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Side Effects of Orthopedic Products in Veterinary Medicine in South Korea

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Abstract As more veterinary clinics become specialized with the growth of the companion animal market, an increasing number of veterinary clinics perform orthopedic surgery and use orthopedic products, some of which are defective and have side effects. Thus, the present study aimed to prepare fundamental data for the revision and development of manufacturing standards for these products in order to prevent their side effects. We conducted a survey targeting veterinary clinics as consumers and medical device companies as suppliers. Veterinary clinics were surveyed via offline and online methods; 320 clinics that offered orthopedic surgery and approximately 4,000 veterinary clinics that were registered in the Korean Veterinary Medical Association were targeted, and 153 veterinary clinics responded to the survey. The survey for medical device companies, was performed online, targeting 29 companies; 14 companies responded. The number of side effects of orthopedic products was higher in animal orthopedic products than in those for human use. Many consumers tended to suspect that side effects were caused by product defects. To resolve side effects after using orthopedic products, consumers mostly underwent reoperation. Meanwhile, some severe cases proceeded to legal disputes. Similarly, medical device companies, or the suppliers, responded that most side effects occurred in veterinary orthopedic products and that product defects and mistakes in use were the causes. As for most of the follow-up actions for side effects, these companies either reported the issue to those in charge or analyzed and resolved the issues themselves. Therefore, to develop quality products, suppliers should be provided with clear standards for the production, and information disclosure and a report system for side effects should be particularly established to gain consumers' trust regarding the safety of these products.

Key words adverse effect, Korea, orthopedic materials, survey.

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Introduction

With the recent increase in income level, the number of companion animals has rapidly increased, and animal owners' demands for quality medical services have grown, leading to a 10% annual growth in the veterinary medical device industry. In response to this trend, veterinary clinics have recently expanded and offered more specialized services. However, the veterinary medical device market is small compared to the one for human use due to a small batch production, hampering the development of the industry (1). Thus, human medical devices were introduced to veterinary medicine, dividing the veterinary medical device market into medical devices for animals and for humans. However, the veterinary medical device market has also recently been growing (1,3,5-7).

Orthopedic products in particular have also been in increasing demand due to the specialization of veterinary clinics and the development of veterinary medical products. However, many human orthopedic products are still utilized, which has resulted in a number of side effects since the anatomical and physiological characteristics of animals are not reflected in human orthopedic products. Moreover, there is little information on the side effects of veterinary orthopedic products, making it difficult to analyze the current situation and prospects of the veterinary medical device market.

Thus, it is necessary to evaluate the side effects of veterinary orthopedic products in order to reduce their incidence. Hence, the present study surveyed the side effects of orthopedic products for animals and humans that are used in veterinary medicine at the time of writing from the points of view of the consumers and suppliers with the aim to use the results as fundamental data for the revision and development of manufacturing standards for the further prevention of these side effects.

Materials and Methods

Consumer survey

To investigate the side effects of orthopedic products used in veterinary clinics in South Korea, a survey was conducted from September 1 to September 30, 2020. The survey targeted 320 veterinary clinics that performed orthopedic surgery and approximately 4,000 veterinary clinics that were

