Viral Hepatitis in Blood Donors

VHPB country meeting

Prof Asc.Vjollca Durro
Microbiology Service
Medicine Faculty, Medical University

Tirana, 27-28 OCTOBER 2016
• Transfusion-transmitted viral infections as HBV and HCV are still one of the most serious complications of blood transfusion particularly in country with high and intermediate prevalence of them.

• They lead to chronic and life-threatening disorders in blood recipients, so a huge number of scientific researchers have focused on this problem in order to improve blood transfusion practice and, particularly, to improve the safety of blood transfusions.

• This problem is even more sensible in the present situation of our country because on the epidemiological maps, Albania is shown among high prevalence countries for HBV, over 8% and intermediate prevalence of HCV.

• Continuous monitoring of HBV and HCV marker among blood donors permits an assessment of the occurrence of infection in the blood donor population and consequently the safety of the collected donations.
Hepatitis viral in blood donors

Blood safety is depend from:

a) Quality of blood donors
b) Selection procedure of blood donors
c) Testing methods used for blood screening

In Albania blood donation system is mix. The blood was collected from:

a) commercial blood donors (CBDs)
b) Unpaid blood donors
  • voluntary non remunerate blood donors (VNRBD),
  • family replacement donors (FRBD)

Donors were classified:

• first-time
• Repeat/regular blood donors

The VNBD and FRBD have donated blood only one time, so they are first time blood donors
All donors are selected in two phase:

1. Pre-donation selection:
   a) Self evaluation (questionnaire)
   b) Hb test, Blood pressure, temperature and weight

2. Post donation selection:
   a) HBV, HCV, HIV ½, Syphilis

- **Preselected process**:
  - questionnaire
  - temperature
  - blood pressure
  - Hb test
  - weight

  - Negative
    - Yes
      - donor admitted
      - donate
    - No
      - donor rejected
Algorithm of serology blood testing

1. Donate
   - Post donation testing: HBsAg, anti-HCV
     - Reactive/Indeterminate
     - Negative: Blood used
     - Positive: Repeat 2 times
       - Reactive/Indeterminate: Repeat with same sample and method
         - Reactive/Indeterminate: Confirmation PHI
           - Rezult: Neg
             - Blood used
           - Poz
             - Blood used
Blood donors testing

• Reactive samples for Anti-HCV and HBsAg were not performed the confirmation test until June 2016.

• A sample was considered as HBsAg and Anti-HCV positive when found two times repeatedly reactive with CMIA method.

• Virus screening of blood donations started in the 70s with HBsAg assays followed by anti-HIV and anti-HCV (serological assays) in the 80s and 90s respectively.

• In Albania screening of blood donors for viral hepatitis's marker, are mandatory according to national legislation since 1975 for HBsAg and 1993 for anti-HCV.
<table>
<thead>
<tr>
<th>Years</th>
<th>Screening kit</th>
<th>Manufacture</th>
<th>Sensitivity</th>
<th>Method</th>
</tr>
</thead>
<tbody>
<tr>
<td>1975</td>
<td>HBsAG</td>
<td>imunoelctrophoresis</td>
<td></td>
<td>Manual</td>
</tr>
<tr>
<td>1994</td>
<td>HBsAg and HCV</td>
<td>ELISA method</td>
<td></td>
<td>Manual</td>
</tr>
<tr>
<td>1999</td>
<td>Auszyme Monoclonal HBsAg</td>
<td>Quantum II ABBOT</td>
<td>Ad 0.04 ng/ml, ay 0.7 ng/ml</td>
<td>Manual</td>
</tr>
<tr>
<td>2000</td>
<td>Auszyme Monoclonal HBsAg</td>
<td>Quantum II ABBOT</td>
<td>Ad 0.04 ng/ml, ay 0.7 ng/ml</td>
<td>Manual</td>
</tr>
<tr>
<td>2001</td>
<td>Auszyme Monoclonal HBsAg</td>
<td>Quantum II ABBOT</td>
<td>Ad 0.04 ng/ml, ay 0.7 ng/ml</td>
<td>Manual</td>
</tr>
<tr>
<td>2002</td>
<td>Auszyme Monoclonal HBsAg</td>
<td>Quantum II ABBOT</td>
<td>Ad 0.04 ng/ml, ay 0.7 ng/ml</td>
<td>Manual</td>
</tr>
<tr>
<td>2003</td>
<td>IMx</td>
<td>ABBOT</td>
<td>Ad 0.22 ng/ml Ay 0.17 ng/ml</td>
<td>Semi automatic</td>
</tr>
<tr>
<td>2004</td>
<td>IMx</td>
<td>ABBOT</td>
<td>Ad 0.22 ng/ml Ay 0.17 ng/ml</td>
<td>Semi automatic</td>
</tr>
<tr>
<td>2005</td>
<td>IMx</td>
<td>ABBOT</td>
<td>Ad 0.22 ng/ml Ay 0.17 ng/ml</td>
<td>Semi automatic</td>
</tr>
</tbody>
</table>
| 2006  | AxSYM HBsAg (MEIA) | ABBOT | Ad 0.15 ng/mL  
Ay 0.12 ng/mL  
≤0.5 ng/mL  | semi automated |
| 2007  | AXSYM CMIA    | ABBOT        | 100%         | automated    |
| 2008  | Architect     | ABBOT        | 100%         | fully automate |
| June  |               |              |              |              |
| 2016  | NAT test      |              |              |              |
Blood Donation 2010-2014

