アンテロープにおいてはBSEの垂直感染（Aldhous, 1990）が認められ、ウシにおいてはBSEの発症が認められることから、ウシがBSEに感染する際にも垂直感染による可能性も存在するという疑いを払拭することができない（Aldhous, 1991）。

図1：仔ウシが生まれてから母ウシがBSEを発症するまでの時間的長さと、仔ウシの血液検体におけるPrP^{res}の陽性率と陰性率との関係の度数分布（* 母ウシの発症までの時間的長さが1年の際の差、$p<0.05$）

医薬品　研究報告　調査報告書

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販売名（企業名）	－		研究報告の公表状況	Neuropathology. 2009 Oct;29(5):625-31.	公表国 オーストラリア	

研究報告の概要	脳神経外科用器具、脳波計（EEG）用脳内電極、ヒト下垂体ホルモン、硬膜移植片、角膜移植、輸血を介してクロイツフェルト・ヤコブ病（CJD）に罹患した患者は400名を超えている。 医原性CJD患者の新規の罹患数は減少しているが、輸血を介して伝播された多様なCJD症例が2004年以降報告されている。 CJDの医原性感染は、依然として明らかに深刻な問題である。近年、我々はこの9年間に日本CJDサーベイランス委員会（CJD Surveillance Committee）の登録患者に実施された医療（全ての外科処置、脳神経外科処置、眼科手術、および輸血）を調査した。 孤発性CJD（sCJD）患者753名と対照被験者210名で構成した症例対照試験で、プリオン病がsCJD発症以前に調査対照の医療を介して伝播したことを示すエビデンスを見出せなかった。 これまでに報告された症例対照試験のレビューでは、輸血がCJDの有意なリスク因子であることは一度も明らかにされておらず、我々の研究でも同じ結果が得られている。 手術がsCJDの有意なリスク因子であることを報告している症例対照試験もいくつかあるが、外科処置を手術のタイプに分類すると、その結果は相互に相容れないものがあり、これは外科処置を介してのプリオン伝播の可能性がほとんどないことを示唆している。我々の試験では、sCJD患者の4.5%がsCJD発症後に手術を受けており、これには脳神経外科処置0.8%および眼科手術1.9%が含まれる。sCJD発症後ですら、脳神経外科処置を除外できないことを示唆している。 医原病リスクを低減するためには、我々はプリオン病に対して警戒を続けなければならない。
報告企業の意見	今後の対応
輸血がCJDの有意なリスク因子であることは明らかにされていないが、警戒は続ける必要があるとの報告である。 現時点まで血友病以外で血漿分画製剤からvCJD伝播が疑われた報告はなく、血漿分画製剤の製造工程でプリオンが除去できるとの情報もある。 なお、当社血漿分画製剤の原料血漿は現在まで英国の血漿を使用していない。	今後ともvCJDに関する安全性情報等に留意していく。
使用上の注意記載状況・その他参考事項等	
重要な基本的注意 現在までに本剤の投与により変異型クロイツフェルト・ヤコブ病（vCJD）等が伝播したとの報告はないが、しかしながら、製造工程において異常プリオンを低減し得るとの報告があるものの、理論的なvCJD等の伝播のリスクを完全には排除できないので、投与の際には患者への説明を十分行い、治療上の必要性を十分検討の上投与すること。	

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Symposium: Prion diseases — Updated

The risk of iatrogenic Creutzfeldt-Jakob disease through medical and surgical procedures

