage of Multiple Myeloma Patients Who Achieved $\geq 6 \times 10^6$ CD34+ Cells/kg by Apheresis Day\textsuperscript{19}  
[Adapted from DiPersio JF et al, 2009]
Mozobil in combination with G-CSF increases day 1 collection (NHL)

- More NHL patients collect sufficient cells in fewer apheresis days with Mozobil + G-CSF compared to placebo + G-CSF\textsuperscript{17}

\textbf{Figure: Kaplan-Meier Estimate of the Percentage of NHL Patients Who Achieved $\geq 2 \times 10^6$ CD34+ Cells/kg by Apheresis Day}\textsuperscript{17}
[Adapted from DiPersio FJ et al, 2009]
Mozobil in combination with G-CSF increases day 1 collection (MM)

- Mozobil + G-CSF mobilises more cells, more quickly in MM patients than placebo + G-CSF\textsuperscript{19}

Figure: Median Number of CD34+ Cells Collected on Each Apheresis Day In Multiple Myeloma Patients\textsuperscript{19}
[Adapted from DiPersio FJ et al, 2009]
Failed collectors

- Patients failed ≥1 previous mobilisation attempts and are remobilised

Mozobil use in 1st mobilisation attempt

- Pre-emptive use: to prevent collection failure
- Pro-active use: to prevent poor mobilisation
- Difficult to mobilise patient populations

Failed mobilisers

- Patients with too low peripheral counts to proceed to apheresis

Poor/ slow/ mobilisers

- Patients unlikely to collect target yield in one apheresis (based on collection or peripheral count)

Mozobil use in 2nd line use: to ensure successful re-mobilisation

- Patients unlikely to collect target yield based on risk factors

Mozobil use in 1st mobilisation attempt

- Pre-emptive use: to prevent collection failure
- Pro-active use: to prevent poor mobilisation

Difficult to mobilise patient populations

- Patients unlikely to collect target yield based on risk factors

Pro-active use: to prevent poor mobilisation

- Mozobil use in 1st mobilisation attempt
- Difficult to mobilise patient populations

Failed collectors

- Patients failed ≥1 previous mobilisation attempts and are remobilised

Mozobil use in 2nd line use: to ensure successful re-mobilisation

- Patients failed ≥1 previous mobilisation attempts and are remobilised

Accelerate Mozobil adoption across Patient Segments
### Definitions of the four steps

<table>
<thead>
<tr>
<th>Step 1 - Failed collectors</th>
<th>Step 2 - Predicted failed collectors</th>
<th>Step 3 - Poor/slow mobilisers</th>
<th>Step 4 - Difficult to mobilise patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>- Patients who previously failed a mobilisation &amp; collection.</td>
<td>- Patients who are mobilised, but who have low PB CD34+ counts preventing them to proceed to apheresis.</td>
<td>- Patients who have poor collections on the 1st day of apheresis and/or have a low PB CD34+ cell count, (after the 1st day) making it unlikely to achieve a sufficient target yield to proceed to transplant unless significant apheresis efforts</td>
<td>- Patients who, based on risk factors are unlikely to collect the target yield (in the 1st day of apheresis)</td>
</tr>
<tr>
<td>- Patients need a complete re-mobilisation procedure in order to have a chance to collect a sufficient target yield to proceed to transplant</td>
<td>- Cut-off between &gt;10 and &gt;20 PB CD34+/microliter</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- Mozobil is used in 2nd line within a re-mobilisation setting
- Mozobil is used **pre-emptively** in 1st line to prevent collection failure
- Mozobil is used **pro-actively** to prevent poor mobilisation / mobilisation failure
Rescue Protocol

NHL n=298 patients from phase III (DiPersio) study, Pt. with <0.8 after two collections or <2.0 \times 10^6 CD34+/kg after four collections entered rescue protocol.