<table>
<thead>
<tr>
<th>Year</th>
<th>2010</th>
<th>2011</th>
<th>2012</th>
<th>2013</th>
<th>2014</th>
</tr>
</thead>
<tbody>
<tr>
<td>VBDs</td>
<td>4928 (20.42%)</td>
<td>6028 (23.27%)</td>
<td>6830 (24.83%)</td>
<td>7655 (26.18%)</td>
<td>6969 (23.76%)</td>
</tr>
<tr>
<td>FRBs</td>
<td>14532 (60.23%)</td>
<td>15841 (61.17%)</td>
<td>17372 (63.17%)</td>
<td>18774 (64.22%)</td>
<td>20009 (68.22%)</td>
</tr>
<tr>
<td>PBDs</td>
<td>4632 (19.19%)</td>
<td>4018 (15.51%)</td>
<td>3297 (11.98%)</td>
<td>2787 (9.53%)</td>
<td>2329 (7.9%)</td>
</tr>
<tr>
<td>ABDs</td>
<td>35 (0.14%)</td>
<td>7 (0.02%)</td>
<td>0 (0.06%)</td>
<td>20 (0.68%)</td>
<td>9 (0.31%)</td>
</tr>
<tr>
<td>Total</td>
<td>24127</td>
<td>25894</td>
<td>27499</td>
<td>29232</td>
<td>29327</td>
</tr>
</tbody>
</table>

Referred data the total number of donation was increased and the quality structure of blood donors was improved during years.

The data show the Important steps done towards gradually phasing out paid blood donation and increasing unpaid blood donors as FRBDs and VBDs.
• In 2014 commercial donation composed only 7.9% of all donation compared with 19.1% in 2010.

• VNRBD are increased from 20.4% in 2010 to 23.7% in 2014.

• Family replacement donation from 60.2% to 68.2% in 2014.

• But change of quality structure of blood donors resulted in a very high percentage of first time blood donors.

• In 2014 the blood collected from first time blood donors (VBD, FRBD) composed 92% of total blood collected at national level.

• But donations from FRBD consist of the majority of unpaid blood donations yet, 68.2%.

• In this condition, evaluation of trends of Viral hepatitis marker in blood donors remains a critical point for monitoring blood supply safety and donor screening effectiveness in our country.
The change in structure of blood donors are result of the following factors as:

- Strength the promotion of voluntary blood donors
- Desided the special budget for promotion activities from MoH
- Approved the legislation to support the associations included in promotion of VBD
- Interrupted blood donation for first time commercial donors since 2008
Blood donor testing

The prevalence of viral marker in blood donors is depended:

- Prevalence of hepatitis viral marker in general population
- Human demographic characteristics and behaviors
- Structure of blood donors
- Testing method

Albania is a country with high HBV prevalence, intermediate HCV prevalence. So, in the present situation the monitoring of blood donors for viral marker is more sensible.
• The prevalence of viral hepatitis in our donor populations in 2014 was 4.7%.

• While during period time of study, the prevalence of hepatitis viral marker has decrease tendency from 6.9% in 2010 to 4.7 in 2014

• The prevalence of HBsAg in our donor populations in 2014 was 5.48 %.

• While during period time of study, the prevalence of HBsAg varies from 6.15% in 2010 to 5.48 in 2014

• The prevalence of HCV in our donor populations in 2014 was 0.76 %.