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There have been more than 400 patients who contracted Creutzfeldt-Jakob disease (CJD) via a medical procedure, that is, through the use of neurosurgical instruments, intracerebral electroencephalographic electrodes (EEG), human pituitary hormone, dura mater grafts, corneal transplant, and blood transfusion. The number of new patients with iatrogenic CJD has decreased; however, cases of variant CJD that was transmitted via blood transfusion have been reported since 2004. Clearly, iatrogenic transmission of CJD remains a serious problem. Recently, we investigated medical procedures (any surgery, neurosurgery, ophthalmic surgery, and blood transfusion) performed on patients registered by the CJD Surveillance Committee in Japan during a recent 9-year period. In a case-control study comprising 753 sporadic CJD (sCJD) patients and 210 control subjects, we found no evidence that prion disease was transmitted via the investigated medical procedures before onset of sCJD. In a review of previously reported case-control studies, blood transfusion was never shown to be a significant risk factor for CJD; our study yielded the same result. Some case-control studies reported that surgery was a significant risk factor for sCJD. However, when surgical procedures were categorized by type of surgery, the results were conflicting, which suggests that there is little possibility of prion transmission via surgical procedures. In our study, 4.5% of sCJD patients underwent surgery after onset of sCJD, including neurosurgeries in 0.8% and ophthalmic surgeries in 1.9%. The fact that some patients underwent surgery, including neurosurgery, even after the onset of sCJD indicates that we cannot exclude the possibility of prion transmission via medical procedures. We must remain vigilant against prion diseases to reduce the risk of iatrogenesis.

Key words: blood transfusion, Creutzfeldt-Jakob disease, medical procedure, neurosurgery, ophthalmic surgery, prion, surgery.

INTRODUCTION

Prion diseases such as Creutzfeldt-Jakob disease (CJD) are characterized by spongiform change and abnormal prion protein deposition in the brain, and are transmissible under certain conditions. Human prion disease is divided into three categories: genetic prion diseases resulting from mutations of the prion protein (*PrP*) gene, acquired prion diseases contracted due to prion transmission via exposure to contaminated materials, and sporadic CJD (sCJD) with no *PrP* mutation or evidence of exposure to prions. Acquired prion diseases include kuru in Papua New Guinea,[1,2] variant CJD (vCJD) that may be transmitted to humans from cows with bovine spongiform encephalopathy (BSE),[3] and iatrogenic CJD transmitted via medical procedures.[4,5] To date, iatrogenic CJD has been reported in more than 400 patients, who were exposed to prion transmission via contaminated neurosurgical instruments, intracerebral electroencephalographic electrodes, human pituitary hormone, corneal transplant, or dura mater grafts.[5] The incidence of iatrogenic CJD has greatly decreased,[5] but a new type of iatrogenic CJD "vCJD transmitted via blood transfusion" was reported in 2004.[6]

Some case-control studies reported that medical procedures were possible risk factors for sporadic CJD (sCJD).[7–13] However, other studies found no significant association between medical procedures and sCJD.[14–17] Therefore, the risk posed by such procedures is unclear. Recently, we analyzed medical procedures (any surgery, neurosurgery, ophthalmic surgery, and blood transfusion) in patients registered by the CJD Surveillance Committee in Japan over a recent 9-year period to determine if there is an association between medical procedures and sCJD.[18] Here, we review reports on iatrogenic CJD, and the results of our and other studies, to determine if there is an association between medical procedures and sCJD.

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IATROGENIC CREUTZFELDT-JAKOB DISEASE

Dura mater graft-associated CJD

Since the first report of dura mater graft-associated CJD (dCJD) in 1987,[19,20] 196 cases have been identified worldwide,[5] and more than 50% of dCJD cases have occurred in Japan.[5] At this writing, the number of patients with dCJD in Japan has reached 132.[21] The mean age at onset of the 132 patients with dCJD was 55 years (range: 15–80 years), and the mean incubation period (duration from receipt of dura mater to onset of CJD) was 11.8 years (range: 1.2–24.8 years).[21] All the 132 patients had received dura mater grafts between 1978 and 1993.[21] Two-thirds of dCJD patients display subacute progression of neurologic manifestations that are almost identical to those of classic sCJD; however, the other one-third of dCJD patients present with atypical clinicopathologic features: relatively slow progression of neurologic manifestations, scarcity of periodic sharp-wave complexes (PSWCs) on electroencephalography (EEG), and the pathological presence of amyloid plaques immunoreactive for PrP.[22,23]