Micallef, BBMT 2009
A second chance to transplant

Table: Summary of Patients in Phase 3 Rescue Procedure for both NHL and MM

<table>
<thead>
<tr>
<th>Original Treatment</th>
<th>NHL Study\textsuperscript{17}</th>
<th>MM Study\textsuperscript{19}</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mozobil+ G-CSF</td>
<td>G-CSF+ Placebo</td>
</tr>
<tr>
<td>Total patients randomised</td>
<td>150</td>
<td>148</td>
</tr>
<tr>
<td>Consented to enter rescue</td>
<td>10</td>
<td>52</td>
</tr>
<tr>
<td>Collected $\geq 2 \times 10^6$ CD34+ cells</td>
<td>4</td>
<td>33</td>
</tr>
<tr>
<td>Proceeded to transplant</td>
<td>$6^{22}$</td>
<td>$46^{22}$</td>
</tr>
</tbody>
</table>

In both Phase 3 studies (in NHL\textsuperscript{17} and MM\textsuperscript{19} patients), patients who failed initial within study mobilisation (defined as failure to collect $2 \times 10^6$ CD34+ cells/kg in 4 days, or less than $0.8 \times 10^6$ CD34+ cells/kg after 2 days) were offered the option to enter into an open label rescue protocol with Mozobil + G-CSF.

- 55% (34/62) patients mobilised $\geq 2 \times 10^6$ CD34+ cells and had successful engraftment.
- Demonstrates the clinical benefit of Mozobil in failed mobilisers: giving patients a second chance to successfully collect a sufficient stem cells for transplant.
Rescue Protocol

Four/10 (40%) in plerixafor and 33/52 (63%) in placebo group mobilized >2 x10^6/kg CD34+.

Engraftment: Ne D+11, Plt D+20. All grafts durable after 12 months.

Data supports safe mobilization with plerixafor+ G-CSF after previous mobilization failure.

Micallef, BBMT 2009
Compassionate Use Program

Plerixafor available through compassionate use program to poor mobilizers,

European compassionate use program included 56 pt (MM=32, NHL=24),

75% successfully collected >2x $10^6$/kg CD34+ in median two apheresis,

In MM group 84% mobilized, including those with previous ASCT or lenalidomide treatment.

Duarte, BMT 20010
Heavily Pretreated

Thirty five patients (NHL=29, HL=6) classified as poor mobilizers,

Median no. of previous therapies three and previous no. of attempts two,

Thirteen (40%) patients collected >2 x10^6/kg CD34+ cells.
Clinical features of 35 poor mobilizer patients with lymphoma.

<table>
<thead>
<tr>
<th></th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. of patients</td>
<td>35</td>
</tr>
<tr>
<td>Median age</td>
<td>50 (range 19–70)</td>
</tr>
<tr>
<td>Male/female ratio</td>
<td>17/18</td>
</tr>
<tr>
<td>Histology</td>
<td></td>
</tr>
<tr>
<td>Diffuse large B cell lymphoma</td>
<td>13</td>
</tr>
<tr>
<td>Follicular lymphoma</td>
<td>6</td>
</tr>
<tr>
<td>Mantle cell lymphoma</td>
<td>3</td>
</tr>
<tr>
<td>Peripheral T cell lymphoma</td>
<td>2</td>
</tr>
<tr>
<td>T-angioimmunoblastic lymphoma</td>
<td>1</td>
</tr>
<tr>
<td>CNS lymphoma</td>
<td>1</td>
</tr>
<tr>
<td>Transformed splenic marginal zone lymphoma</td>
<td>1</td>
</tr>
<tr>
<td>Lymphoplasmocytic lymphoma</td>
<td>1</td>
</tr>
<tr>
<td>Anaplastic large cell lymphoma</td>
<td>1</td>
</tr>
<tr>
<td>Hodgkin’s lymphoma</td>
<td>6</td>
</tr>
<tr>
<td>Median number of previous lines of therapy</td>
<td>3 (range 1–5)</td>
</tr>
<tr>
<td>Previous radiotherapy</td>
<td>10</td>
</tr>
<tr>
<td>Previous radioimmunoconjugates</td>
<td>7</td>
</tr>
<tr>
<td>Previous purine analogues</td>
<td>4</td>
</tr>
<tr>
<td>Previous autotransplant</td>
<td>2</td>
</tr>
<tr>
<td>Median no. of previous attempts with +G-CSF</td>
<td>2 (range 1–3)</td>
</tr>
<tr>
<td>1 attempt</td>
<td>15 pts</td>
</tr>
<tr>
<td>2 attempts</td>
<td>16 pts</td>
</tr>
<tr>
<td>3 attempts</td>
<td>4 pts</td>
</tr>
<tr>
<td>Median CD34+ cells/mL attained with previous attempts</td>
<td>5/mL</td>
</tr>
</tbody>
</table>

Mobilization with plerixafor plus G-CSF in 35 poor mobilizer patients with lymphoma.

