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Chapter 11
Vibrio parahaemolyticus Risk Management in Japan

Hajime Toyofuku

Introduction

In Japan, raw consumption of fish and shellfish is common; therefore, the risk of gastroenteritis caused by *Vibrio parahaemolyticus* (*Vp*) is high. In the first half of the 1980s, *Vp* was identified as the causal agent of more than half of the reported cases and outbreaks of foodborne illnesses in Japan, and it remained the most common causal agent of foodborne illnesses in subsequent years with its incidence peaking in 1998 (839 outbreaks and 12,318 cases). Since 1998, however, the numbers of both outbreaks and cases of *Vp* infection have decreased, with 14 outbreaks and 280 cases reported in 2009.

Purpose

The purpose of this study is to review available data for foodborne illnesses caused by *Vp*, as published by the Ministry of Health, Labour and Welfare (MHLW), Japan, from 1990 to 2009 and to find out any factors that could be useful to understand the relationship between the decrease in *Vp* outbreaks and risk management tools that were implemented during the same period along with other potential factors.

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G. Sauvé (ed.), *Molluscan Shellfish Safety*, DOI 10.1007/978-94-007-6588-7_11,

Methods

The number of cases and outbreaks of *Vp* infection were obtained from the Food Poisoning Investigation Report published by the MHLW, Japan (2000, 2001, 2002, 2003, 2005, 2006, 2007, 2008, 2009, 2010, 2011a, b).

Data on the number of outbreaks caused by different serotypes were obtained from the risk profile prepared by the Food Safety Commission (2012).

Food source attribution obtained through *Vp* outbreak investigations in 2000–2009 was reviewed based on the summary of food poisoning reports published by the MHLW.

The implemented risk management strategies were identified based on the regulations and directives published by the MHLW.

Results

Since Japanese people eat raw seafood, they are often exposed and are frequently infected by *Vp*. Therefore, *Vp*-related food poisoning has been the most frequently reported foodborne illness, particularly during the first half of the 1980s. Figure 11.1 shows the number of outbreaks and cases of *Vp* infection. Beginning in 1993, the numbers of cases and outbreaks of *Vp*-related food poisoning increased and peaked in 1998 (837 outbreaks and 12,318 cases); conversely, since 1999, both numbers have decreased significantly, and in 2009 only 14 outbreaks and 280 cases were reported. The number of outbreaks and cases of *Vp* infection in 2009 was only 1.6 and 2.3 % of those in 1998, respectively.

Table 11.1 shows the number of *Vp* outbreaks by serotype from 2000 to 2009. Unfortunately, serotype data are only available from 2000. The percentage of *Vp*-related outbreaks caused by the pandemic strain O3:K6 among serotype-identified *Vp*-related outbreaks ranged between 50 and 80 % (average, 66.7 %) from 2000

