Curing Myeloma
So Close and Yet So Far!

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What is cure after all?

- “Getting rid of it”? 
- “Stopping treatment without disease coming back”? 
- “Restoring life expectancy”?
Multiple Myeloma – Age at Diagnosis

Cumulative percentage of cases

Years

- White men
- White women
- Black men
- Black women

- 67
- 70
- 65
- 71
The majority of patients with MM had a life expectancy > 10 years prior to diagnosis.
Overall Survival (probability) vs Time (months)

- Median OS
  - R-ISS I: NR
  - R-ISS II: 83 months
  - R-ISS III: 43 months
The main challenge remains to improve long term relative survival for older patients.

Improvement in 5- and 10-year relative survival rate of patients diagnosed with myeloma in the US.

Multiple Myeloma, Circa 2017

- Treatment initiation dictated by presence of morbidity
- Therapy anchored on proteasome inhibitors, IMIId and corticosteroids
- Treatment stratification based mostly in age
- “One size fits all” treatment approach
- Success defined by improvement in surrogates of gross disease
- Continuous therapy until failure/intolerance
- Most patients will die from MM
Depth of response and outcome in MM

"Deeper" CRs, better outcome

Figure 1. Overall survival in CR patients treated with ASCT or Conventional chemotherapy.

Figure 2. Progression-free survival in CR patients treated with ASCT or Conventional chemotherapy.

Mina R et al. Blood 2015, abstract 927
# How to cure blood cancer?

<table>
<thead>
<tr>
<th>Blood Cancer Type</th>
<th>Use best agents upfront and make disease undetectable</th>
<th>Treat past undetectable point</th>
<th>Stop therapy</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>DLBCL</strong></td>
<td>R-CHOP x 2 to PET negative</td>
<td>R-CHOP x 4</td>
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<td><strong>Relapsed DLBCL</strong></td>
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<td>Induction to MRD negative</td>
<td>Consolidation</td>
<td>Observation</td>
</tr>
<tr>
<td><strong>CML?</strong></td>
<td>TKI, 2nd generation TKI(?) to MRD negative</td>
<td>TKI continuation</td>
<td>Observation and monitoring</td>
</tr>
</tbody>
</table>
“MRD” in curable blood cancers

AML - Standard risk

**A** Overall Survival

<table>
<thead>
<tr>
<th>MRD-negative</th>
<th>No. of Patients</th>
<th>No. of Events</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>MRD-negative</td>
<td>164</td>
<td>40</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>MRD-positive</td>
<td>30</td>
<td>21</td>
<td></td>
</tr>
</tbody>
</table>

Survival (%)

No. at Risk

<table>
<thead>
<tr>
<th>MRD-negative</th>
<th>164</th>
<th>144</th>
<th>116</th>
<th>77</th>
<th>39</th>
<th>8</th>
</tr>
</thead>
<tbody>
<tr>
<td>MRD-positive</td>
<td>30</td>
<td>18</td>
<td>10</td>
<td>5</td>
<td>3</td>
<td>2</td>
</tr>
</tbody>
</table>

Years since Entry

Sensitivity $10^{-5}$

Hodgkin Lymphoma

**Pediatric ALL**

**A** Event-Free Survival

<table>
<thead>
<tr>
<th>Time Since Diagnosis (years)</th>
<th>Patients</th>
<th>Events</th>
<th>5-year EFS</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 0.1</td>
<td>343</td>
<td>33</td>
<td>99.9% (1.7)</td>
</tr>
<tr>
<td>0.1% - 10%</td>
<td>382</td>
<td>73</td>
<td>79.3% (2.3)</td>
</tr>
<tr>
<td>≥ 10%</td>
<td>90</td>
<td>44</td>
<td>46.1% (5.5)</td>
</tr>
</tbody>
</table>

Event-Free Survival

<table>
<thead>
<tr>
<th>Time Since Diagnosis (years)</th>
<th>Patients</th>
<th>No. relapsed</th>
<th>5-year cumulative incidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 0.1</td>
<td>343</td>
<td>24</td>
<td>7.5% (1.5)</td>
</tr>
<tr>
<td>0.1% - 10%</td>
<td>382</td>
<td>62</td>
<td>17.5% (2.1)</td>
</tr>
<tr>
<td>≥ 10%</td>
<td>90</td>
<td>38</td>
<td>47.2% (5.9)</td>
</tr>
</tbody>
</table>