<table>
<thead>
<tr>
<th>Parameter</th>
<th>N</th>
<th>%</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median level of CD34+ cells/μL in PB following plerixafor</td>
<td>11</td>
<td></td>
<td>1.7–69</td>
</tr>
<tr>
<td>Pts reaching &gt;10 CD34+ cells/μL in PB</td>
<td>17</td>
<td>49</td>
<td>–</td>
</tr>
<tr>
<td>Pts reaching &gt;20 CD34+ cells/μL in PB</td>
<td>10</td>
<td>29</td>
<td>–</td>
</tr>
<tr>
<td>Median number of apheresis procedures</td>
<td>1</td>
<td></td>
<td>1–4</td>
</tr>
<tr>
<td>Median no. of CD34+ cells/kg collected</td>
<td>2.6</td>
<td></td>
<td>0.7–5.7</td>
</tr>
<tr>
<td>Pts collecting ≥2 × 10^6 CD34+ cells/kg</td>
<td>13</td>
<td>37</td>
<td>–</td>
</tr>
<tr>
<td>Pts collecting ≥4 × 10^6 CD34+ cells/kg</td>
<td>4</td>
<td>11</td>
<td>–</td>
</tr>
</tbody>
</table>

PB, peripheral blood.
Plerixafor Use After Autologous SCT

MM patients after autoSCT, n=30, control group n=46,

The MM group was significantly different regarding intensity and number of previous therapies,

In MM group 70% mobilized >2 x10^6/kg CD34+

Plerixafor + G-CSF might overcome negative prognostic factors.

Basak, Eur J Haematol 2011
Plerixafor in MM Patients with Advanced Renal Failure

Twenty MM patients and one prim. amyloidosis all with advanced renal failure,

All patients had previous mobilization attempt, four with plerixafor,

Fifteen pt. received reduced dose 0.16 mg/kg/day, six 0.24 mg/kg/day.

<table>
<thead>
<tr>
<th>a.m.</th>
<th>G-CSF</th>
<th>G-CSF</th>
<th>G-CSF</th>
<th>G-CSF</th>
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<th>G-CSF</th>
<th>G-CSF</th>
<th>G-CSF</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Dialysis</td>
<td></td>
<td></td>
<td></td>
<td>Dialysis</td>
<td>Apheresis (PBSC)</td>
<td>Apheresis (PBSC)</td>
<td>Apheresis (PBSC)</td>
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<tr>
<td>p.m.</td>
<td></td>
<td></td>
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</tr>
</tbody>
</table>

(For patients dialysing Mon/Wed/Fri)
(For patients dialysing Tues/Thurs/Sat)

Douglas, BMT 2012
Plerixafor in MM Patients with Advanced Renal Failure

Median dose of $4.6 \times 10^6$/kg was achieved,

Median two (1-4) apheresis were performed,

Only one patient failed to collect sufficient cell dose. Later underwent re-mobilization with 0.24 dose and collected $2.12 \times 10^6$/kg CD34+ cells,

Five patients had mild GIT symptoms,

Fifteen were transplanted, 12 remaining alive, two regaining endogenous renal function,

Plerixafor is highly effective in this patient population.
Plerixafor in Combination with Chemotherapy + G-CSF

Fourty patients (MM=26, NHL=24) were mobilized with conventional chemotherapy and G-CSF, Plerixafor can be safely added to chemotherapy based mobilization.