CJD transmitted via corneal transplant

In 1974, a 56-year-old woman who died of autopsy-confirmed CJD after an 8-month illness was reported in the United States. She had received a corneal graft 18 months before disease onset from a donor with autopsy-confirmed CJD.[24] This case was the first reported case of iatrogenic CJD. In 1997, a 45-year-old woman who developed CJD 30 years after corneal transplant from a donor with autopsy-confirmed CJD was reported in Germany.[25] In addition to these cases, eight CJD patients with a history of corneal transplantation have been reported; however, the CJD status of their donors was not confirmed.[26]

CJD related to treatment with human growth hormone and gonadotoropin

The occurrence of autopsy-confirmed CJD in three young adults in 1985, all of whom had been treated with cadaveric pituitary-derived human growth hormone (hGH), suggested the possibility of iatrogenic transmission of CJD.[27–29] Since these reports, more than 190 patients with hGH-related CJD have been reported worldwide.[5] France has the highest number of such patients, at more than 100. No patients have been reported in Asia.[5] A number of factors, such as the method of chromatography purification in the hormone production process, may contribute to these regional differences.[5] Interestingly, the incubation period of hGH-related CJD was shorter in patients that were homozygous for codon 129 polymorphisms (methionine [M]/valine [V]) of the PrP gene, as compared to heterozygotes, which confirms the findings of a previous report indicating that MM homozygosity at codon 129 of PrP gene is a significant risk factor for sCJD.[30] In addition, four patients with CJD who had undergone hormone therapy with cadaveric pituitary-derived gonadotropin were reported in Australia.[5]

CJD transmitted via surgical instruments and stereotactic EEG needles

In 1977, two patients who had developed CJD 15 and 18 months after stereotactic electroencephalographic exploration using silver electrodes that had been previously implanted on a patient with proven CJD were reported in Switzerland.[31] The electrodes had been sterilized with 70% alcohol and formaldehyde vapor, but one of the electrodes subsequently transmitted spongiform encephalopathy to a chimpanzee 18 months after implantation in the cerebral cortex.[32] Furthermore, in a review of a report in 1960,[33] two patients with CJD possibly transmitted via neurosurgical instruments were identified.[34,35] There has been no case of CJD transmitted via surgical instruments or stereotactic EEG needles since the 1980s.

vCJD transmitted by blood transfusion

In 2004, the first case of human-to-human secondary transmission of vCJD via blood transfusion was reported in the UK.[6] This patient had received a transfusion of non-leucodepleted red blood cells that had originated from a donor who developed clinical vCJD 3 years and 4 months after donation.[6] Two additional patients with vCJD transmitted via blood transfusion have been identified.[36] All

Table 1 Medical procedure-related risk for sporadic Creutzfeldt-Jakob disease (sCJD) divided into three categories according to age at disease onset in patients monitored by the CJD Surveillance Committee, Japan[18]

Age		*n*	Any surgery	Neurosurgery	Ophthalmic surgery	Other surgery†	Blood transfusion
All	sCJD	753	49.4%	3.3%	5.6%	44.8%	10.4%
	Control	210	49.5%	6.2%	5.2%	42.4%	9.5%
31–50	sCJD	32	50.0%	6.3%	6.3%	40.6%	3.1%
	Control	37	45.9%	10.8%	2.7%	37.8%	5.4%
	Odds ratio		1.66	0.38	2.15	0.78	0.64
	95% CI		0.04–74.09	0.02–6.64	0.05–101.51	0.02–33.39	0.05–9.09
	P		0.79	0.50	0.70	0.90	0.74
51–70	sCJD	414	43.7%	1.7%	2.2%	41.8%	9.4%
	Control	97	46.4%	5.2%	3.1%	40.2%	11.3%
	Odds ratio		0.18	0.69	2.71	5.57	0.84
	95% CI		0.02–1.73	0.13–3.62	0.24–30.38	0.62–50.05	0.40–1.77
	P		0.14	0.66	0.42	0.13	0.64
71–	sCJD	317	57.0%	5.2%	10.1%	49.2%	12.4%
	Control	60	65.0%	6.7%	10.0%	56.7%	11.7%
	Odds ratio		0.81	0.76	1.15	0.83	1.27
	95% CI		0.15–4.37	0.15–3.80	0.38–3.48	0.17–4.02	0.52–3.10
	P		0.80	0.74	0.81	0.82	0.60

