

Report from the 3rd Meeting of the IFBDO Medical counsellors in Copenhagen, Denmark, 20 – 22 June 2009.

Present:

President of FIODS, Niels Mikkelsen

Estonia: Dr. Julia Tamme

France: Dr. Jean-Jaques Huart

Greece: Dr Kostas Stamolinis

Italy: Dr. Filippo Drago, Dr. Tiziano Gamba

The Netherlands: Dr. Cees van der Poel

Denmark: Dr. Mette Møller-Larsen chairman of the Danish international committee, Dr. Karin Magnussen, Dr. Jens Halkjær Kristensen, Dr. Bettina Sørensen, Dr. Jan Jørgensen, Jørgen Jakobsen volunteer, Henning Karlby volunteer,

Saturday the 20.6.09

The Meeting was opened by Niels Mikkelsen and Mette Møller-Larsen. It was a great pleasure to be able to host the 3rd meeting between FIODS and the Medical counsellors. The last 2 meetings had been very prolific and of great value to FIODS, and Niels Mikkelsen expressed the hope that the topics of this meeting would be of interest for the participants.

Main theme: Complications related to blood donation.

Dr Bettina Samuelsen from the Skejby Hospital Blood bank held a lecture on the collection of data, the work and definitions from the ISBT working group on Complications related to Blood donors with special focus on Danish data on injuries to donors.

Denmark has had national registration of complications related to blood donation since 1995. Unfortunately it is not possible to compare data at the international level because of the lack of agreement on definitions. The data presented here was from the period of 1997-2003. The total number of donations in this period were 2.5 millions, almost exclusively whole-blood donations. In that period there were reported 772 donor injuries of which 559 were needle injuries and 193 were vaso-vagal reactions. Of the 559 needle injuries 121 resulted in long-term morbidity and 56 ended up with disablement. Of the 193 donors who suffered vaso-vagal reactions 5 donors ended up with long-term morbidity and 2 donors had disablement (mostly related to donor falling due to having a vaso-vagal reaction thereby getting injured teeth or prolonged headache)

The donors with needle injuries and long term morbidity reported symptoms such as pain in the arm when using it (60%), pain in the arm and sensory changes (26%) and radiation pain/sensory changes (14%)

Danish data from 2000-2007 show that if you look at symptoms such as haematoma's, nerve irritation, nerve injury and painful arm, in a rate pr. 100,000 donations, 3.4 had long term morbidity. 39 % of the donors who reported symptoms of nerve injury had constant pain or pain when moving the arm one year after donating. Of the donors suffering from painful arm 44 % had pain when moving the arm and 56 % has constant pain one year after donation.

The data show that the most frequent complication is vaso-vagal reactions, but nerve injury/nerve irritation/painful arm is the most frequent severe complication, which can result in long term morbidity.

As nerve injury can develop to permanent pain, it is important that donors complaining of pain

should not be neglected.

A high professional standard of bleeding facility actions is proven by its care for the donors

- Their symptoms are not serious when compared with hospitalized patients, but their symptoms disturb them in the daily life
- Healthy voluntarily donors
- They should be handled in a professional manner
- Efforts that improve the donation experience and enhance the likelihood of a donor becoming a repeat donor

Acceptable recommendations:

- Gentle treatment, serving drinks and food before and after donation
- Observation of donor for a while and if complications occur treat the donor and do not let the donor leave before absolutely well
- Stop donation immediately when symptoms or complications occur and apply pressure at puncture site
- Advise donor about re bleeding, driving, rest and to contact blood bank if symptoms reoccur