Dugan, BMT 2010
Plerixafor after Fludarabine and Lenalidomide Therapy

Fludarabine and lenalidomide have deleterious effect on stem cell mobilization,

Fludarabine (6 cycles) was used in 48 patients and lenalidomide (5 cycles) in 35 patients,

Median numbers of collected cells were $2.3 \times 10^6$ and $3.4 \times 10^6$/kg CD34+ cells,

In fludarabine group 58% and in lenalidomide group 69% of patients successfully mobilized.
Cost and Clinical Analysis
G-CSF+Plerixafor / G-CSF+Cy

Retrospective analysis (USA) of Cy 3-5 g/m² + G-CSF vs. plerixafor + G-CSF,

Thirty-three patients in each group were studied,

In Cy+G-CSF group 88% of patients started apheresis on scheduled day, 48% required weekend apheresis,

No differences in number of SC collected,

Median cost of mobilization was not different.

Shaughnessy, BBMT 2011
### Table 4. Mobilization and Apheresis Results

<table>
<thead>
<tr>
<th></th>
<th>Plerixafor/G-CSF</th>
<th>Chemo/G-CSF</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median total CD34&lt;sup&gt;+&lt;/sup&gt; cells × 10&lt;sup&gt;6&lt;/sup&gt;/kg, n (range)</td>
<td>10.7 (3.5-37.9)</td>
<td>11.6 (2.1-69.3)</td>
<td>.5</td>
</tr>
<tr>
<td>Number of patients collecting ≥2 × 10&lt;sup&gt;6&lt;/sup&gt; CD34&lt;sup&gt;+&lt;/sup&gt; cells/kg (%)</td>
<td>33 (100%)</td>
<td>33 (100%)</td>
<td>—</td>
</tr>
<tr>
<td>Number of patients collecting ≥5 × 10&lt;sup&gt;6&lt;/sup&gt; CD34&lt;sup&gt;+&lt;/sup&gt; cells/kg (%)</td>
<td>31 (94%)</td>
<td>25 (76%)</td>
<td>.04</td>
</tr>
<tr>
<td>Number of MM patients collecting ≥ 3 × 10&lt;sup&gt;6&lt;/sup&gt; CD34&lt;sup&gt;+&lt;/sup&gt; cells/kg (%)</td>
<td>13/13 (100%)</td>
<td>11/13 (85%)</td>
<td>.14</td>
</tr>
<tr>
<td>Number of MM patients collecting ≥ 6 × 10&lt;sup&gt;6&lt;/sup&gt; CD34&lt;sup&gt;+&lt;/sup&gt; cells/kg (%)</td>
<td>20/20 (100%)</td>
<td>18/20 (90%)</td>
<td>.49</td>
</tr>
<tr>
<td>Median number of apheresis days (range)</td>
<td>1 (1-4)</td>
<td>1 (1-4)</td>
<td>.45</td>
</tr>
<tr>
<td>Number of patients initiating apheresis on scheduled day (%)</td>
<td>33 (100%)</td>
<td>29 (88%)</td>
<td>.04</td>
</tr>
<tr>
<td>Number of patients requiring weekend apheresis (%)</td>
<td>0</td>
<td>16 (48%)</td>
<td>≤.0001</td>
</tr>
<tr>
<td>Total number of weekend apheresis procedures</td>
<td>0</td>
<td>19</td>
<td>≤.0001</td>
</tr>
</tbody>
</table>

Chemo indicates chemotherapy (cyclophosphamide 3-5 g/m<sup>2</sup>); MM, multiple myeloma; NHL, non-Hodgkin lymphoma; G-CSF, granulocyte-colony stimulating factor.

### Table 5. Mobilization Outcomes

<table>
<thead>
<tr>
<th></th>
<th>Plerixafor/G-CSF</th>
<th>Chemo/G-CSF</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Median G-CSF mcg dose/day (range)</td>
<td>780 (600-1440)</td>
<td>900 (480-1260)</td>
<td>.82</td>
</tr>
<tr>
<td>Median total number of G-CSF doses (range)</td>
<td>5 (4-8)</td>
<td>10 (6-17)</td>
<td>≤.0001</td>
</tr>
<tr>
<td>Median plerixafor dose mg/day (range)</td>
<td>16.8 (13.3-24.4)</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Median number of plerixafor doses (range)</td>
<td>1 (1-4)</td>
<td>—</td>
<td>—</td>
</tr>
<tr>
<td>Total number of mobilization-related hospitalizations (%)</td>
<td>0</td>
<td>19 (58)</td>
<td>≤.0001</td>
</tr>
<tr>
<td>Median days of stay for mobilization-related hospitalization</td>
<td>0</td>
<td>1 (0-2)</td>
<td>≤.0001</td>
</tr>
<tr>
<td>Total number of patients who received transfusions during mobilization (%)</td>
<td>0</td>
<td>4 (12.1)</td>
<td>.06</td>
</tr>
</tbody>
</table>