† Other surgery: Surgery other than neurosurgery or ophthalmic surgery. 95% CI, 95% confidence interval.

three of these patients had MM at codon 129 of the PrP gene, as did all other previous vCJD patients. However, a fourth patient with asymptomatic infection after blood transfusion and MV at codon 129 was reported in 2004.[37] This patient died of a non-neurological disorder 5 years after receiving a blood transfusion from a donor who subsequently developed vCJD.[37] Protease-resistant PrP was detected by Western blot, paraffin-embedded tissue blot, and immunohistochemistry in tissue from the spleen, but not in brain tissue.[37] This case was the first indication that individuals with codon 129 polymorphisms other than MM could be infected by the vCJD agent.

THE RISK OF sCJD TRANSMISSION VIA MEDICAL PROCEDURES

The association between sCJD and medical procedures before disease onset

To determine if an association exists between medical procedures and sCJD, we investigated medical procedures (any surgery, neurosurgery, ophthalmic surgery, and blood transfusion) in patients registered by the CJD Surveillance Committee in Japan over a recent 9-year period.[18] We conducted an age-stratified case-control study with 753 sCJD patients and 210 control subjects. We also investigated sCJD patients who underwent neurosurgery or ophthalmic surgery at a hospital where other patients with any type of prion disease had undergone neurosurgery or ophthalmic surgery.[18] In our case-control study, the cases were patients with definite or probable sCJD, and patients with "prion diseases definitely denied" and "prion diseases probably denied" as the controls.[18] The frequencies of medical procedures before disease onset in cases and controls are shown in Table 1. Among both cases and controls, approximately 50% had a history of surgery, and approximately 10% had received a blood transfusion. There was no significant difference between cases and controls in the frequencies of any surgery, neurosurgery, ophthalmic surgery, other surgery or blood transfusion (Table 1). On logistic regression analysis, there was no significant risk associated with any investigated medical procedure (Table 1). Although the control group was relatively small, there was no evidence that prion disease was transmitted via medical procedures before onset of sCJD in this study.

The results of 11 case-control studies and a meta-analysis investigating the history of medical procedures as a risk factor for sCJD are shown in Table 2. In these studies, blood transfusion was never shown to be a significant risk for developing CJD, which conforms with our results (Table 2).[7–12,15–18] However, the association between surgical procedures and the development of CJD has been controversial (Table 2).[7–18] Our results, which indicated that surgery was not a significant risk for sCJD, were consistent with those of two previous case-control studies with large sample sizes[15,16] and a meta-analysis that included three case-control studies (Table 2).[17] In studies that claimed to reveal an association,[7–12] the results were conflicting when surgical procedures were categorized by type of surgery. With respect to neurosurgeries, one case-control study observed a significant risk for sCJD;[8] however, other studies indicated that there was no significant risk, when cadaveric dura mater grafts were excluded.[7,9–12] Ophthalmic surgery was reported to be a significant risk for sCJD in a case-control study from Australia,[9] but not in other studies.[11–14,16] In a recent study in the UK,[12] an increase in risk associated with having had surgery was observed. This association was mainly noted in the category of "other surgery," for example, stitches to skin, and the association largely disappeared when "other surgery" was excluded from the analysis. These results suggest that although the possibility of prion transmission via surgical procedures is slight, we cannot entirely exclude this because of the existence of iatrogenic CJD. A recent study reported that methodological differences might partially explain the conflicting results regarding the association between surgery and CJD.[38] In particular, it is important to consider where the control participants are recruited (hospital or community) and how information on them is obtained (from participants or proxy informants).[38] Such methodological inconsistencies are serious limitations of case-control studies.