• HCV prevalence was increased from 0.77% in 2010 to 1.01 in 2012 and decreased in 0.76 in 2014
**HBsAg prevalence according to type of blood donors**

- Prevalence of HBsAg in voluntary blood donors was 4.6%, in FRBD 7.71% and PBDs 0.02%
- Prevalence of HBsAg in VBDs varies from 5.72 in 2010 to 3.51 in 2014
- Prevalence of HBsAg in FRBDs varies from 8.25% in 2010 to 10.7 in 2012 and decreased to 6.79 % in 2014
HCV prevalence according to type of blood donors

- Prevalence of HCV in voluntary blood donors was 0.71%, in FRBD 0.98% and PBDs 0.05%
- Prevalence of HCV in VBDs was increased from 0.7% in 2010 to 0.93% in 2012 and decreased in 0.53 in 2014
- Prevalence of HCV in FRBDs varies from 0.99% in 2010 to 1.24% in 2012 and decreased to 0.92 % in 2014
- While in PBD the prevalence is in low level
Conclusion

1. The data show decreased the prevalence of viral hepatitis marker in blood donors but its higher compare with neighbouring countries. In Balkan countries the prevalence of HBV in blood donors varies from 0.5-2%. HBV.

These figures are results of some important measure implemented in blood transfusion service as:

a) Centralization of blood testing for ITT (all blood collected in whole country), only in one center, in Tirana since 2010.

b) Improved the testing method and sensitivity of test screening during years. The method of blood testing for ITT is full automatic and high sensitivity.

c) Interrupted first time blood donors from donation since 2008.

d) Implementation of national hepatitis B immunization programs since 1993, also have played an important role in decreasing the occurrence of hepatitis B in general population included and blood donors.

<table>
<thead>
<tr>
<th>State</th>
<th>HBsAg RBD</th>
<th>HBsAg FTBDs</th>
<th>HCV RBD</th>
<th>HCV FTDs</th>
</tr>
</thead>
<tbody>
<tr>
<td>Turkey</td>
<td>1.7 %</td>
<td></td>
<td>0.07 %</td>
<td></td>
</tr>
<tr>
<td>Greece**</td>
<td></td>
<td>3%</td>
<td></td>
<td>0.6%</td>
</tr>
<tr>
<td>Kosovo</td>
<td>4.7 %</td>
<td></td>
<td>0.3 %</td>
<td></td>
</tr>
<tr>
<td>Serbia *</td>
<td>0.09%</td>
<td></td>
<td>0.06%</td>
<td></td>
</tr>
<tr>
<td>Croatia *</td>
<td>0.009 %</td>
<td>0.2%</td>
<td>0.003 %</td>
<td>0.06</td>
</tr>
<tr>
<td>Macedonia</td>
<td>0.45 %</td>
<td></td>
<td>0.003%</td>
<td></td>
</tr>
<tr>
<td>Bosnja</td>
<td>0.78%</td>
<td></td>
<td>0.26%</td>
<td></td>
</tr>
<tr>
<td>Albania</td>
<td>5.48%</td>
<td></td>
<td>0.76%</td>
<td></td>
</tr>
</tbody>
</table>

For HBV, the prevalence in first-time blood donors ranged from 0.0% to 5.2% in EU country. For HCV, the prevalence in first-time blood donors ranged from 0.02% to 3.3%.

The prevalence in first-time donors was lower than the prevalence in general population. (according to CDC 2010 (Hepatitis B and C in the EU neighbourhood).
Conclusion

2. The prevalence of HBsAg and HCV was lower in VBDS than FRBd, but the prevalence of HBsAg and HCV still is higher comparing with neighbouring countries because the majority of blood donation are from first time blood donors.

• While in first time blood donors group, the majority of donation are from family replacement blood donors.

• This data in blood donors reflected the epidemiological situation in our country for these markers. According to PHI the prevalence of Hepatitis B in Albania varies from 7-9% and hepatitis C from 0.5-1.5 (PHI)

3. Implementation a good quality control practice starting from history taking of blood donors and extending up to laboratory practices, can minimize the risk of ITT to patients.
Recommandation

Improve the coverage of the surveillance systems of transfusion services focused attention on improvement the quality of donors.

a) To define the strategy for recruitment the new voluntary blood donors and retention of VNRBD donors and return them in regular VNRBD donors. Replacement on family blood donor with voluntary non remunerate blood donors, It’s important to increase the frequency of donation per donors/ year.

b) More strict selected procedure of donors through direct questioning of donors regarding risks for these viruses (more detailed pre-donation ), more privacy for the donor at the time of completing the questionnaire (private areas), preparing the informative paper about viral hepatitis.

Information of people about viral hepatitis together with improving the testing methods is important thing to prevent the installation of this infection.
Thank you