

newsletter

BSE and vCJD

The variant of Creutzfeldt-Jakob disease (vCJD) was first identified in 1996. Despite a continuous decline in the number of definite or probable cases in the United Kingdom since 2000, this emerging risk remains a focus of attention as insurers identify associated risk components.

Introduction

Current scientific opinion suggests that the infectious agent that causes Variant Creutzfeldt-Jakob Disease (vCJD) in humans is probably identical to the agent that triggers bovine spongiform encephalopathy (BSE) - also known as mad cow disease - in cattle. Both belong to the group of diseases known as transmissible spongiform encephalopathies (TSEs) that are triggered by prion protein. The most likely infection path is via food. From the eighties to the start of the nineties, it is very likely that humans were exposed to the BSE agent primarily via food containing or contaminated with highly infectious material from beef cattle (the primary infection path). The risk of exposure in the United Kingdom was evidently much higher than in other European countries. Thanks to the measures now in place, the danger of vCJD being transmitted via food has now been significantly reduced in Europe.

Latest figures

In many countries, systems are in place in both human and veterinary medicine that allow data on TSE diseases to be captured systematically. The EU ban on British beef exports (the animals and the meat) introduced in 1996 and relaxed again in 1999, together with the total EU-wide suspension at the start of 2001 on the use of processed animal protein for animals farmed for the production of food, led to a drastic reduction in the number of BSE cases in cattle. Thus, in 2005, only around 560 cases of BSE were registered in the EU in 2005, whereas the number was 2 129 in 2002 (<http://www.oie.int>). In the meantime, the age specification for performing BSE tests on cattle in the EU has been increased from 24 to 30 months (it is currently still 24 months in Germany). Moreover, in May this year, the European Parliament approved an amendment to the TSE Directive and, in doing so, set out the legal framework for the implementation of BSE countermeasures geared to the TSE Roadmap published in July 2005 (http://ec.europa.eu/food/food/biosafety/bse/roadmap_en.pdf).

Although the incubation period of vCJD contracted from BSE agents is currently thought to be between 10 and 23 years (Science 294 (5547): 1726-1728), experts are of the opinion that it could actually be more than 50 years (J. Collinge, Lancet 367, 2006, 2068). For this reason, the application of safety measures already introduced for safeguarding and maintaining the current level of consumer protection will need to be continued, and consistent efforts taken to prevent BSE-infected material from entering food or medicines.

To date, 194 cases of vCJD have been registered worldwide (www.eurocjd.ed.ac.uk). In the United Kingdom, the country worst affected, there have been 162 cases (August 2006).

That said, the annual number of newly confirmed cases has been declining continuously since 2000, and it appears that the much-feared scenario of a large number of victims has not materialised. But there is still uncertainty with regard to the incubation period and the actual number of people infected. The latest models point to the total number of clinical cases of vCJD (in the UK) being much lower than earlier estimated, albeit with a much greater level of dispersion. Previous claims that there would be as many as 6 000 cases of primary vCJD infection in the UK up to 2040 are now probably untenable. But it is still unclear just how dangerous the BSE agent is for humans.

**Current
relevance**

The extent of primary vCJD infection is only partially quantifiable, and increasing attention is now also being paid to the risk posed by secondary infection (transmission between humans). Following scares in 2003 and 2004, a third case of vCJD associated with a blood transfusion was reported by the London Health Protection Agency in February this year. The case involved a person from a 30-strong group who had received blood products from a donor who had later died of vCJD. The new, variant Creutzfeldt-Jakob Disease (vCJD) contrasts with the classic, sporadic form of Creutzfeldt-Jakob Disease (sCJD), the latter showing no evidence of transmissibility between humans via blood products.

Another issue of significance is the risk of accidental transmission during medical or surgical procedures (iatrogenic transmission). Since the fifties it has been known that classic Creutzfeldt-Jakob Disease can be transmitted via inadequately sterilised medical equipment. Research has shown that patients undergoing surgery are also at risk of contracting vCJD through infected surgical instruments. Prions generally adhere well to stainless-steel instruments and they cannot be removed satisfactorily using conventional sterilisation methods. What is more, instruments such as endoscopes are too sensitive to be subject to vigorous but necessary sterilisation processes. Scientists in Great Britain believe that vCJD may already have been transmitted via operations. But so far researchers have been unable to provide accurate information on the actual risk of infection as many people who may have been infected have yet to display symptoms (unknown prevalence of sub-clinical vCJD carriers). The principle target group here are medical disciplines that involve surgery with risk tissue (the central nervous system, peripheral lymphatic tissue), eg neurosurgery, abdominal surgery, ENT procedures, ophthalmology, dentistry.

Classic prion diseases (vCJD not included) can be transmitted between humans as a result of corneal or dura-mater transplants, or through the administration of human-derived growth hormones acquired from patients with CJD. Corresponding measures have been taken to mitigate this risk. Nevertheless, iatrogenic infection is still observed today (3 cases in 2005).

Information for the underwriter

Further occurrences of BSE and the continuing absence of a satisfactory means of testing live bovines show that employees of the animal-processing industry are still at risk from primary CJD infection. By implication, a residual risk exists for the consumer (emerging risk).

According to the EMEA, thanks to the stringent regulations in force since 1998, there is no risk of BSE being transmitted via vaccines, serums and drugs manufactured from the organs, tissues or bodily fluids of bovine animals (risk material). Catgut for surgical sutures made from animal tissue is banned in the EU.

But there is a risk with products sourced from human material, eg human albumin and unstable blood components (erythrocytes, thrombocytes, blood plasma). Here, there is a theoretical risk of transmission of vCJD (secondary infection route). However, the German Paul Ehrlich Institute believes that fears of transmission of the vCJD agent in mainland Europe are unfounded as blood plasma is never acquired from donors with a high risk of vCJD. What is more, Germany and many other European countries no longer use blood and plasma produced in Great Britain. Another aspect is the process of leucocyte depletion applied during blood transfusions. In the case of plasma products (eg coagulation factors), the proportion of prions contained in the product is so heavily diminished by the manufacturing process that the risk of infection is minimal. The third case of vCJD associated with a blood transfusion again involved the United Kingdom in February 2006. But this is not to say that other countries which have so far recorded no or only isolated cases of vCJD are entirely exempt of risk potential, especially since there is still no means of testing live animals for vCJD agents or other prion diseases, and the incubation period of vCJD is still unknown. The same applies to corneal or dura-mater transplants.

There is certainly a risk of disease being transmitted via surgical instruments in the case of operations performed on tissue that is known to exhibit a high prevalence of prions. Adhering to valid sterilisation procedures is therefore an essential preventative measure here. A precise statement concerning the actual risk of infection cannot be made at the moment.

The risks discussed above are primarily a matter for the liability insurer. Persons who might potentially be held liable include those involved in the acquisition and manufacture of blood products (liability for defective products) and those responsible for using them (due diligence) in the field of medical malpractice liability insurance.

Literature

"Prion infection on the rise? Hospitals in need of modern risk management", Swiss Re Focus Report 2003; "apropos Prions", AssTech 1997, "apropos Prions, Follow-up", AssTech 2002

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