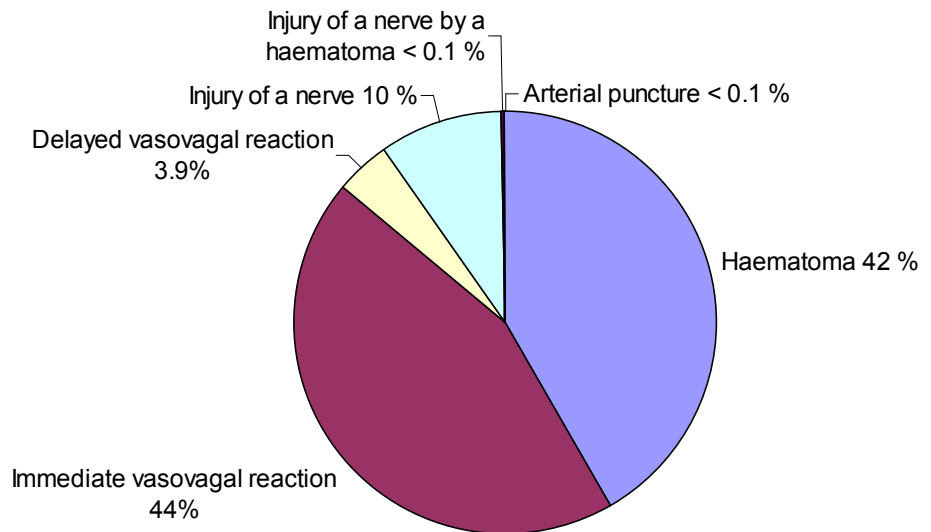
The challenge is that many of the symptoms are not classical neurological symptoms- and might therefore be overlooked.

Vibe Maria Sørensen, a medical student from the University of Copenhagen, Denmark, held a lecture on her study entitled : The Copenhagen Donor Haemovigilance Study: Computer based registration of Adverse reactions following Blood Donation in a 3-year Period.

From 2004-2006 they made a computer based registration feasibility study to monitor donor adverse reactions. The data were compared to the data from the national register. The computer based registration was done by the staff in the blood bank according to information given by the donor

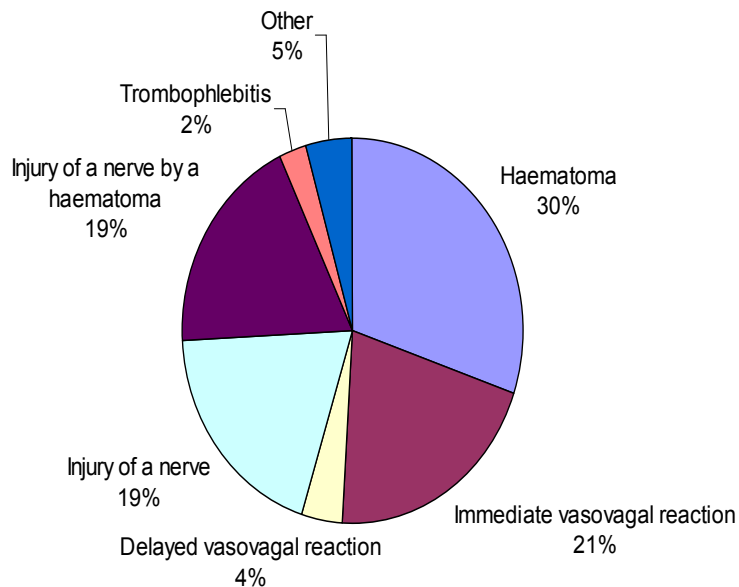
In the 3 year period there were 2707 donor adverse reactions out of 180,664 donations, which is 1.5% of all blood donations. The corresponding incidence was 1498/100,000 donations

Distribution of CBR DAR registered in 2004 - 2006 (n = 2707)



In the same period the national register had registered 174 adverse donor events in the same donor population. The corresponding incidence was 96/100,000 donations

Distribution of NR DAR registered in 2004 - 2006 (n = 174)



The study found that the computer based registration had 10-30 times higher frequencies compared with the national register, and that most donors experiencing delayed vaso-vagal reactions did not consult a doctor at the time of the incidence. The incidences were not reported to the blood bank staff until the next donation, and the events were therefore not registered in the national register.

The study concludes that the computer based registration should be monitored and dealt with immediately in order to optimize service and security for all blood donations

Dr. Jens Halkjær Kristensen a senior consultant in Rheumatology from the National hospital in Copenhagen held a lecture on The diagnosis and treatment of donor injuries.

The patients seen by him are referred from the blood bank at the National Hospital. A thorough anamnesis about the vein puncture, the draining, removal of the needle, compression after draining and the function of the arm before the draining/after the draining is important.