Cumulative Incidence

Time Since Diagnosis (years)
<table>
<thead>
<tr>
<th></th>
<th>NGS</th>
<th>Flow</th>
</tr>
</thead>
<tbody>
<tr>
<td>Require diagnostic sample</td>
<td>Yes</td>
<td>No</td>
</tr>
<tr>
<td>Applicability</td>
<td>92%</td>
<td>100%</td>
</tr>
<tr>
<td>Sensitivity</td>
<td>$10^{-5}$ to $10^{-6}$</td>
<td>$10^{-4}$ to $10^{-5}$</td>
</tr>
<tr>
<td>Number of cells required</td>
<td>&gt;1 million</td>
<td>&gt;5 million</td>
</tr>
<tr>
<td>Availability</td>
<td>Improving</td>
<td>Broad</td>
</tr>
<tr>
<td>Standardization</td>
<td>Done</td>
<td>Ongoing</td>
</tr>
<tr>
<td>TAT</td>
<td>Several days</td>
<td>Hours</td>
</tr>
</tbody>
</table>
Myeloma Kill and Response

- **PR** 50% kill
- **VGPR** 90% kill
- **CR** 95% kill
- **sCR** 99% kill
- **Neg 1st gen flow** 99.99% kill
- **Neg NGF** 99.999% kill
- **Neg NGS** 99.9999% kill
- **Cure?**
All patients in CR after transplant MFC with sensitivity of $10^{-4}$

MRD at pre-maintenance

P-value (trend) : p<0.0001

Months since randomization

N at risk (events)

$<10^6$  
$[10^6,10^7]$  
$[10^7,10^8]$  
$[10^8,10^9]$  
$[10^9,10^{10}]$

87  (0)  87  (0)  87  (2)  95  (2)  83  (9)  74  (4)  54  (3)  31  (0)  8
31  (0)  31  (1)  30  (2)  28  (0)  27  (4)  22  (1)  17  (2)  8  (1)  4
49  (0)  49  (2)  47  (2)  45  (2)  43  (7)  34  (4)  22  (6)  8  (0)  2
79  (0)  79  (9)  70  (11)  59  (9)  50  (11)  38  (6)  28  (9)  6  (3)  0
CR is only a good thing because of the MRD- cases

MRD conclusions

• Depth of remission matters

• CR is not enough- justification to treat pass CR

• NGS the most sensitive test

• MRD validated prognostic feature.

• No study ever performed utilizing MRD to determine subsequent therapy
Newer Agents
CASTOR - Study Design
Multicenter, randomized, open-label, active-controlled, phase 3 study

N = 498

Key eligibility criteria
- RRMM
- ≥1 prior line of therapy
- Prior bortezomib exposure, but not refractory

Stratification factors
- ISS (I, II, and III)
- Number of prior lines (1 vs 2 or 3 vs >3)
- Prior bortezomib (no vs yes)

DVd (n = 251)
Daratumumab (16 mg/kg IV)
Every week: Cycles 1-3
Every 3 weeks: Cycles 4-8
V: 1.3 mg/m² SC on Days 1, 4, 8, and 11 of Cycles 1-8
d: 20 mg PO-IV on Days 1, 2, 4, 5, 8, 9, 11, and 12 of Cycles 1-8

D only
Every 4 weeks: Cycles 9+

Vd (n = 247)
V: 1.3 mg/m² SC on Days 1, 4, 8, and 11 of Cycles 1-8
d: 20 mg PO-IV on Days 1, 2, 4, 5, 8, 9, 11, and 12 of Cycles 1-8

Obs only

Primary endpoint
- PFS

Secondary endpoints
- TTP
- OS
- ORR, VGPR, CR
- MRD

Statistical analyses
- Planned to enroll 480 patients
- Primary analysis: ~177 PFS events