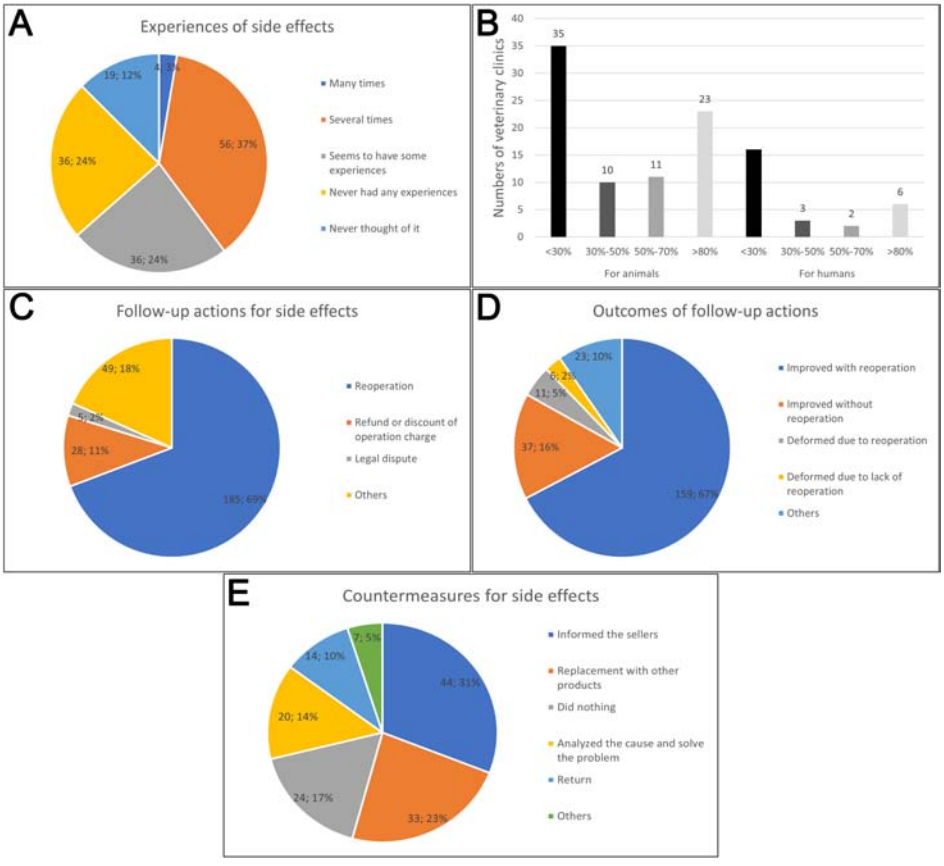

Fig. 1. Side effects of orthopedic products that consumers experienced. Side effects during the last 5 years. (A, B) Ninety-six veterinary clinics had the side effects of orthopedic products during the last 5 years, while 36 veterinary clinics had never experienced it. According to the responses, 79 and 27 veterinary clinics had side effects in orthopedic products for animals and humans, respectively. (C) The most follow-up action for side effects was reoperation (185 cases), followed by the refund or discount of operation charge (28 cases). Five cases were resolved legally. (D) In total, 159 cases had improvement after reoperation, while 37 cases improved without reoperation. Patients had crippling sequelae with (11 cases) or without (6 cases) reoperation. (E) Forty-four clinics informed sellers after the occurrence of side effects, 33 clinics replaced the supplies with other products, 20 clinics analyzed the cause and resolved it, 24 clinics did nothing, and 14 clinics returned the products.

registered in the Korean Veterinary Medical Association, with orthopedic veterinarians being given instructions for the survey. The survey was administered both online and offline. For the offline survey, a questionnaire was sent to the 320 clinics, and phone calls were made to encourage them to participate in the survey. We informed the clinics registered in the Korean Veterinary Medical Association of the online (Google) survey using text and email messages. A total of 153 veterinary clinics, including 33 offline and 120 online participants, responded.

Supplier survey

To investigate the side effects and manufacturing standards for orthopedic products used by veterinary clinics in South Korea, a survey was conducted from September 1 to September 30, 2020, targeting companies that were licensed or applied for the approval of the production of orthopedic products and those supplying veterinary clinics with orthopedic products. An online (Google) survey was conducted, targeting 29 suppliers of orthopedic products that manufacture or import the products. Among these suppliers, 14 companies responded to the survey.

Results

Side effects of orthopedic products that consumers experienced

Side effects during the last 5 years

In total, 96 veterinary clinics encountered side effects of orthopedic products during the last 5 years, while 36 veterinary clinics claimed to never have encountered these effects (Fig. 1A). According to the responses, 79 and 27 veterinary clinics encountered side effects in animal and human orthopedic products, respectively. These indicated that veterinary orthopedic products used in veterinary clinics more frequently induced side effects than did human orthopedic products (Fig. 1B).

Causes of side effects

In total, 47 veterinary clinics answered that side effects were caused by 'product defects,' while 30 and 31 clinics answered 'mistakes in use' and 'unknown causes,' respectively (Table 1).

