



Original Article

Characteristics of claims in the management of septic arthritis in Japan: Retrospective analyses of judicial precedents and closed claims

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Abstract

Background: Septic arthritis (SA) cases can result in claims or litigation because of poor prognosis even if it is unavoidable. Although these claims or litigation are useful for understanding causes and background factors of medical errors, the characteristics of malpractice claims associated with SA remain undetermined in Japan. This study aimed to increase our understanding of malpractice claims in the clinical management of SA.

Methods: We analyzed 6 civil precedents and 16 closed claims of SA from 8530 malpractice claims processed between July 2004 and June 2014 by the Tokyo office of Sampo Japan Nipponkoa Insurance, Incorporated. We also studied 5 accident and 21 incident reports of SA based on project data compiled by the Japan Council for Quality Health Care.

Results: The rate of negligence was 83.3% in the precedents and 75.0% in closed claims. Two main malpractice claim patterns were revealed: SA in a lower extremity joint following sepsis caused by methicillin-resistant *Staphylococcus aureus* in newborns and SA in an injection site following joint injection. These two patterns accounted for 83.3% and 56.3% of judicial cases and closed claim cases, respectively. Breakdowns in care process of accident and incident reports were clearly differentiated from judicial cases or closed claim cases (Fisher's exact test, $p < 0.001$).

Conclusion: It is important to pay particular attention to SA following sepsis in newborns and to monitor for any signs of SA after joint injection to ensure early diagnosis. Analysis of both malpractice claims and accident and incident reports is essential to ensure a full understanding of the situation in Japan.

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Keywords: Closed claim; Malpractice; Precedence; Septic arthritis

1. Introduction

In 1999, the Institute of Medicine published a sensational report, “*To Err is Human: Building a Safer Health System*,” suggesting that medical errors could be responsible for between 44,000 and 98,000 deaths of hospitalized patients annually in the United States.¹ This report served as a wake-up call for many countries, including Japan. Recently, it was

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reported that medical errors are not only traumatic to patients and health care providers, but also have a considerable negative impact on society and the economy.^{2–4} Thus, there is a global need to accurately identify medical errors and implement appropriate preventative measures to reduce the number of cases in all medical fields.

Septic arthritis (SA) refers to acute monoarthritis caused mainly by common bacteria such as *Staphylococci* or *Streptococci*. The incidence of SA in adults is only estimated at approximately four to eight cases per 100,000 annually. Despite advances in medical treatment, SA can potentially result in severe morbidity or mortality, estimated to be higher than 10%.^{5–7} Therefore, any suspected case of SA demands immediate medical attention and surgical intervention.^{8,9} SA incidence in children is approximately eight cases per 100,000 children annually, with high prevalence in those aged ≤ 5 years.¹⁰ Although SA in children is not common, it should not be underestimated because it can be associated with sepsis and result in severe dysfunction or death if not treated quickly and correctly.^{11–13} In recent years, Methicillin-resistant *Staphylococcus aureus* (MRSA) has become increasingly common as a causative bacteria of SA.^{14–17}

SA cases can result in claims or litigation in situations where patients and their families find it difficult to accept an unfavorable prognosis such as severe dysfunction or death. Unlike United States and Europe, previous studies of medical errors in Japan have typically been limited to the analysis of publicly accessible judicial precedents, largely because Japan does not possess a comprehensive reporting system for medical errors.^{18–23} The situation in Japan has resulted in a dearth of previous studies on medical errors associated with the clinical management of SA. In Japan, medical errors are normally treated within facilities with the corporation of malpractice insurers. Insurer claim files contained various information allowing for an in-depth analysis of medical errors. Here, we analyzed not only judicial precedents but also SA-related closed claims provided by Sompo Japan Nipponkoa Incorporated (SJNK), a leading insurer in Japan. It will reveal the context and characteristics of medical errors associated with SA leading to a claim or litigation. We also analyzed accident and incident reports (IRs) collected by the Japan Council for Quality Health Care (JCQHC). Our overall aim was to increase our understanding of medical errors in the clinical management of SA and explore its potential implications for medical error prevention.