Premedication for the DVd treatment group consisted of dexamethasone 20 mg, acetaminophen, and an antihistamine

DVd, daratumumab, bortezomib and dexamethasone; IV, intravenous; V, bortezomib; SC, subcutaneously; d, dexamethasone; PO, orally; VD, bortezomib and dexamethasone; D, daratumumab; Obs, observation; PFS, progression-free survival; TTP, time to progression; OS, overall survival; ORR, overall response rate; VGPR, very good partial response; CR, complete response; MRD, minimal residual disease; ISS, International Staging System.
Updated Efficacy

- Median (range) follow-up: 13.0 (0-21.3) months
- An additional 7% of patients receiving DVd achieved ≥CR with longer follow-up

Responses continue to deepen in the DVd group with longer follow-up

ITT, intent to treat.
Note: PFS: ITT population; ORR: response-evaluable population.

*Kaplan-Meier estimate.

^P <0.0001 for DVd versus Vd.
MRD rates by prior lines of therapy

ITT (N = 498)

<table>
<thead>
<tr>
<th>Sensitivity threshold</th>
<th>10^{-4}</th>
<th>10^{-5}</th>
<th>10^{-6}</th>
</tr>
</thead>
<tbody>
<tr>
<td>DVd</td>
<td>18.3</td>
<td>10.4</td>
<td>4.4</td>
</tr>
<tr>
<td>Vd</td>
<td>3.6</td>
<td>2.4</td>
<td>0.8</td>
</tr>
</tbody>
</table>

1 prior line (n = 235)

<table>
<thead>
<tr>
<th>Sensitivity threshold</th>
<th>10^{-4}</th>
<th>10^{-5}</th>
<th>10^{-6}</th>
</tr>
</thead>
<tbody>
<tr>
<td>DVd</td>
<td>23.0</td>
<td>12.3</td>
<td>5.7</td>
</tr>
<tr>
<td>Vd</td>
<td>3.5</td>
<td>2.7</td>
<td>1.8</td>
</tr>
</tbody>
</table>

- MRD was evaluated by ClonoSEQ-NGS-based assay in a central lab at three sensitivity thresholds, for patients with suspected CR and also for patients who maintain CR at C9 and C15.

MRD-negative rates for DVd were ≥3-fold higher across all thresholds.

***P < 0.0001; **P < 0.01; NS, not significant.
P values calculated using likelihood-ratio chi-square test.
MRD-negativity rate = proportion of patients with negative MRD test results at any time during treatment.
POLLUX - Study Design
Multicenter, randomized (1:1), open-label, active-controlled, phase 3 study

**Key eligibility criteria**
- RRMM
- ≥1 prior line of therapy
- Prior lenalidomide exposure, but not refractory
- Creatinine clearance ≥30 mL/min

**Stratification factors**
- No. of prior lines of therapy
- ISS stage at study entry
- Prior lenalidomide

**Randomize 1:1**

**DRd (n = 286)**
- Daratumumab 16 mg/kg IV
  - Qw in Cycles 1 to 2, q2w in Cycles 3 to 6, then q4w until PD
- R 25 mg PO
  - Days 1 to 21 of each cycle until PD
- d 40 mg PO
  - 40 mg weekly until PD

**Rd (n = 283)**
- R 25 mg PO
  - Days 1 to 21 of each cycle until PD
- d 40 mg PO
  - 40 mg weekly until PD

**Primary endpoint**
- PFS

**Secondary endpoints**
- TTP
- OS
- ORR, VGPR, CR
- MRD
- Time to response
- Duration of response

**Statistical analyses**
- Primary analysis: ~177 PFS events

**Pre-medication for the DRd treatment group consisted of dexamethasone 20 mg,\(^a\) acetaminophen, and an antihistamine**

ISS, international staging system; DRd, daratumumab/lenalidomide/dexamethasone; IV, intravenous; qw, weekly; q2w, every 2 weeks; q4w, every 4 weeks; PD, progressive disease; R, lenalidomide; PO, oral; d, dexamethasone; Rd, lenalidomide/dexamethasone; PFS, progression-free survival; TTP, time to progression; OS, overall survival; ORR, overall response rate; VGPR, very good partial response; CR, complete response; MRD, minimal residual disease.