Types of surgery with side effects of orthopedic products and their symptoms

During the last 5 years, the surgery that induced maximum side effects of orthopedic products was fracture surgery (85 cases), followed by cranial cruciate ligament surgery (10 cases) (Table 2). Orthopedic products related to fracture surgery were the intramedullary pin, orthopedic fixation plate, orthopedic bone screw (non-biodegradable), and orthopedic bone wire; the most frequently used were the orthopedic fixation plate and orthopedic bone screw (non-biodegradable). The side effects of the orthopedic bone screw (non-biodegradable) used for fracture surgery were loosening (24 cases) and breakage (22 cases) of the screw. The side effects of the orthopedic fixation plate were breakage (18 cases) and deformation of the plate (2 cases). In addition, some clinics used artificial ligaments for the operation of patella luxation or cranial cruciate ligament, while other clinics used crimps. The side effects of the artificial ligament were rupture and inflammatory reaction of the ligament.

Follow-up actions for side effects

The most frequent follow-up action for side effects was reoperation (185 cases), followed by a refund or discounted operation charge (28 cases) (Fig. 1C). In addition, five cases were resolved in a judicial manner. There were 49 cases that had other follow-up actions.

Outcomes of follow-up actions for side effects

A total of 159 cases had improvement after reoperation, while 37 cases improved without reoperation. Patients had crippling sequelae with (11 cases) or without (6 cases) reoperation (Fig. 1D). The number of other cases was 49.

Countermeasures for side effects

In total, 44 clinics informed the sellers after the occurrence of side effects, while 33 clinics replaced the supplies with other products, and 20 clinics analyzed the cause and resolved it (Fig. 1E). Another 24 clinics did nothing, and 14 clin-

Table 1. Causes and case numbers of side effects associated with orthopedic products reported by consumers

Causes	Numbers of cases	Numbers of clinics
Product defects	<4	38
	5-9	7
	10-14	1
	>15 cases	1
Mistakes in use	<4	25
	5-9	4
	10-14	0
	>15 cases	1
Unknown causes	<4	24
	5-9	4
	10-14	2
	>15 cases	1

Table 2. Types of surgery, orthopedic products used, and symptoms of side effects of orthopedic products during the last 5 years

Types of surgery	Orthopedic products	Symptoms	Numbers of cases
Fracture	Intramedullary pin	Breakage	6
		Bending, and inflammatory reaction	3
	Orthopedic bone wire	Rupture	3
	Orthopedic bone screw	Loosening and osteolysis	1
		Poor orthopedic bone screw (abrasion of the orthopedic bone screw head)	2
		Breakage of the orthopedic bone screw	22
		Loosening of the orthopedic bone screw	23
		Inflammation	1
	Orthopedic fixation plate	Breakage of the orthopedic fixation plate	18
		Deformation of the orthopedic fixation plate	2
		Lysis of bone tissue	2
Patella luxation	Orthopedic fixation plate kit	Defective product	2
Cranial cruciate ligament rupture	Orthopedic fixation plate and orthopedic bone screw	Breakage of the orthopedic fixation plate	2
	Tissue adhesive	Arthritis	1
	Artificial ligament	Rupture	5
		Inflammation	1
	Crimp	Defective product	1