2. Methods

2.1. Judicial precedents

Judicial precedents related to SA were retrieved using two private online search systems: Westlaw Japan (<http://www.westlawjapan.com/>) and Hanreihisho (<http://www.hanreihisho.com/hhi/>). We found six civil judicial precedents related to SA by searching for both civil and criminal cases using a Boolean search strategy with the query terms “septic arthritis” and “negligence” and (“hospital” or “clinic”) and

(“indemnity” or “accusation”). Duplicates and cases where management related to SA was not the primary reason for litigation were excluded. These search criteria yielded 19 cases; 13 cases were excluded as they had no primary relation to the diagnosis and management of SA.

2.2. Closed claims

The present study also evaluated SA-related claims closed between July 2004 and June 2014. The closed claims were provided by SJNK, which covers more than 70% of all medical facilities in Japan, including various types of hospitals and clinics. The present study was conducted in the Tokyo headquarters office of SJNK, which handles the highest number of claims within the company as a centralized library of claims for all of Japan. A claim was defined as a written statement demanding compensation for injuries caused by medical practice.²⁴ Claims were classified as closed when they had been dropped, dismissed, or settled by monetary compensation. Claim files provided by the insurer contained various information including initial reports from the insured party when the allegations arose; legal reports; expert opinions; and relevant medical records from medical facilities. The total number of closed claims processed in the Tokyo headquarters office between July 2004 and June 2014 was 8530, of which 16 closed claims were associated with SA. We searched claim cases using the same method as for judicial precedents.

2.3. Anonymity and ethics statement

Anonymity was preserved in the present study: all claim files underwent a contextual de-identification process before being received by the reviewers. This study complied with Japanese epidemiological study guidelines and was approved by the ethics committee of Teikyo University.

2.4. Accident and incident reports from the JCQHC

There were 5 accident reports (ARs) and 21 IRs related to SA between October 1, 2004 and April 30, 2016, according to the data in the Project to Collect Medical Near-Miss Adverse Event Information. The definition of ARs is the reports related to medical practice that resulted in patient's harm and the definition of IRs is the near miss reports related to medical error. ARs in this research were caused by medical error distinctively. These data are compiled by the JCQHC. All reports related to SA management are included in the analysis.

2.5. Statistical analysis

Descriptive statistics were computed regarding the various features of the judicial precedents and claim files. Reviewers identified the most fundamental allegations in each case and categorized them into different allegation types. The term “Medication” was defined as “a problem of pharmacotherapy following a diagnosis,” while “Medical Treatment” referred to “a problem of medical treatment other than pharmacotherapy

Table 1
Overview of judicial precedents.

Case	Point at issue	Summary of judicial decisions for allegations made by patients
1	Inappropriate performance of joint injection	Considering possible causes of the infection, the infection must have been caused either by inadequate sterilization of the hands or the injection site or by a lack of effort to prevent contamination of the syringe or the dressing used when the joint injection was performed.
2	Delayed diagnosis of SA of right hip joint	The nursing record shows that the patient was crying hard while changing the diaper at 10 days of birth. One of the physicians indicated the need for making different diagnosis between femoral SA and osteomyelitis at 16 days of birth, but there was no record of the attending physician making any consideration for the suggestion. An orthopedic physician should have been able to identify dislocation of the right hip joint on the X-ray taken at 16 days of birth, and thus, able to diagnose SA. In conclusion, the treatment of SA could have been initiated earlier under a condition where the orthopedic consultation had been made by 16 days of birth at the latest.
3	Delayed diagnosis of SA of left hip joint	The patient frequently complained of pain in the lower extremity, the left femoral area and the left hip joint, starting on the 17th day after the operation. The patient also presented with the elevated WBC in the blood test. The abdominal X-ray indicated atrophy of left femoral head on the 40th day after the operation. The change was obvious for the surgeon, although the X-ray was not interpreted by a specialized radiologist. In conclusion, the orthopedic consultation should have been made to confirm SA by the 40th day after the operation at the latest.
4 ^a	(1) Primary allegation: Delayed diagnosis of SA of bilateral knee joints (2) Secondary allegation: Negligence in MRSA infection control	(1) The pediatrician (the defendant) should have been able to suspect MRSA at 11 days of birth as the causative organism based on the fact that the antibiotic therapy using Cephem was unresponsive without any improvement in the symptoms or the blood test results. The pediatrician continued using Cephem while missing the chance to initiate VCM therapy as early as possible. (2) The defendant was meeting the standard of MRSA infection control expected at the time. No negligence was found.
5 ^a	(1) Primary allegation: Delayed medication of SA of right knee joint (2) Secondary allegation: Negligence in MRSA infection control	(1) The defendant should have been able to suspect MRSA infection of the febrile patient and initiated antibiotic therapy effective for MRSA infection as early as 5 days of birth, considering the fact that 5 infants had been simultaneously infected with MRSA in the NICU at the time and 3 infants earlier. (2) The defendant was meeting the standard of MRSA infection control expected at the time. No negligence was found.
6	Delayed treatment of SA of right knee joint	Gram-positive bacteria were identified by the smear culture obtained at the end of the joint lavage drain tube on the 5th day after the operation. The patient should have been treated with VCM since MRSA infection was highly suspected. However, there was no significant disadvantage of refraining from initiating VCM at the time as the second operation was followed immediately. VCM therapy was initiated during the operation; thus, the defendant was not obligated to initiate VCM therapy any earlier.