\(^a\)On daratumumab dosing days, dexamethasone 20 mg was administered as pre-medication on Day 1 and Day 2.
Updated Efficacy

**Median (range) follow-up: 17.3 (0-24.5) months**

Responses continue to deepen in the DRd group with longer follow-up

HR, hazard ratio; CI, confidence interval; sCR, stringent complete response; PR, partial response.
Note: PFS = ITT population; ORR = response-evaluable population.

Kaplan-Meier estimate;

$P < 0.0001$ for DRd vs Rd.
MRD-negative Rate

MRD-negative rates were >3-fold higher at all thresholds

Intent-to-treat population.

$P$ values are calculated using likelihood-ratio chi-square test.

* $P < 0.0001.$
Autologous Transplant
What is autologous HCT?

- High dose Melphalan, requires autologous hematopoietic cells for hematologic reconstitution
- 1 cycle, consolidative therapy
- Feasible outpatient
- Requires transfusion support (?), median 0-2 units of blood product
- GI toxicity main non-hematologic toxicity
- <1% mortality in 100 days
- The cheapest therapy for multiple myeloma.
## Early vs. Late-Transplant Modern Studies

<table>
<thead>
<tr>
<th>Group</th>
<th>No</th>
<th>Induction</th>
<th>Comparator</th>
<th>&gt; VGPR</th>
<th>PFS</th>
<th>OS</th>
</tr>
</thead>
<tbody>
<tr>
<td>GIMEMA NEJM 2014</td>
<td>402</td>
<td>RD x4</td>
<td>MPR x6 ASCT x2</td>
<td>63</td>
<td>22mo median 43mo</td>
<td>65% 4y 81%*</td>
</tr>
<tr>
<td>MultiCenter Lancet Oncol 2015</td>
<td>389</td>
<td>RD x4</td>
<td>CDR x6 ASCT x2</td>
<td>50</td>
<td>29mo 43mo*</td>
<td>68% 4y 77%*</td>
</tr>
<tr>
<td>EMN ASH 2016</td>
<td>1192</td>
<td>VCD x3-4</td>
<td>VMP x4 ASCT 1 or 2</td>
<td>74</td>
<td>57% @ 3 yrs 65%</td>
<td>NS (short fu)</td>
</tr>
<tr>
<td>IFM 2009 NEJM 2017</td>
<td>700</td>
<td>VRD x3</td>
<td>VRD x5 ASCT + VRD x2</td>
<td>78</td>
<td>36mo 50mo*</td>
<td>82% 4y 81%</td>
</tr>
</tbody>
</table>

There has been NO MODERN transplant vs. No transplant trial
Lenalidomide, Bortezomib, and Dexamethasone with Transplantation for Myeloma

Michel Attal, M.D., Valerie Lauwers-Cances, M.D., Cyrille Hulin, M.D., Xavier Leleu, M.D., Denis Caillot, M.D., Martine Escoffre, M.D., Bertrand Arnulf, M.D., Margaret Macro, M.D., Karim Belhadj, M.D., Laurent Garderet, M.D., Murielle Roussel, M.D., Catherine Payen, M.D., Claire Mathiot, M.D., Jean P. Fernand, M.D., Nathalie Meuleman, M.D., Sandrine Rollet, M.S., Michelle E. Maglio, B.S., Andrea A. Zeytoonjian, B.S., Edie A. Weller, Ph.D., Nikhil Munshi, M.D., Kenneth C. Anderson, M.D., Paul G. Richardson, M.D., Thierry Fagon, M.D., Hervé Avet-Loiseau, M.D., Jean-Luc Harousseau, M.D., and Philippe Moreau, M.D., for the IFM 2009 Study®

RVD x3

Cy 3 g/m²
Stem cell collection

RANDOMIZE

MEL 200 + ASCT

RVD x2

Len x 1 year

Progression

Len x 1 year

MEL 200 + ASCT
Median PFS **50 vs. 36 months** (14 months advantage) – HR of 0.65
B Overall Survival