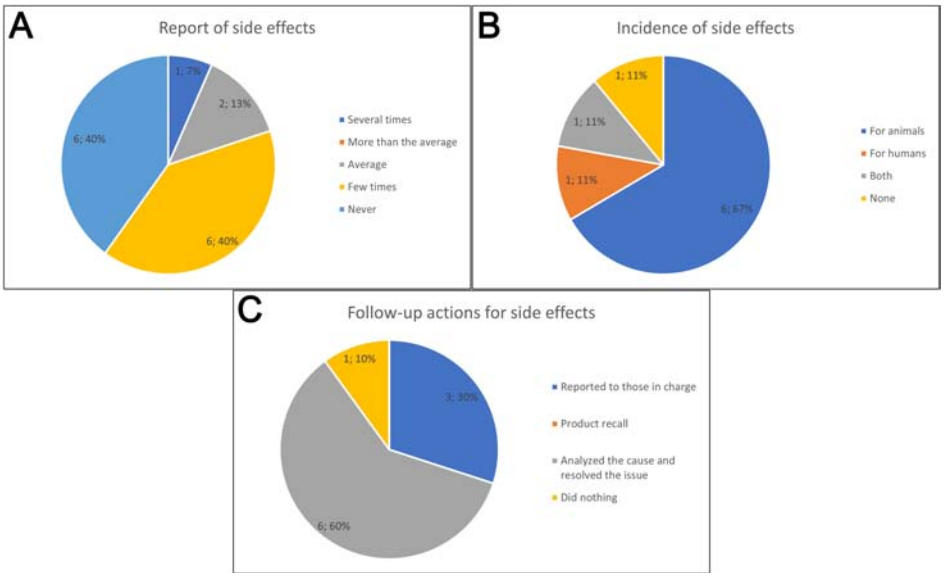

Fig. 2. Side effects of orthopedic products that suppliers encountered. (A) One supplier replied that they had many cases, and two suppliers had an average number of side effects. (B) Of nine suppliers, six suppliers replied it was for animals, one supplier said it was for human use, and the other one supplier mentioned that side effects occurred in products for humans and for animals. (C) In cases of side effects, three suppliers mentioned that they reported to "those in charge", while six suppliers answered that they "analyzed the cause and resolved the issue." One supplier said that they "did nothing".

ics returned the products. There were seven cases that had other countermeasures.

Side effects of orthopedic products that suppliers experienced

Side effects during the last 5 years

For the question on whether the suppliers recognized the side effects of orthopedic products or provided veterinary clinics with a report on these effects, one supplier answered that they had many cases of side effects, two had an average number of side effects (Fig. 2A), six had few cases, and the other six never encountered side effects.

Incidence of side effects

Nine suppliers answered the question about the incidence rate of side effects of products that were provided to veterinary clinics. Specifically, six suppliers replied that the effects occurred with animal-targeted products, one, with hu-

man-targeted products, and one, with both (Fig. 2B).

Causes of side effects

Regarding the causes of these side effects, one supplier responded that there were 7-10 cases of product defects, and two encountered <3 cases with such defects (Table 3). Eight suppliers considered 'mistakes in use' as the cause, and all of these suppliers they encountered <3 cases. Six suppliers were unable to identify the cause.

Follow-up actions for side effects

For the question on what actions were taken when side effects of veterinary orthopedic products were recognized, three suppliers mentioned that they reported the side effects to "those in charge," while six answered that they "analyzed the cause and resolved the issue." One supplier said that they "did nothing" (Fig. 2C).

Manufacturing standards and safety evaluation of orthopedic products

Essential points in the production of veterinary orthopedic products

In an investigation to identify principles that should be used as a standard for the production of orthopedic products, five companies followed the regulation of the Animal and Plant Quarantine Agency. Two companies imported the products, and four applied their own descriptions for quality improvement while simultaneously following the regulation of the Animal and Plant Quarantine Agency (Fig. 3A). The other three companies were found to manufacture products according to the medical device manufacturing standards. In

Table 3. Causes and case numbers of side effects associated with orthopedic products reported by suppliers

Causes	Numbers of cases	Numbers of clinics
Product defects	0	8
	<3	2
	3-6	0
	7-10	1
	>10	0
Mistakes in use	0	1
	<3	8
	3-6	0
	7-10	0
	>10	0
Unknown causes	0	3
	<3	6
	3-6	0
	7-10	0
	>10	0