In our study,[18] five patients with sCJD had a history of neurosurgery or ophthalmic surgery at hospitals where neurosurgery or ophthalmic surgery had been performed on patients who later developed prion diseases; however, the interval between surgeries at the same hospitals was always more than 3 years.[18] According to the Incident Panel in the UK, most instruments that have gone through 10 cycles of use and decontamination are unlikely to pose a significant risk.[39] We assume that all instruments had indeed gone through more than 10 cycles of use during the 3-year interval and that they were not infective. Therefore, it is unlikely that an infectious agent was transmitted via these surgeries. In Japan, a large number of dCJD patients have been identified, but there have been no cases of other types of iatrogenic CJD. This study confirms that there were no cases of surgical transmission among patients diagnosed with sCJD.

Table 2 Review of case-control studies and a meta-analysis of medical procedure-related risk for sporadic Creutzfeldt-Jakob disease (sCJD)

	Year	Case	Control	Country	Medical procedures associated with sCJD
Kondo & Kuroiwa[7]	1982	60	56	Japan	Surgery within 5 years before onset of disease
Davanipour, *et al.*[8]	1985	26	40	USA	Injury to, or surgery for the head, face, or neck
					Suture
					Ocular tonometry
Collins, *et al.*[9]	1999	241	784	Australia	Surgery
					Surgeries for heart, hemorrhoids, gallbladder, hernia, cataract/eye, varicose veins, carpal tunnel and hysterectomy
Nakamura, *et al.*[10]	2000	52	102	Japan	Surgery with cadaveric dura mater
Ward, *et al.*[11]	2002	326	326	France, Germany, Netherlands, UK	Surgery
					Gynecologic surgery and other surgery (any surgery other than neurologic, eye, ear, gallbladder, gastrointestinal, gynecologic operations, tonsilectomy and appendectomy)
Ward, *et al.*[12]	2008	431	454	UK	Surgery
					Other surgery
Mahillo-Fernandez, *et al.*[13]	2008	167	3059	Sweden, Denmark	Major surgical procedures conducted 20 or more years before onset of sCJD
Harries-Jones, *et al.*[14]	1988	92	184	UK	None
van Duijn, *et al.*[15]	1998	405	405	Belgium, France, Germany, Italy, Netherlands, UK	None
Zerr, *et al.*[16]	2000	405	405	Belgium, France, Germany, Italy, Netherlands, UK	None
Wientjens, *et al.*[17] (meta-analysis)	1996	178	332	Japan, USA, UK	None
Ours[18]	2009	753	210	Japan	None

Surgical procedures after onset of sCJD

Surgical procedures after onset of sCJD might result in secondary transmission of the disease through the use of contaminated instruments. In particular, neurosurgery is categorized as a high-risk procedure, and ophthalmic and olfactory surgery as medium-risk procedures, for transmission of the infectious agent for sCJD, according to the guidelines of the CJD Incident Panel in the UK.[39] We found that 34 (4.5%) sCJD patients had undergone some type of surgery before receiving a diagnosis of prion disease, and that six (0.8%) had undergone neurosurgery and 14 (1.8%) had undergone ophthalmic surgery (Table 3).[18] The six cases that underwent neurosurgery did so within 3 months after sCJD onset: the procedures were performed for subdural hematoma ($n = 3$), aneurysm ($n = 2$), and meningioma ($n = 1$) (Table 3).[18]

Our findings suggest that a delayed diagnosis of sCJD may be linked to an increase in the risk of secondary transmission of prion diseases via surgical instruments. Among the neurosurgery cases, the symptoms of sCJD were misdiagnosed as those of other neurological diseases, and the surgeries were performed near disease onset. In ophthalmic surgery, all the patients underwent surgery for

Table 3 Sporadic Creutzfeldt-Jakob disease (sCJD) patients who underwent neurosurgery or ophthalmic surgery after onset of sCJD in a study of patients investigated by the CJD Surveillance Committee, Japan[18]