No. at Risk

<table>
<thead>
<tr>
<th></th>
<th>Data Points</th>
</tr>
</thead>
<tbody>
<tr>
<td>RVD alone</td>
<td>350 339 325 293 95</td>
</tr>
<tr>
<td>Transplantation</td>
<td>350 330 313 281 89</td>
</tr>
</tbody>
</table>

P = 0.87
No. at Risk

<table>
<thead>
<tr>
<th>Arm</th>
<th>Patients (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>RVD Arm - MRD Negative</td>
<td>0</td>
</tr>
<tr>
<td>Transplantation Arm - MRD Negative</td>
<td>0</td>
</tr>
<tr>
<td>RVD Arm - MRD Positive</td>
<td>350</td>
</tr>
<tr>
<td>Transplantation Arm - MRD Positive</td>
<td>350</td>
</tr>
</tbody>
</table>

P < 0.001
Response Rates Over the Course of Treatment

**KRd + ASCT**

<table>
<thead>
<tr>
<th>Cycles</th>
<th>4 cycles (n=75)</th>
<th>8 cycles (n=70)</th>
<th>18 cycles (n=50)</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥VGPR</td>
<td>73%</td>
<td>91%</td>
<td>94%</td>
</tr>
<tr>
<td>≥nCR</td>
<td>23%</td>
<td>81%</td>
<td>94%</td>
</tr>
</tbody>
</table>

**KRd w/o ASCT**

<table>
<thead>
<tr>
<th>Cycles</th>
<th>4 cycles (n=49)</th>
<th>8 cycles (n=44)</th>
<th>18 cycles (n=41)</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥VGPR</td>
<td>69%</td>
<td>89%</td>
<td>90%</td>
</tr>
<tr>
<td>≥nCR</td>
<td>43%</td>
<td>66%</td>
<td>80%</td>
</tr>
</tbody>
</table>

Response after ASCT (n=71)

- 90% ≥VGPR
- 44% ≥nCR
- 27% 21%

nCR, near complete response; VGPR, very good partial response
MRD Evaluation

**Multiparameter Flow Cytometry (MFC)**
- 10 color
- Sensitivity: $10^{-4}$ – $10^{-5}$

**Next generation sequencing (NGS)**
- Adaptive Biotechnologies
- Sensitivity: $10^{-6}$

- **8 cycles**
  - MRD negative, %
  - MFC: 86 (n=37)
  - NGS: 64 (n=39)

- **18 cycles**
  - MRD negative, %
  - MFC: 97* (n=30)
  - NGS: 74* (n=27)

*Actual rates in subgroup of pts evaluated for MRD at the end of 8 and 18 cycles regardless of level of response*

*27/30 pts (90%) MRD (-) by MFC and in sCR and 20/27 (74%) MRD (-) by NGS and in sCR; KRd w/o ASCT estimated rates of MRD (-) and in ≥CR 51% by MFC and 39% by NGS*
Auto-HCT conclusions

- Best inducer of MRD(-) status
- Prolongs PFS and likely OS, even in the context of IMIDs and P.I.
- Acceptable toxicity
- If we develop better induction regimens and more sensitive MRD detection, it will be worth to test if additional therapy, Auto-HCT included, can be withheld in early achievers of MRD negativity
Allogeneic Transplant
What is allogeneic HCT?

- Intermediate/High dose chemotherapy with low dose total body irradiation
- Stem cells from a matched donor, sibling or unrelated
- Requires transfusion support, prolonged immunosuppression therapy
- GI toxicity main non-hematologic toxicity
- Risk of graft versus host disease
- Short term mortality ~12%
- Life-long commitment
Standard risk

High risk

**Allogeneic HCT conclusions**

- Much higher risk of death from complications than autologous-HCT
- Not feasible in most MM patients
- Risk of GVHD is substantial
- Lower risk of myeloma relapse than autologous-HCT
- Some patients will be cured
- Should be performed only in clinical trials, particular in younger and higher risk patients
# How to cure blood cancer?