^a Case 4 and Case 5 also argued negligence regarding MRSA infection control in facilities.

following a diagnosis.”²⁵ The reviewers identified the main aspect of the clinical process, in which the breakdown contributing to identified negligence had occurred in judicial cases (JCs) and closed claim cases (CCCs). “Assessment process” includes physical examination, test ordering and performance, consideration of available clinical information or addressing of abnormal findings. “Planning and ordering treatment” includes selection/management of invasive/surgical procedures, medical treatments, or medication. “Performance of treatment” includes poor technique or misidentification of anatomic structures. The presence of negligence was determined from judgment documents or case dispositions, which were predominantly based on expert opinions of claim files, to control for potential bias from the reviewers' personal in-

terpretations. The reviewers also identified the primary aspect of the clinical process, in which the breakdown occurred in accident and incident cases complied by JCQHC. Statistical significance (defined as a *P* value of <0.05) was determined using the Fisher's exact test, and IBM SPSS Statistics for Windows, Version 24.0 (IBM Corp., Chicago, IL, USA) was used for calculations.

3. Results

3.1. Overview of judicial precedents

We analyzed six judicial precedents associated with SA. An overview and summaries of each case are shown in [Table 1](#)

Table 2
Background demographic information from judicial precedents and claim files.

	JCs ^a	CCCs ^a	All cases ^a
Age groups (patient) ^b			
<20	3	5	8
20–40	0	1	1
40–60	2	3	5
>60	0	7	7
Sex (patient) ^b			
Male	1	6	7
Female	4	10	14
Total	5	16	21
Characteristics of cases ^c			
Disabled (negligent cases)	6 (5)	13 (9)	19 (14)
Cured (negligent cases)	0 (0)	3 (3)	3 (3)
Total	6 (5)	16 (12)	22 (17)
Duration required for closure ^d			
<1	0	6	6
1–3	1	5	6
3–5	0	5	5
>5	5	0	5
Total	6	16	22

^a Numerical values. Age and duration are presented in years.

^b Each judicial case was not available for analysis.

^c The frequency of cases in which negligence was identified or cases determined as disabled did not differ significantly between JCs and CCCs (Fisher's exact test, $p = 1.00$ or $p = 0.53$). Similarly, the frequency of disabled cases associated with negligence did not differ significantly between JCs and CCCs (Fisher's exact test, $p = 1.00$).

^d The distribution of duration required for closure (<5 years) differed significantly between JCs and CCCs (Fisher's exact test, $p < 0.001$).

and Supplement 1. Three of the six cases (Cases 2, 4 and 5; 50%) entailed MRSA SA in newborns following systemic MRSA infection. The hospitals, as defendants, lost all three cases. The court ruled that the primary allegation of Cases 4 and 5, negligence, was proved. However, the court dismissed those claims in Cases 4 and 5 regarding infection control at the facilities, as the court found that each facility was performing adequate infection control per the accepted standards at the time. Two of the six cases (Cases 1 and 6; 33.3%) were SA following joint injections.

Table 3
Identified infected joints and causative bacterial agents of SA in JCs and CCCs.

	JCs ^a	CCCs ^a
Infected joint ^b		
Knee joint	4	4
Hip joint	2	4
Other joint	0	8
Causative bacterium identified ^c		
MRSA identified	4	7
MRSA not identified	2	9

^a Numerical values.