Patient no.	Reason for surgery	Interval between surgery and onset of sCJD symptoms	Age (years) at onset of sCJD	Symptom at onset of sCJD
1	Subdural hematoma	0 M	71	Dementia
2	Subdural hematoma	0 M	77	Psychiatric symptoms
3	Subdural hematoma	1 M	57	Dementia
4	Meningioma	1 M	74	Vertigo
5	Aneurysm	2 M	46	Dementia
6	Aneurysm	3 M	67	Vertigo
7	Cataract	0 M	60	Gait disturbance
8	Cataract	0 M	61	Dementia
9	Cataract	0 M	63	Visual impairment
10	Cataract	0 M	71	Visual impairment
11	Cataract	0 M	74	Visual impairment
12	Cataract	0 M	74	Visual impairment
13	Cataract	1 M	66	Dementia
14	Cataract	1 M	74	Psychiatric symptoms
15	Cataract	1 M	85	Visual impairment
16	Cataract	2 M	79	Tremor
17	Cataract	4 M	81	Visual impairment
18	Cataract	8 M	77	Psychiatric symptoms
19	Cataract	10 M	57	Dementia
20	Cataract	14 M	64	Visual impairment

M, months.

cataract, and 50% of the patients (7/14) presented with visual disturbance as the initial symptom of sCJD (Table 3).[18] These findings are similar to those of a report from the UK,[40] and those of our previous study.[41] Visual disturbance might prompt ophthalmic surgery. Of greater concern is the fact that three patients underwent surgery eight or more months after sCJD onset. In our studies,[18,41] all surgeons who provided us with information regarding instrument cleaning and sterilization procedures reused some surgical instruments. However, the sterilization methods were inadequate to sterilize against infectious PrP, according to WHO guidelines.[42] These inadequate methods included the use of ethylene oxide gas and incomplete autoclaving. Neurosurgeons and ophthalmologists must become better informed about prion diseases and the necessity of using disposable instruments whenever possible. Furthermore, a more sensitive method for the early diagnosis of sCJD is required, because clinical diagnosis is sometimes difficult, particularly in atypical sCJD cases, which include the MM2, MV2, VV1, and VV2 phenotypes[43–46] according to six phenotypes of sCJD based on codon 129 *PrP* polymorphisms and type of protease-resistant PrP as determined by Western blotting.[47] Even neurologists sometimes misdiagnose atypical sCJD in patients with other neurodegenerative disease, such as Alzheimer's disease or progressive supranuclear palsy.[43]

CONCLUSIONS

According to the conflicting results of case-control studies, including ours, we cannot assert that medical procedures are risk factors for the development of sCJD. However, the fact that some sCJD patients had surgeries, including neurosurgery, even after the onset of sCJD, indicates that we cannot completely exclude the possibility of transmission of prion diseases via medical procedures. Neurosurgeons, ophthalmologists, other surgeons and physicians must pay more attention to the possibility of prion diseases in order to reduce the risk of transmission. In addition, careful long-term surveillance of prion diseases is necessary.

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研究報告　調査報告書

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一般的名称	乾燥濃縮人アンチトロンビンⅢ				2010年3月15日	該当なし	
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研究報告概要

とのようにプリオン病が脳を破壊するのかを研究しているアメリカ国立保健研究所の科学者は、プリオン関連の障害に特有のスポンジ様の脳の損傷を引き起こさないマウスでプリオン病の新しい形状を観察した。
NIH プレス・リリースによると、新しいプリオン病は、脳アミロイド血管障害（脳動脈を損傷するアルツハイマー病に関連した状態）に似ている。
プリオン病（感染性海綿状脳症として知られている）は主に脳に損傷を与え、牛における狂牛病又はウシ海綿状脳症と散発性 CJD、vCJD を含む。
本研究は、スコットランドで National Institute of Allergy and Infections Diseases と Veterinary Laboratories Agency によって行われ、プリオン病の通常の徴候の多くが発現した。しかしながら、プリオン病を代表するニューロン内外のスポンジ様の穴は観察されなかった。
その代わりに、マウスの脳は血管の外でトラップされたプリオン蛋白質プラークの大きな蓄積（これは脳の動脈、静脈そして毛細血管を損傷させる）を含んでいた。
この研究から得られた知見は、プリオン病の治療の開発において、アルツハイマー病と同様に科学者の役に立つであろう。