<table>
<thead>
<tr>
<th>Disease</th>
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<th>Treat past undetectable point</th>
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<td>CML?</td>
<td>TKI, 2(^{nd}) generation TKI(?) to MRD negative</td>
<td>TKI continuation</td>
<td>Observation and monitoring</td>
</tr>
<tr>
<td>Myeloma</td>
<td>PI/IMID/MoAb induction + Auto-HCT to MRD negativity</td>
<td>Abbreviated consolidation</td>
<td>Observation and monitoring</td>
</tr>
</tbody>
</table>
Our approach- MASTER trial

Consolidation 1

**Auto-HCT**

(KRdD x 4 cycles)*

MRD

KRdD x 4 cycles

2nd MRD(-)

Observation

Consolidation 2

KRdD x 4 cycles

2nd MRD(-)

Observation

Consolidation 3

KRdD x 4 cycles

2nd MRD(-)

Observation

Induction

KRdD x 4 cycles

SOC (lenalidomide maintenance)
Multiple Myeloma, the next 10 years

• Treatment initiation dictated by presence of morbidity or biomarkers

• Therapy anchored in proteasome inhibitors, IMId, monoclonal antibodies, and corticosteroids

• Treatment stratification based mostly on age, on biological features

• “One size fits all” Treatment approach based on biology and depth of response

• Success defined by improvement in surrogates of gross disease, eradication of disease

• Continuous therapy until failure/intolerance disease eradication

• Most patients will die be cured from MM
What is cure after all?

- “Getting rid of it”?
- “Stopping treatment without disease coming back”?
- “Restoring life expectancy”? 
Cured or not cured? G.R.’s case

G.R., 52, had stage 3 myeloma, with bone lesions and anemia. She received treatment with 4 drugs, 2 autologous transplant and indefinite maintenance. She obtained a stringent complete remission with MRD negative and the myeloma did not come back at year 5.
Cured or not cured? G.R.’s case

G.R., 52, had stage 3 myeloma, with bone lesions and anemia. She received treatment with 4 drugs, 2 autologous transplant and indefinite maintenance. She obtained a stringent complete remission with MRD negative and the myeloma did not come back at year 5.

On year 6, she developed bilateral pneumonia and died at age of 58

✓ “Getting rid of it”
✗ “Stopping the treatment without the disease coming back”
✗ “Restoring life expectancy”
Cured or not cured? S.T.’s case

S.T., 66, had stage 2 myeloma, with renal failure and anemia. He received treatment with 3 drugs and 1 autologous transplant. He obtained partial remission but choose not to go on maintenance treatment. On year 5 his M spike is still detectable at 1.2 but he has not required any additional treatment, asymptomatic.
Cured or not cured? S.T.’s case

S.T., 66, had stage 2 myeloma, with renal failure and anemia. He received treatment with 3 drugs and 1 autologous transplant. He obtained partial remission but choose not to go on maintenance treatment. On year 5 his M spike is still detectable at 1.2 but he has not required any additional treatment, asymptomatic.

On year 8, he is still going strong

- X “Getting rid of it”
- √ “Stopping the treatment without the disease coming back”
- ? “Restoring life expectancy”
Cured or not cured? L.E.’s case

L.S, 75, had stage 2 myeloma, with anemia and renal failure. She received treatment with 2 drugs and obtained a partial remission. She stayed on treatment for 3 years until disease progressed with increase in M spike and worsening of anemia. She entered a clinical trial with a new drug. On year 5 she is in VGPR M spike is still detectable at 0.2, she is still on the investigational drug.
Cured or not cured? L.E.’s case

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She stayed on clinical trial until year 6 when disease progressed. She started third line of therapy and had a PR for 3 years. She passed away on year 10 at age of 85 from relapsed myeloma.

“Getting rid of it”
“Stopping the treatment without the disease coming back”
“Restoring life expectancy”
Cure in Multiple Myeloma

- We need to stop saying there isn’t one
- Many “myelomas”, many patients
- Many definitions of cure – Yours is the only one that matters!
- Discuss YOUR goals of therapy, YOUR cure.
- Participate in clinical trials, find the ones that match your goals.
Thank you!

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