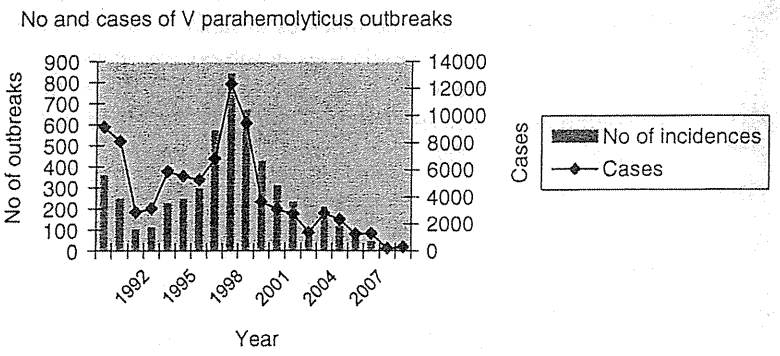

Fig. 11.1 The number of outbreaks and cases of *Vp* infection

Table 11.1 Number of *Vibrio parahaemolyticus* outbreaks by serotype

Year	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009	Total	%
No. of incidences	422	307	229	108	205	113	71	42	17	14	1,528	
No. of incidences that serotype identified	260	178	118	60	94	47	24	18	4	5	808	
Serotypes												
O3:K6	163	106	95	36	82	30	14	14	2	5	547	67.7
O1:K25	8	14	11	7	7	3	2	1	0	0	53	6.6
O4:K8	10	6	6	2	3	0	1	2	1	0	31	3.8
O4:K68	2	18	0	2	2	5	1	0	0	0	30	3.7
O3:K29	1	0	12	1	0	2	1	0	0	0	17	2.1
O1:K56	3	2	1	0	0	2	1	0	0	0	9	1.1
O6:K18	1	2	4	2	0	0	0	0	0	0	9	1.1
O1:KUT	2	1	2	1	0	1	0	0	0	0	7	0.9
O3:KUT	0	4	1	1	1	0	0	0	0	0	7	0.9
O3:K5	1	1	0	2	0	1	0	0	0	0	5	0.6
O4:K9	1	1	0	1	1	0	1	0	0	0	5	0.6
O5:K15	0	0	2	0	1	1	0	1	0	0	5	0.6

Adapted from Food Safety Commission (2012)

to 2008. In addition to O3:K6, the pandemic group included O3:K6 serovariants, such as O3:K6,O1:K25, O1:K56, O1:KUT, O3:K5, O3:KUT, O4:K8, O4:K68, and O6:K18 (Nair et al. 2007), and accounted for 86.4 % of all serotype-identified *Vp*-related outbreaks.

Table 11.2 presents the food sources responsible for *Vp*-related outbreaks, as identified in investigations from 2000 to 2009. Among 780 food source-identified *Vp*-related outbreaks, seafood accounted for 27.5 % of these outbreaks (206 outbreaks). Among seafood-related outbreaks, sashimi, including molluscan shellfish, cooked/processed molluscan shellfish, and cooked/processed crab meat accounted for 27.3, 25.6, and 7.1 % of outbreaks, respectively.

Table 11.3 presents the prevalence of *Vp* in seafood harvested in 2001, 2007, 2008, and 2009. The sampling areas in 2001 and 2007 covered similar areas in five regions in Japan. Sampling in 2008 and 2009 was from retail shops throughout Japan. The prevalence of total *Vp* and the tdh gene in fresh shellfish and fish samples collected and tested in 2001 were 95.4 and 10 % respectively, while those in 2007 were 75.7 and 6.5 %, respectively, and those in 2008 were 90.2 and 6.1 %, respectively (Table 11.3). Compared with the numbers of *Vp* outbreaks (307 in 2001, and 42, 17 in 2007, 2008, respectively), the contributions of both total *Vp* and the tdh gene in the decrease of *Vp* outbreaks were considered to be limited, and the strict temperature control throughout food chain and preventative measures to minimize contamination of seafood, e.g. use of pasteurized seawater, could be more important factors for the reduction of *Vp* outbreaks.

Table 11.4 shows the number of seafood samples in which TDH productivity was confirmed by serotype among the same samples presented in Table 11.3. In 2001, all TDH-expressing strains were O3:K6; however, only one-third of TDH-expressing strains in 2007–2009 were O3:K6.

Table 11.2 Food Source Attribution in *Vp* outbreaks in 2000–2009

Food sources identified by *Vp* outbreak investigations	Number	Outbreaks (%)	Percentage within seafood (%)
Sashimi including Molluscan Shellfish	65	30.50[a]	27.30
Cooked/processed Molluscan Shellfish	61		25.60
Cooked/processed Crab meat	17		7.10
Cooked/processed Fish	11		4.60
Cooked/processed Squids	11		4.60
Cooked/processed Sea Urchin	9		3.80
Sushi	7		2.90
Other seafood	57		23.90
Other food	542	69.5[b]	
Source identified	780	51.05[c]	
Total number of *Vp* outbreaks	1,528		

[a]Percentage of *Vp* outbreaks associated with seafood (238) out of *Vp* outbreaks which sources were identified (780)
[b]Percentage of *Vp* outbreaks associated with non-seafood (542) out of *Vp* outbreaks which sources were identified (780)
[c]Percentage of source identified *Vp* outbreaks (780) out of total number of *Vp* outbreaks (1,528)

Control measures taken by the MHLW were reviewed. In 2001, the MHLW established a labelling requirement which required seafood for raw consumption "shall be labeled for raw consumption purpose". In addition, standard for processing which required water for processing shall be potable, pasteurized seawater or artificial seawater made from potable water. In this case pasteurized seawater shall be *V. parahamolyticus* negative, by e.g. UV irradiation (more than 3 log reduction) (Tsurumi 2001) and storage standards which required fish and shellfish shall be stored at temperature of 10 °C or below (for frozen products: below −15 °C).