報告企業の意見

マウスを用いた動物実験で、プリオン病に特有のスポンジ様の脳損傷を起こさない新しい形状が観察されたことについての報告である。
血漿分画製剤は理論的なvCJD伝播リスクを完全には排除できないため、投与の際には患者への説明が必要である旨を2003年5月から添付文書に記載している。2009年2月17日、英国健康保護庁(HPA)はvCJDに感染した供血者の血漿が含まれる原料から製造された第Ⅷ因子製剤の投与経験のある血友病患者一名から、vCJD異常プリオン蛋白が検出されたと発表したが、弊社の原料血漿採取国である日本及び米国では、欧州滞在歴のある献（供）血希望者を一定の基準で除外し、また国内でのBSEの発生数も少数であるため、原料血漿中に異常型プリオン蛋白が混入するリスクは1999年以前の英国に比べて極めて低いと考える。また、製造工程においてプリオンが低減される可能性を検討するための実験を継続して進めているところである。

今後の対応

本報告は本剤の安全性に影響を与えないと考えるので、特段の措置はとらない。

使用上の注意記載状況・その他参考事項等

代表としてノイアート静注用500単位の記載を示す。
2. 重要な基本的注意
(1)略
2) 現在までに本剤の投与により変異型クロイツフェルト・ヤコブ病（vCJD）等が伝播したとの報告はない。しかしながら、製造工程において異常プリオンを低減し得るとの報告があるものの、理論的な vCJD 等の伝播のリスクを完全には排除できないので、投与の際には患者への説明を十分行い、治療上の必要性を十分検討の上投与すること。

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IN THIS ISSUE

Cord Blood Workshop Answers Industry Questions

Approximately 225 people from across North and South America, Europe, and Asia attended the Cord Blood Licensure Workshop held this week in Rockville, Md. The March 8-10 event provided information on the elements and steps involved in the biologics license application process as outlined in a Food and Drug Administration guidance. The guidance pertains to the manufacturing of minimally manipulated, unrelated, allogeneic placental/umbilical cord blood and applicable regulatory requirements compliance. A draft guidance on investigational new drug applications for HPC-Cs was released at the same time as the licensure guidance and provides recommendations for use of HPC-Cs that are not licensed but are needed for treatment of a patient, with a serious or life-threatening disease or condition. Participants raised concerns about the ability to meet the October 2011 deadline to obtain a license for these products, inquired about how the guidance would affect their patients, and sought clarification on the submission process for BLAs and INDs. FDA speakers noted that some items are facility-specific and should be addressed in pre-BLA meetings, encouraging those with additional questions to submit them to the docket, which is referenced in an Oct. 20, 2009, Federal Register notice. Presenters also emphasized the unique opportunity that licensure presents for collaboration among those in the cellular therapy community, as these could be the first licensed allogeneic cellular therapy products.

Handouts from the workshop will be posted in the coming weeks on AABB's Live Learning Center for attendees to access.

Event Calendar

March 18-21 – 2010 South Central Association of Blood Banks Annual Meeting and Exhibit Show read more »

March 21-22 – SCABB Immunohematology Reference Lab Workshop read more »

March 24 – AABB Audioconference: Distance Education: Is It an Answer to the Personnel Shortage? read more »

March 24-25 – National Cancer Institute's 3rd Annual Biospecimen Research Network Symposium read more »

March 31 – AABB Audioconference: Molecular Approaches to Rh Problems read more »

Full Calendar read more »

Poster Created to Help Meet New Standard 1.5 Requiring Process for Reporting Quality Concerns to AABB

AABB has developed a poster for facilities to use in the workplace to help them comply with a new standard that requires a process for personnel to be able to anonymously communicate concerns about quality or safety to AABB. Standard 1.5 is included in the 26th edition of Standards for Blood Banks and Transfusion Services, which took effect Nov. 1, 2009. Facilities are not required to use the poster; it is an aid to compliance with the intent of this new standard. Any questions can be directed to AABB's Department of Accreditation and Quality.

