SHOULD WE CHANGE OUR CURRENT PRACTICE OF BLOOD DONOR SCREENING IN SWITZERLAND? THE ALAT DATA

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Background

ALAT testing at present is a compulsory screening test before releasing blood products in Switzerland. There is increasing evidence that with the introduction of specific and sensitive tests for hepatitis B- and C-infections, especially HCV nucleic acid amplification testing (NAT), elevated levels of ALAT do not contribute any longer to blood product safety (1,2). The use of this screening test was never an FDA requirement and the Council of Europe does not recommend to perform ALAT testing (3). Expert panels do suggest to stop performing ALAT testing as a compulsory screening test (4). To evaluate the significance of ALAT testing with respect to donor and blood product safety we performed a retrospective analysis of our blood donor data.

Methods

Firstly, we analyzed donors with elevated levels of ALAT (> 70 U/l male, > 50 U/l female) between March 2002 and March 2004 with a minimum observation period of eight months. Secondly, we analyzed donors with reactive screening results for HBsAg and/or anti-HBc and for anti-HCV and/or HCV-NAT between January 1994 and September 2004.

Results

Among abnormal screening results between *March 2002 and March 2004* elevated levels of ALAT were seen 1092 times, whereas reactive screening results for HBV, HCV, HIV and TPHA were documented 79, 52, 127 and 63 times, respectively. The frequency of elevated levels of ALAT was equally distributed between all age groups (data not shown). The characteristics of blood donors with elevated levels of ALAT in the beforementioned period are shown in *Table 1*. Of 1011 blood donors with elevated levels of ALAT, only 3 (0.3%) had a confirmed positive screening result - all three for HCV - and 580 (57%) had a blood sample taken for control. At that time there was only one donor (0.2%) with a newly confirmed positive screening result - for TPHA - and ALAT returned to normal values in 474 (82%) cases. 113 donors had a check-up at their family doctor after an elevated level of ALAT had been documented at the time of blood donation. At the time of the check-up ALAT returned to normal values in 70 (62%) cases. Following diagnoses were made: steatosis (20), viral infection (6), no obvious cause (6), drug-induced (5), cholelithiasis (1), alcohol-induced without steatosis (1), not specified (2) (*Figure 1*).
The characteristics of blood donors with reactive screening results for HBsAg between *January 1994 and September 2004* are shown in *Table 2*. There was an elevated level of ALAT in 8 (9%) of 87 confirmed HBsAg positive donors. Among 47 HBsAg negative, anti-HBc positive blood donors there was no elevated level of ALAT. With regard to reactive screening results for anti-HCV in the beforementioned period there were 334 blood donors totally, in 38 there are no follow-up data, 173 had a false positive screening result and 71 had an indifferent confirmation test. The characteristics of blood donors with a confirmed HCV-infection are shown in *Table 3*. Of those 52 donors, only 13 (25%) had an elevated level of ALAT.

Table 1: Blood donors with elevated levels of ALAT between March 2002 and March 2004

Characteristics	Value
total – no.	1011
male sex – no. (%)	660 (65)
ALAT medium (range)	M: 91 (71-500)
	F: 73 (51-389)
no. of donors with control (%)	**580 (57)**
days between blood donation and control	
medium (range)	M: 199 (7-906)
	F: 204 (7-764)
elevated level of ALAT at control – no.	M: 77 / F: 29 — 106 (18%)
normal value of ALAT at control – no.	M: 285 / F: 189 — **474 (82%)**

Figure 1: Diagnoses at check-up

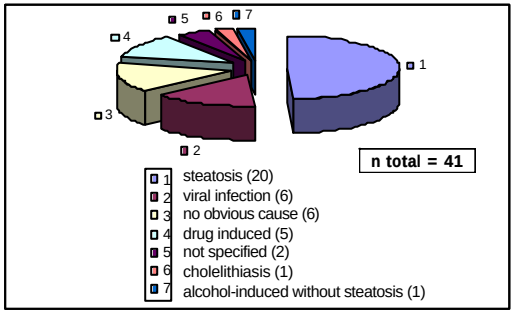

Table 2: Blood donors with reactive screening results for HBsAg 1994-09/2004

Characteristics	Value
total – no.	276
confirmation	
no data – no.	**5**
false positive – no.	**184**
ALAT elevated – no.	2 (M: 74, 76)
positive – no.	**87**
male sex – no. (%)	59 (68)
Age – medium (range)	M: 34 (18-78)
	F: 35 (18-63)
ALAT medium (range)	M: 46 (10-370)
	F: 26 (14-74)
ALAT elevated medium (range) / no.	M: 193 (73-370) / **5**
	F: 65 (56-74) / **3**

Table 3: Blood donors with confirmed positive anti-HCV results 1994-09/2004

Characteristics	Value
confirmation	
positive – no.	**52**
male sex – no. (%)	33 (63)
without HCV-NAT – no. / ALAT elevated – no.	18 / **5**
with positive HCV-NAT – no. / ALAT elevated – no.	27 / **8**
with negative HCV-NAT – no. / ALAT elevated – no.	7 / **0**
Age – medium (range)	M: 39 (19-76)
	F: 38 (22-56)
ALAT medium (range)	M: 69 (15-311)
	F: 40 (21-66)
ALAT elevated medium (range) / no.	M: 140 (71-311) / **9**
	F: 60 (52-66) / **4**

Conclusions

1. An elevated level of ALAT is by far the most common cause of abnormal screening results leading to disposal of blood products.
2. There is no evidence that an elevated level of ALAT is a valuable early marker of infection with HBV, HCV, HIV or Treponema pallidum.
3. Elevated levels of ALAT are most often only temporarily present and very rarely a diagnosis relevant for the donor or blood donation is made.
4. An elevated level of ALAT is an unspecific surrogate marker for a minority of donors with confirmed hepatitis B- and hepatitis C-infection.
5. We recommend to stop performing ALAT testing and using ALAT as a compulsory laboratory value for releasing blood products in Switzerland.

References

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