The physical examination is bilateral for comparison and involves:

- Circulation
 - Pulse
 - Venous stasis,
 - Local Inflammation
 - Calor
 - Rubor
 - Tumor
 - Dolor
 - Functio laesa
- Neurological
 - Sensation
 - Muscle function
 - Reflexes
 - Etc.
- Palpation
 - Fossa cubiti
 - Biceps muscle and tendon
 - Muscles in the forearm
- Elbow joint
 - movements, pain etc.
- Shoulder
 - movements, pain etc.
- Cervical spine and neck muscles
 - movements, pain etc.
- Supraclavicular fossa and muscles
 - movements, pain etc.

Any other symptoms from any part of the body which the donor feels related to the actual blood donation.

Based upon the results and objective findings the donor is given a careful thorough explanation of the most plausible (the most likely) explanation for the pain and complaints- especially in relation to the worries of the donor. Explanation is presented in daily terms by use of “pictures” to facilitate understanding and coping with the symptoms.

Treatment:

- Ultrasound treatment (“physiotherapy”),
1- 2 W/cm², 5 – 10 min. initiated by myself and given simultaneously with the detailed explanation of the incident.

Ultrasound treatment will facilitate the resorption of the haematoma and shorten the period of inflammation and thereby diminish the unwanted scar-formation in the arm.

Ultrasound treatment is continued on a daily basis 3 – 8 days without delay by a local

physiotherapist or by me.

- Local application of NSAID can be used as coupling-media during the ultrasound treatment or as supplement between treatments.

The hospital makes a follow up by phone call after a couple of weeks or if symptoms persists and they send a report of the "unintended incidence" to the "Patients Insurance"

In order to avoid damage to the donor the conclusion and future precautions must be:

- Alternate between sites of vein puncture e.g. change of arm and/or actual vein in fossa cubiti - to allow the scar-tissue to mature properly.
- Avoid multiple needle insertions and "search" as well as manipulation of the needle in order to improve blood flow.
- Proper compression after removal of the needle - >1-2 hours.
- Take any complains related to the blood donation seriously and professionally.

We cannot completely avoid complications - but by acting professionally we must try to reduce the number of persons giving up blood donation.

Dr. Bettina Samuelsen commented that the blood bank in Skejby, Denmark had also referred donors suffering from injuries to physiotherapy with good results.

What conclusions should FIODS take from the above ?

It is important that in the future we keep monitoring and working with the subject of donor injuries. Previous focus has mostly been on vaso-vagal reactions but it would be preferable, if we in the future could also focus on treatment of donor injuries. It is important that we establish a international co-operation and sharing of knowledge.

The participants of this meeting are asked investigate the extent of donor injuries in their own countries.

When FIODS meets with the Steering Group of the Council of Europe in November 2009 it is important that the European Union is made aware of the problem with donor injuries. Attentions shall also me made to proper insurance of blood donors, so that any economic disadvantages caused by accidents related to blood donation will be covered.

Sunday the 21.6.09

Main theme: The Council of Europe Guide to the on the preparation, use and quality assurance on blood components.

Dr. Cees van der Poel, Sanquin and chief advisor to the Council of Europe introduced the Guide and its background: (His power point slides will be added to this report).

There are 4 key reasons to promote Voluntary Non-remunerated blood donations (VNRD) as defined by Keown in J.Medical Ethics 1997:

Safety of blood and blood components,
Stop for exploitation and commercialization of the human body,
Necessity (need, supply), and
Altruism and social solidarity.

In his lecture he presented historical data showing that blood has become much safer over the last four decades, and that donor selection is a powerful tool as it has brought 100-1000 fold risk-reduction, even before test regimes for HIV or HCV were introduced.

From data taken from donations in California he and his colleagues had calculated the relative risk in order to assess if the relative risk of paid donors diminished over time compared to VNRD. Over time the relative risk did not change significantly and VNRD remained on average 5 times safer than paid donations.

Discussions in the EU arose questioning whether VNRD was an issue of the past or of the present. So they compared and published an 28 comparative study for VNRD against paid donations. On average they found that VNRD are 10 times safer than paid donations

Data obtained from paid donors in Vietnam showed that: 10% were malnourished, 32% were anaemic, 19,5% gave blood more frequently than regulations outlined, and many became paid donors as a result of economic difficulties.