The following microbiological limits were also established:

- boiled octopus: *V. parahaemolyticus* negative /25 g
- boiled crab: *V. parahaemolyticus* negative /25 g
- fresh fish and shellfish for raw consumption: MPN 100/g or less
- shucked oyster for raw consumption: MPN 100/g or less
- frozen fish and shellfish for raw consumption purpose: MPN 100/g or less

Furthermore, the guidance for industries and consumers was published as a directive from the Director of the Food Safety Department. The guidance for industries is as follow:

- Seawater used for transportation of harvested fish, shellfish, live fish, and fish tanks and seawater used for washing unprocessed fish, shellfish, and shell-on bivalves should be pasteurized seawater (more than 3 log reduction) (Tsurumi 2001) or seawater which is not contaminated with *V. parahaemolyticus*. During this process, care should be taken to prevent contamination of other products.

Table 11.3 *Vp* isolation from fresh fish and shellfish

	Total *Vp*			*Vp* with *tdh* gene					
Samples	No. of samples	No. of samples from which *Vp* isolated	%	No. of samples	No. of samples from which tdh gene identified	%	No. of samples from which TDH producing *Vp* were isolated	Sampling year	Sampling month
Fresh shellfish and fish	173	165	95.4	329	33	10	11	2001	June–October
	247	187	75.7	247	16	6.5	5	2007	July–December
Bivalve and fresh fish	407	367	90.2	407	25	6.1	6	2008	June–October
Bivalve harvested in Japan	66	58	87.9	66	3	4.5	0	2009	July–December
Bivalve imported	123	106	86.2	123	21	17	7	2009	July–December

Adapted from Food Safety Commission (2012)

Table 11.4 Serotypes of TDH producing *Vp* isolated from fresh fish and shellfish

Sampling year	No. of samples from which TDH producing *Vp* were isolated	Serotype	Samples from which the serotype *Vp* were isolated
2001	11	O3:K6	11
2007	5	O4:K9	1
		O4:K37	1
		O4:K38	1
		O4:KUT	2
		OUT:K37	2
		OUT:K38	1
		OUT: KUT	2
		NT(O3: K6 negative)	1
		subtotal	11
2008	6	O3:K6	2
		O4:KUT	1
		O5:K17	1
		O10: K52	2
		O10: KUT	1
2009	7	O3:K6	4
		O1:KUT	1
		O3:K17	1
		O5: KUT	1
		O8: K21	2
		O10: KUT	1

Adapted from Food Safety Commission (2012)

- Pasteurized seawater and artificial seawater used for processing should be prepared immediately before use, and frequently changed. Re-use should be avoided.
- Fish and shellfish for raw consumption should be kept at a temperature of 4 °C or lower unless the products have a quality problem due to the temperature.
- The shelf-life of packed sushi, which is stored and sold at a temperature of 10 °C or above should be established based on scientific evidence.
- Sushi and sashimi served at restaurants should be served immediately after preparation, and should be consumed within 2 h after exposure to room temperature.

The guidance for consumer is as follow:

- Fresh fish and shellfish without a label 'for raw consumption purpose' should not be consumed raw. During shucking of bivalves for raw consumption, edible parts should be washed thoroughly with potable water.
- Sushi served at restaurants should be consumed as soon as possible.
- Fresh fish and shellfish for raw consumption should be kept at a temperature of 4 °C or lower at home, and should be consumed within 2 h after exposure to room temperature.

These strategies focused on minimizing contamination from environments including seawater and preventing the growth of *Vp* throughout the food chain from harvest to consumption.