Latest Issue of AABB News Explores New Government Health Care Leadership

The March issue of AABB News focuses on the changes in health care leadership since President Obama took office — and how this affects the transfusion and cellular therapy communities. In one article, Howard Koh, MD, MPH, assistant secretary for health at the U.S. Department of Health and Human Services, speaks to AABB News about HHS' priorities — including an increased focus on preventive medicine and forging new relationships with industry. Another article examines the changes in store at the National Institutes of Health under Director Francis Collins, MD, PhD. This issue — to be mailed next week — also includes an update on the Donor Hemovigilance System and a column about how to record references in standard operating procedures.

Enrollment Under Way for National Hemovigilance System

One month following the launch of the Hemovigilance Module of the Centers for Disease Control and Prevention's National Healthcare Safety Network, approximately 60 facilities have agreed to enroll. The module is a surveillance system that allows for the real-time tracking of adverse events associated with blood transfusions as well as the quick identification of trends within a facility. All hospitals with transfusion medicine services are encouraged to join the module as well as AABB's special data analysis group within the system. The goal of AABB's Hemovigilance Module group is to provide individual institutions with in-depth analyses and recommendations for specific enhancements to patient safety and reductions in health care costs. To join, facilities should express their interest to AABB and complete the Intent to Participate form. Assistance with the NHSN enrollment process also is being offered by AABB. Interested facilities should visit the AABB Web site or contact Barbee I. Whitaker, PhD, director of data and special programs at AABB, for further guidance.

FDA, Makers of WinRho SDF Warn of Potentially Fatal Complications in ITP Patients

The Food and Drug Administration issued a MedWatch announcement on Wednesday alerting the medical community to potentially fatal risks of intravascular hemolysis in patients being treated for immune thrombocytopenic purpura with WinRho SDF. In the announcement, FDA indicated that the manufacturer and distributor of WinRho SDF, Cangene Corporation and Baxter Healthcare Corporation, have sent a letter informing health care professionals that a new boxed warning has been added to the product labeling, which specifies what complications can

result and provides guidelines for proper administration and follow-up to help ensure WinRho SDF is used safely and effectively. The letter also advises of specific changes to the warnings, contraindications, precautions, and dosage and administration. Other resources included in the announcement include prescribing information and patient information. This notification does not apply to patients receiving WinRho SDF for the suppression of Rh isoimmunization.

Global Cellular Therapy Organizations Gather New Data

The Alliance for Harmonisation of Cellular Therapy Accreditation — of which AABB is a member — has partnered with the World Marrow Donor Association to gather data on cellular therapy collection facilities. Collection facilities are asked to complete a form seeking certain license and accreditation data to include in this registry, which will serve as a resource for WMDA members and regulatory organizations.

WMDA also is in the process of updating country-specific import and export requirements. This data — which was originally collected in 2003 — is located in the regulatory section of the WMDA Web site.

＊「NIH Scientists Find New Form of Prion Disease That Damages Brain Arteries」

National Institutes of Health scientists studying how prion diseases damage the brain have observed a new form of prion disease in mice that does not cause the sponge-like brain deterioration characteristic of prion-related disorders. According to an NIH press release, the new prion disease resembles cerebral amyloid angiopathy, a condition related to Alzheimer's disease that damages brain arteries. Prion diseases — known as transmissible spongiform encephalopathies — primarily damage the brain and include mad cow disease or bovine spongiform encephalopathy in cattle, sporadic Creutzfeldt-Jakob disease and variant CJD. The study, conducted by scientists at NIH's National Institute of Allergy and Infectious Diseases and the Veterinary Laboratories Agency in Scotland, revealed many of the usual signs of prion disease. However, the sponge-like holes in and around nerve cells typical of prion disease were not observed. Instead, the mouse brains contained large accumulations of prion protein plaques trapped outside blood vessels, which damages arteries, veins and capillaries in the brain. The knowledge gained from this study may help scientists in developing therapies for prion diseases as well as Alzheimer's disease.

Region Watch

Demand for most frozen products is increasing; the need for cryoprecipitate and fresh frozen plasma is especially steady. A robust supply of frozen products easily serves these needs, according to the National Blood Exchange. Platelet products are readily available throughout the country, and the surplus of red blood cells continues to climb.

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