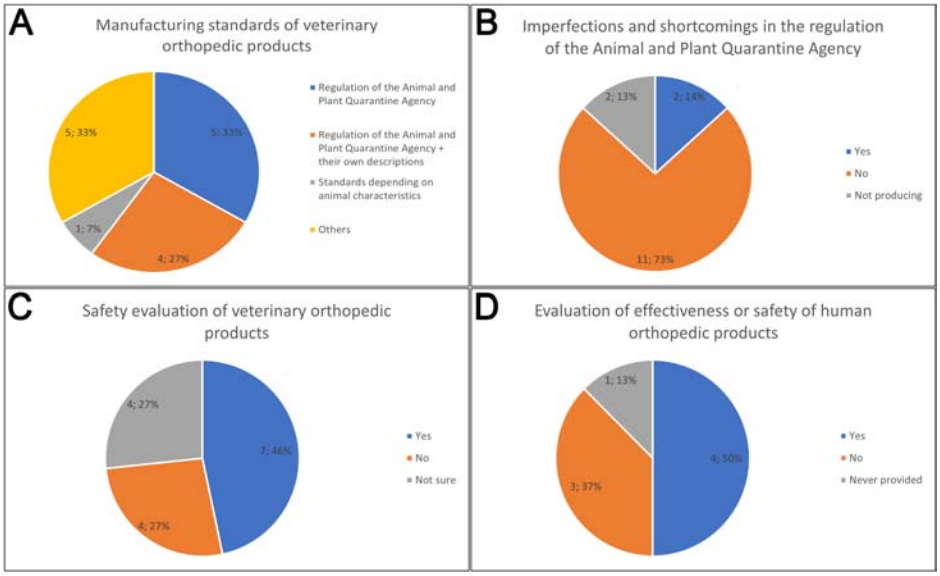

Fig. 3. Manufacturing standards and safety evaluation of orthopedic products. (A) Five companies followed the regulation of the Animal and Plant Quarantine Agency except for two companies that import without production, while four companies applied their own descriptions for quality improvement though they were following the regulation of the Animal and Plant Quarantine Agency. (B) Eleven companies responded that there were neither imperfections nor shortcomings in the regulation of the Animal and Plant Quarantine Agency, while two companies thought that there were imperfections or shortcomings. (C) Seven suppliers answered that they perform safety evaluations for veterinary orthopedic products or a test on their own, while four suppliers had no evaluation. (D) Of eight suppliers, four suppliers performed the evaluation of effectiveness or safety for human orthopedic products, whereas three suppliers had no evaluation.

an unusual case, one company manufactured the products following their standards depending on animal characteristics.

Imperfections and shortcomings in the regulation of the Animal and Plant Quarantine Agency

Eleven companies responded that there were neither imperfections nor shortcomings in the regulation of the Animal and Plant Quarantine Agency, while two companies thought that there were imperfections or shortcomings (Fig. 3B). The remaining two companies did not manufacture their own products. The two companies that answered that there were imperfections mentioned the need for guidelines for clinical and performance evaluation (e.g. clinical trial numbers, evaluation methods for mechanical characteristics) for the approval of production items and detailed standards for performance tests.

Safety evaluation of veterinary orthopedic products

Regarding the products these companies manufacture or import, it was asked if they received any safety evaluations or performed a test on their own. Seven suppliers answered that they performed safety evaluations or their own test, while four suppliers performed no such evaluations (Fig. 3C).

Evaluation of effectiveness or safety for human orthopedic products

Of eight suppliers, four performed the evaluation of effectiveness or safety for human orthopedic products, whereas three did not perform any evaluation (Fig. 3D).

Discussion

The present study investigated the side effects of orthopedic products used in veterinary medicine, aiming to use the study findings as fundamental data for the revision and development of standard manufacturing standards to prevent the future occurrence of side effects. Veterinary orthopedic products were found to induce a higher incidence rate of side effects or defects than did human products. Veterinary clinics, the consumers, tended to think that the cause of side effects were product defects, and mostly performed reoperation as a solution for these side effects. Likewise, medical device companies, the suppliers, encountered more side effects associated with veterinary orthopedic products than with those for humans and reported product defects and mistakes in use as the most frequent causes. In many cases, they reported the side effects to those in charge or analyzed the cause and resolved the issue.

The survey for the use of orthopedic products revealed that veterinary clinics, considered the consumers, and medical device companies, considered the suppliers, acknowledged the issues of side effects and safety of orthopedic products. In particular, both the veterinary clinics and companies reported that side effects occurred more due to products for animals than due to those for humans, showing a consistent response between consumers and suppliers. However, consumers and suppliers showed a small difference in opinion on the incidence of side effects. As for the cause of side effects, consumers cited product defects, while suppliers insisted on mistakes in use. No matter what the most common cause of side effects was, veterinary orthopedic products induced a higher incidence of side effects than did human products. This could be because there is no unified standard to date for the management, production, or importation of veterinary orthopedic products, and also because there was no complete pre-evaluation of orthopedic products to test for safety and effectiveness. As for veterinary medical devices in South Korea, the treatment regulation of medicines for animals had no rules for the reporting of side effects in veterinary medical devices; thus, safety information, such as those for side effects, has never been systematically reported and managed (2). This could be a blind spot in safety management and the cause of the ineffectiveness of veterinary medical devices.