^b The frequency of cases involving the knee or hip joint did not differ significantly between JCs and CCCs (Fisher's exact test, $p = 0.13$ or $p = 1.00$).

^c The frequency of cases involving MRSA did not differ significantly between JCs and CCCs (Fisher's exact test, $p = 0.63$).

3.2. Background demographics of judicial precedents and claim files

Background demographic information derived from judicial precedents and claim files is shown in Table 2. Cases in which the patient was <20 years old accounted for eight cases. Three of the five CCCs (18.8%) were associated with MRSA SA in newborns, similarly to the aforementioned three JCs. Overall, six of the cases (75.0%) in age category <20 years old were associated with MRSA SA in newborns. Five of the 16 CCCs (31.3%) concerned SA after joint injections, all of which identified negligence. A total of seven cases were associated with SA after joint injection. Seventeen (77.2%) of the 22 cases were recognized as negligent cases and resolved by monetary compensation. Of the 19 cases in which patients were disabled 14 cases (73.7%) were identified as negligent cases. There was no death case in this study. There was no statistically significant difference in the frequency of negligence or disabled between JCs and CCCs ($p = 1.00$ or $p = 0.53$), or in the frequency of disabled associated with negligence ($p = 1.00$), as per Fisher's exact test. There was a statistically significant difference in the duration required for closure (>5 years) between JCs and CCCs ($p < 0.001$).

Primarily infected joints and causative bacterial agents of SA in JCs and CCCs are shown in Table 3. All JCs involved lower extremity joints, knee or hip joint. Similarly, nine CCCs (50%) involved lower extremity joints and eight cases involved the knee or hip joint. The cases identified as MRSA accounted for a total of 11 cases, including 4 JCs (66.6%) and 7 CCCs (43.8%). The frequency of cases involved with MRSA did not differ significantly between JCs and CCCs (Fisher's exact test, $p = 0.63$).

3.3. Comparative characteristics of all cases

Table 4 shows allegation types and breakdowns in the clinical care process in JCs and CCCs. The table also shows breakdowns in the clinical care process in the ARs and IRs. Overall, the most common allegation type in all cases was *Diagnosis-related*, which accounted for seven cases (31.8%). Of these, six cases (85.7%) were recognized as negligent. *Surgery-related* or *Management-related* allegations were identified in three or five CCCs, whereas neither allegation type was primarily identified in JCs. An analysis of breakdowns in the care process showed that *Assessment process* was the most common among JCs and CCCs, affecting six cases (35.3%). The frequency of *Assessment process* breakdown did not differ significantly between JCs and CCCs.

Four of the five ARs (80.0%) were submitted by nurses, whereas one report was submitted by a physical therapist. All of the IRs were submitted by nurses except for one report submitted by a physician. All breakdowns in the clinical care process identified in ARs and IRs were associated with *Patient management* except for the one report submitted by the physician. The frequency of breakdown in *Patient management* differed significantly between claim group (JC and CCC) and report group (AR and IR) (Fisher's exact test, $p < 0.001$).

Table 4
Summary of allegation types, breakdowns in clinical processes.

	JCs ^a (negligence cases) (N = 6)	CCCs ^a (negligence cases) (N = 16)	ARs ^{a,b} (N = 5)	IRs ^{a,b} (N = 21)
Allegation types ^c				
Diagnosis-related	3 (3)	4 (3)	—	—
Medication-related	2 (1)	1 (1)	—	—
Surgery-related	0 (0)	3 (3)	—	—
Medical treatment-related	1 (1)	3 (3)	—	—
Management/nursing-related	0 (0)	5 (2)	—	—
Total	6 (5)	16 (12)	—	—
Breakdowns in clinical process ^d				
Assessment process	3	3	0	1
Planning and ordering treatment	1	4	0	0
Performance of treatment	1	4	0	0
Patient management	0	0	5	20
Others	0	1	0	0
Total	5	12	5	21

^a Numerical values.

^b ARs and IRs that do not have allegation types or negligence because of their characteristics.

^c The frequency of each allegation type did not differ significantly between JC and CCC (Fisher's exact test).