Discussion

After 1998, the year in which the numbers of cases and outbreaks of *Vp* infection peaked (839 outbreaks, 12,318 cases), the numbers of both cases and outbreaks of *Vp* infection decreased continuously, reaching 14 outbreaks and 280 cases in 2009. The microbiological limit and processing and storage standards implemented as legal requirements from 2001 onwards, partially contributed to this decline. In addition, efforts to minimize the contamination and growth of *Vp* throughout the food chain could also have contributed to this decline. However, the prevalence of total *Vp* and *tdh*-positive *Vp* in seafood did not show the same drastic changes. At this moment, we do not have concrete data to explain this public health outcome, although it is possible that a new pandemic strain may appear in the future. Thus, we should continue to implement control measures and perform baseline surveillance, both of public health and of seafood to prevent outbreaks of *Vp* infection.

Conclusion

After the incidence of *Vp* foodborne outbreaks peaked in 1998, the numbers of cases and outbreaks of foodborne *Vp* infection decreased. The MHLW implemented several risk management strategies, including the establishment of a microbiological regulatory limit in 2001. Even though the factors responsible for this decrease are not completely understood it is hoped that this low level of public health burden is maintained by implementing risk management strategies throughout the food chain.

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世界に通用する衛生管理手法とは

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食品の国際規格として，世界貿易機構（WTO）の衛生動植物SPS協定においてベンチマークされているのはコーデックス委員会が作成した規格等である。WTO加盟国はコーデックス規格に適合させることが求められ，コーデックス規格より厳しい規格を設定する場合には，リスク評価結果をもって，その根拠を示さなければならない。まず，世界に通用する衛生管理としては，コーデックス委員会の規範，規格，ガイドライン等が最も重要なreferenceになる。

1. コーデックス委員会

コーデックス委員会では食品微生物，食品添加物，農薬の最大値，残留動物用医薬品のMRL等，リスク管理のための文書を多数作成してきた（表1参照）。

微生物分野では食品衛生の一般原則およびその附属文書であるHACCPのガイドラインがリスク管理の基本となる。安全な食品は食品衛生の一般原則に代表される優良衛生規範（GHP），優良製造規範（good manufacturing practices (GMP)）および優良農業規範（good agricultural practices (GAP)）を遵守していればできるというGHPベースの考え方が最初に登場した。次のステップとして食品安全リスクマネジメントシステムであるHACCPのように，ハザードの汚染率または濃度を下げればリスクは下がるだろうが，実際にどの程度リスク低減が期待できるかは定量的に示すことが困難なザードベースのリスク管理が広まった。さらに患者発生確率に基づき，政府がALOP (Appropriate Level of Protection：適切な衛生健康保護水準)を

表1　コーデックスが作成したガイドライン，規範等

■食品衛生の一般原則及びHACCP附属文書（CAC/RCP 1-1969）
■食品のMicrobiological Criteriaの設定及び適用のための原則（CAC/GL 21-1997, 2013年改定）
■微生物リスク評価実施の原則とガイドライン（CAC/GL 30-1999）
■微生物リスク管理実施の原則とガイドライン（数的指標の付属文書）（CAC/GL 63-2007）
■食品衛生コントロール措置の妥当性確認（Validation）のガイドライン（CAC/GL 69-2009）
■生鮮果実及び野菜の衛生規範（CAC/RCP 53-2003）
■卵及びその製品の衛生規範（CAC/RCP 15-1976, rev2007）
■活及び生の二枚貝の規格（CODEX STAN 292-2008）
■食品衛生の一般原則を食品中のリステリア・モノサイトジェネス制御に適用するためのガイドライン（CAC/GL61-2007）
■食品衛生の一般原則を海産食品中の病原性ビブリオ属の制御に適用するためのガイドライン（CAC/ GL73-2010）
■鶏肉中の*Campylobacter*及び*Salmonella*属菌を制御するためのガイドライン（CAC/GL 78-2011）
■食品衛生の一般原則を食品中のウイルスの制御に適用するためのガイドライン（CAC/GL79-2012）