Chemo indicates chemotherapy (cyclophosphamide 3-5 g/m<sup>2</sup>); MM, multiple myeloma; NHL, non-Hodgkin lymphoma; G-CSF, granulocyte-colony stimulating factor.
Mobilization in Healthy Donors

Donors (n=25) were mobilized using plerixafor without G-CSF,

Two thirds of patients collected allograft after single dose of plerixafor,

Two patients (8.3%) were poor mobilizers (one collected 1.9 x10^6/kg CD34+ and the patient was transplanted).

Devine, Blood 2008
Mobilization in Healthy Donors

All transplanted patients (n=20) engrafted, median Ne D+10, Plt D+12,

aGvHD grades 2-4 occurred in 35%, one patient died,

Fourteen patients in remission had trilineage hematopoiesis after median 277 days,

Plerixafor may provide rapid mobilization in normal donors.

Devine, Blood 2008
Patient Data – UMC Ljubljana

- Period 2008-2011: 16 patients (11 m, 5 f), median age 57 years (21-71).

- Diagnosis: MM (13), LPI (1), MCL (1), Burkitt's lymphoma (1).

- Therapy response: CR 3, VGPR 4, PR 6,
Patient Data – UMC Ljubljana

- Previous chemotherapy (no. of pt.):
  - bortesomib 13,
  - irradiation 7,
  - cyclophosphamide 5,
  - purine analogues 3,
  - revlimid 3,
  - thalidomide 1.
Patient Data – UMC Ljubljana

- Patients with previous mobilization (n=10):
  G-CSF (6),
  G-CSF+cyclophosphamide (5),
  pegfilgrastim (4).

- A single patient collected >2x10^6 CD34+/kg.
Patient Data – UMC Ljubljana - year 2012

- Patient No: 8 (5 m, 3 f),
- Diagnosis: MM (4),
  Amyloidosis (2),
  LPI (1),
  NHL (1).
- Prior mobilization G-CSF (6),
  G-CSF+Cy (1),
  pegfilgrastim (1).
- Median CD34+ cell collected: 2,84 x10^6/kg (1.52-6.21).
CD34+ Mobilization with Standard vs. High Volume Apheresis

Table 1. Patient characteristics

<table>
<thead>
<tr>
<th></th>
<th>Plerixafor</th>
<th>Control</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Number of patients</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Multiple myeloma</td>
<td>45</td>
<td>178</td>
</tr>
<tr>
<td>Malignant lymphoma</td>
<td>21</td>
<td>60</td>
</tr>
<tr>
<td></td>
<td>24</td>
<td>118</td>
</tr>
<tr>
<td><strong>Median age (y)</strong></td>
<td>52</td>
<td>50</td>
</tr>
<tr>
<td><strong>Male/female</strong></td>
<td>24/21</td>
<td>109/69</td>
</tr>
<tr>
<td><strong>Median height (cm)</strong></td>
<td>170</td>
<td>172</td>
</tr>
<tr>
<td><strong>Median weight (kg)</strong></td>
<td>76</td>
<td>78</td>
</tr>
<tr>
<td><strong>Number of apheresis</strong></td>
<td>89</td>
<td>281</td>
</tr>
</tbody>
</table>
CD34+ Mobilization with Standard vs. High Volume Apheresis

Figure 1. A) CD34+ in PB prior to apheresis (baseline) and CD34+ collected;

Figure 1. B) Relative yield according to processed BV (SV or LV) in plerixafor and control group in 1st apheresis.
Thank You