^d The frequency of breakdown in patient management differed significantly between the claim group (JC and CCC) and report group (AR and IR) (Fisher's exact test, $p < 0.001$).

4. Discussion

In Japan, civil medical lawsuits have increased dramatically since the late 1990s, leading to several malpractice- and medical error-related issues that demand urgent action.^{19,26} The rate of negligence identified in CCCs of SA, 75.0%, was much higher than the rate publicized by the Japanese Supreme Court in 2014, i.e. 20.6% (http://www.courts.go.jp/saikosai/vcms_lf/2016053103ijikankei.pdf). This discrepancy can be attributed to the fact that the publicized rate only entails litigation closed by judicial decisions and not lawsuits closed by reconciliation or claims treated by insurers. However, the rate of negligence identified in JCs of SA, 83.3%, was also much higher than the rate publicized by the Japanese Supreme Court. Although further investigation is required, the rate of identified negligence from all malpractice claims would be much higher than the rate publicized by the Japanese Supreme Court and/or lawsuits of SA might be difficult to defend substantially.

In this study, age group <20-related JCs and CCCs were most common and accounted for eight cases (36.3%). These cases had the following characteristics: (i) a patient population consisted mostly of newborns (six of the eight cases [75.0%]); (ii) SA mainly developed in the large extremity joints, the hip or knee joints, in newborns following systemic infection such as sepsis and (iii) MRSA was identified as the causative agent in seven cases (87.5%). Allegation type of these cases was divided into two patterns. One was *Diagnosis-related or Medication-related allegation* in referral to orthopedic treatment or antibiotic therapy leading to breakdown in assessment process. Another was *Management-related allegation* in infection control in the treating facilities. SA in newborns is a known, serious disorder that requires special attention as there is an increased probability of delayed treatment because of the

patients' limited ability to communicate pain; additionally, hip joint symptoms are less obvious than those in other parts of the body. Our findings suggested that these points require reiteration from the viewpoint of malpractice.^{27,28} In contrast, *Management-related allegations* involving negligent infection control were either closed before proceeding to court or discontinued in court without monetary compensation. All of these cases concluded that the facilities had met the standards of the time. This discrepancy might depend on the fact that unlike clinical decisions or the maturity of the culture of safety in the facility, infection control could be promoted consistently via facility-wide interventions such as the dissemination of information and notices. Another claim pattern of SA development in injection sites following joint injections was revealed. These claims accounted for seven cases (31.8%) and typically categorized into medical treatment-related allegations, leading to breakdown in performance of treatment. Six cases (85.7%) of SA after joint injection were ruled to be cases of negligence except for one judicial case. Although it is rare, SA is a complication that occurs with a fixed probability, with the prevalence of the disease following joint injection in adults reported as 0.04%.³ It may be difficult to completely avoid injection-related SA. To reduce legal risk, the importance of informed consent might be reconsidered. Patients receiving joint injections need to be informed of the risk of developing SA as a complication and of their responsibility to seek immediate medical attention if they develop or suspect SA symptoms.

The comparative analysis of breakdowns in the clinical care processes in ARs and IRs revealed that the frequency of breakdown in patient management differed significantly between the claim group (JC and CCC) and report group (AR and IR). The differences may be explained by the following. First, almost all ARs and IRs in this study were submitted by

non-physician medical professionals, mostly nurses. Second, unlike the arguments in the JCs and CCCs, which mainly focused on decisions made by physicians, the arguments in the ARs and IRs were mainly focused on aspects of the clinical care processes following a physician's orders. To capture an overall view of medical errors, it may be required to include not only the ARs and IRs, which are commonly collected in facilities, but also the JCs, and furthermore, the CCCs in the analyses.

This study did have some limitations. First, our study was a retrospective review of the JCs and CCCs provided by a malpractice insurer, and thus, did not represent all cases associated with SA claims. Second, nationwide and long-term analyses collaborating with malpractice insurers should be conducted to further improve the quality of closed claim analyses. Despite these limitations, this is the first study to analyze medical errors in the clinical management of SA in Japan. We hope that the findings of the present study will help physicians who manage SA to better understand claim patterns or clinical processes vulnerable to breakdown in the practice.

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Appendix A. Supplementary data

Supplementary data related to this article can be found at <https://doi.org/10.1016/j.jcma.2017.06.023>.

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