James et al. showed in 2004 that it is a deliberate policy of donor clinics for paid donors to move to areas where the under-privileged dwell, and also showed that commercial donor clinics were 5 times more likely to be in areas with a drug economy.

WHO data indicate that rich countries take good care of themselves in terms of supply and they achieve this mainly with VNRD.

A study of Dr. Cruz indicate that by managing towards VNRD not only the safety but also the supply increases.

In the European environment, establishments are obliged to submit very detailed data on donor populations. Not only infectious disease incidence rates must be reported per collection centre, these rates must be submitted to statistical process control, and submission of risk assessments based on the incidence data are requested as well. It is a pity that such data from most VNRD systems are published, for instance by the Council of Europe, whereas data from the paid donor systems are not, and are considered proprietary information.

The supply of IVIG was used as an argument to stress the need for paid donations. In some countries like the USA, much higher revenues for IVIG can be obtained in the USA. It seems that most IVIG goes where demand is high, with much off-label use and higher prices. It can be questioned whether only market mechanisms are sufficient to manage sufficient supply in other parts of the world.

In countries like Belgium and Netherlands with a 100% VNRD system, also for plasma aphereses donations, sufficient plasma is obtained for self-sufficiency of IVIG, given that per Litre of plasma 3 grams of IVIG can be produced.

Netherlands uses totally (all vendors) about 50 grams / 1000 inhabitants, and can produce 60 grams / 1000 inhabitants without increasing the donor base. Although other vendors are on the market given the EU regulations, the Dutch blood establishment could easily produce enough IVIG for self-sufficiency.

The conclusions of the lecture were:

Voluntary non-remunerated donations are associated with:

- a safer supply of blood and blood components
- a sufficient supply with 100% VNRD can be obtained
- VNRD avoids exploitation of the human body
- collection of blood and blood components can be managed or “embedded”

Further:

- Unemployment and poor economy increased the number of donations from paid donors in highly developed countries, suggesting that the term “volunteer” is not appropriate in this setting.
- Managing collection of blood and blood components needs to be directed towards VNRD.

General discussion

20 litres of plasma pr. 1000 inhabitants will insure self-supply of plasma derivatives in Europe. In order to accomplish this Europe will have to double their production from the present level.

The costs of producing plasma derivatives is high, and for instance in France the blood banks do not get their costs covered when selling. France is not completely self sufficient in plasma products and is therefore vulnerable if there is a demand for import of products from paid donors.

In Estonia plasma derivatives are bought from a company that fractionate the blood given by donors. The problem is that if plasma is given to a company that fractionates you are not sure that it is your ”own” plasma products that returns after fractionation - or are you at risk that your products ends up in the USA where the demand is much higher ?

A country must be able to demand that the fractionating company guarantees that the products returning after fractionation are from voluntary unpaid donors.

FIODS wants to change the directive so that a country can stop import of plasma products if they are made from plasma of paid donors.

In Italy, donors are given a day off after donating blood. The C.of. E guidelines only allow donors to be excused from work in the amount of time it takes to donate blood. A day off is in a way remuneration. It also gives a wrong impression to the general population, that donating blood gives you that much discomfort that you need a day off to rest. Finally people are more tempted to cheat on the questionnaire if they receive a benefit from donating blood.

At the meeting it is suggested that the Italian government uses the money given to the employers in order to pay for the donors day off, instead is used on donor recruitment and donor retention/ service.

Questionnaire

Drs. Karin Magnussen, Filippo Drago and Tiziano Gamba had been working hard on updating the questionnaire to member associations about pertinent medical questions and donations. It was agreed that the group would meet again in Milan during the summer and finalize the questionnaire, so that it can be presented at the European Meeting in Vilnius 3 October 2009.

Next meeting.

Dr Kostas Stamolinis agreed to consult with his national donor association, whether the 4th IFBDO medical counsellors meeting could take place I n Athens, Greece, Saturday 22. May 2010. Generally it was most practical, if participants arrived Friday evening and departed Sunday fairly early.

Niels Mikkelsen thanked the volunteers and the participants for spending their weekend for the benefit of FIODS.