The present study found that because there is currently no reporting system for the side effects of orthopedic products in South Korea, both consumers and suppliers respond to side effects in various ways. Thus, in many cases, only the person directly concerned keeps the corresponding information of side effects. In addition, medical device companies that receive reports of side effects have no established system to share the information of these effects or prepare fundamental measures. As such, it was identified that there is no system to collect and manage related information of side effects except for the simple management of individual cases (2). In the USA, Foods and Veterinary Medicine is under the Food and Drug Administration, in which the Center for Veterinary Medicine controls medical devices for animals (2,8,9), regulating the manufacturers or sellers of veterinary medical devices to clearly describe and label the safety information of the devices. In addition, they operate an integrated electronic reporting system of side effects, enabling the production and sales of quality medical devices. The European Union (EU) also requires every medical device, including those for animals, to be approved for conformance before sales (2). Recently, there have been growing demands for animal med-

ical devices. Because of this, the EU has attempted to enforce the clear description of safety and effectiveness through guidebooks and the operation of a system (EudraVigilance Veterinary) to collect and summarize the information related to side effects of veterinary medical devices (2,4). Thus, South Korea also needs to establish a system that can perform integrated management when side effects of veterinary orthopedic products occur as in the USA and Europe.

In surgery using orthopedic products, side effects cause serious pain in animals and additional medical costs to owners. In this survey, the most frequent follow-up action for side effects was reoperation; refunds or a discounted operation charge also accounted for a significant portion. Thus, side effects of orthopedic products seriously affect all clinics, patients, and animal owners. Therefore, we concluded that one method to prevent the development of these side effects, thereby avoiding the development of pain in animals and removing a cause of dispute between the animal owners and veterinary clinics, is the development of quality products. To achieve this, suppliers should be provided with clear standards for production. In particular, a system to disclose and report side effects to secure the assurance of safety should be established.

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Conflicts of Interest

The authors have no conflicting interests.

References

1. An HJ, Kim CH, Yoon HJ, Wee SH, Moon JS. Performance evaluation of registration and sales of veterinary medical devices in Korea. J Vet Clin 2015; 32: 85-90.
2. Animal and Plant Quarantine Agency Web site. Animals medical device: safety information and side effects casebook. Available at: https://www.qia.go.kr/downloadwebQiaCom.do?id=30658. Accessed Mar 2, 2017.
3. Chang JH, Paik MJ, Chang DW. Survey on utilization of ultrasonographic machine in small animal clinics in South Korea. J Vet Clin 2011; 28: 408-411.
4. European Medicines Agency Web site. EU VICH adverse event report implementation guide. Available at: https://www.ema.europa.eu/documents/regulatory-procedural-guideline/eu-vich-adverse-event-report-implementation-guide_en.pdf. Accessed Jun 4, 2021.
5. Fine EJ, Herbst L, Jelicks LA, Koba W, Theele D. Small-animal research imaging devices. Semin Nucl Med 2014; 44: 57-65.
6. Green MV, Seidel J, Vaquero JJ, Jagoda E, Lee I, Eckelman WC. High resolution PET, SPECT and projection imaging in small animals. Comput Med Imaging Graph 2001; 25: 79-86.
7. Koba W, Kim K, Lipton ML, Jelicks L, Das B, Herbst L, et al. Imaging devices for use in small animals. Semin Nucl Med 2011; 41: 151-165.
8. U.S. Food & Drug Administration Web site. CPG Sec. 607.100. Adequate directions for use (species designation). Animal drugs and veterinary devices. Available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cpg-sec-607100-adequate-directions-use-species-designation-animal-drugs-and-veterinary-devices. Accessed Mar, 1995.
9. U.S. Food & Drug Administration Web site. How FDA regulates animal devices. Available at: https://www.fda.gov/animal-veterinary/animal-health-literacy/how-fda-regulates-animal-devices. Accessed Jun 29, 2021.