

Analysis of Closed Claims in the Clinical Management of Rheumatoid Arthritis in Japan

Yasuhiro Otaki¹, Makiko DaSilva Ishida², Yuichi Saito³, Yasuaki Oyama³, Giichiro Oiso⁴, Mitsuru Moriyama⁵

¹General Medical Education and Research Center, Teikyo University, Tokyo 1738605, Japan

²National Center of Neurology and Psychiatry, Tokyo 1878551, Japan

³Specialty Claims Department, Sompo Japan Nipponkoa Insurance Incorporated, Tokyo 1648608, Japan

⁴Department of Integrated Human Sciences, Hamamatsu University School of Medicine, Shizuoka 4313192, Japan

⁵Moriyama Management Law Office, Tokyo 1010052, Japan

Abstract

Background: Despite an increasing awareness of the risk of medical errors, few data sources are available to highlight the characteristics and patterns of medical errors in the clinical management of rheumatoid arthritis (RA). The present study aimed to evaluate medical malpractice claims associated with the management of RA and other autoimmune connective tissue diseases (ACTDs).

Methods: We analyzed 38 ACTD-associated closed claims extracted from a total of 8530 claims processed between July 2004 and June 2014 by the Tokyo headquarters office of Sompo Japan Nipponkoa Incorporated, a leading malpractice insurer in Japan.

Results: RA was the most common ACTD assessed in this study, accounting for 20 cases. Although the male-to-female ratio among these cases was 5:15, in accordance with the general demographic distribution of RA, the proportion of patients older than 60 years (77.8%) was relatively high as the general range of RA susceptibility is 30–50 years. The analysis of allegation types among RA cases revealed statistically significant differences from non-RA cases (Fisher's exact test) as well as the following key findings: diagnosis-related allegations were absent ($P < 0.01$), whereas medication-related allegations were distinctively common ($P = 0.02$). Clinical processes related to the assessment process were most vulnerable to breakdown and leading to negligence identified with subsequent medication-related allegations, particularly among RA cases.

Conclusions: The characteristics of malpractice claims associated with RA management, including the high frequency of medication-related allegations, breakdowns in the assessment process, and high claim numbers among patients older than 60 years, suggest the importance of caution exercised by physicians when administering immunosuppressants for the clinical treatment of RA.

Key words: Autoimmune Connective Tissue Disease; Closed Claim; Rheumatoid Arthritis

INTRODUCTION

Recent significant paradigm shifts in the diagnosis and treatment of rheumatoid arthritis (RA), the representative autoimmune connective tissue disease (ACTD), have led to increases in unforeseen clinical issues, such as biologics-mediated interstitial pneumonia or infection.^[1-7] Inevitably, the complexity of the current RA management has increased considerably with the utilization of both traditional and novel treatment modalities. Furthermore, in Japan, RA patients are generally treated by both rheumatologists and nonrheumatologists. Despite an increasing awareness of the risk of medical errors, few data sources are available to highlight the characteristics and patterns of medical errors in the clinical management of RA.

Previous studies on medical errors in Japan have typically been limited to analyses of publicly accessible judicial precedents, largely because Japan lacks a comprehensive medical error reporting system.^[8,9] Medical malpractice claims are often addressed by facilities within malpractice insurance corporations. In the United States and Europe, considerable malpractice research has evaluated closed

Address for correspondence: Dr. Yasuhiro Otaki,
General Medical Education and Research Center, Teikyo University,
Tokyo 1738605, Japan
E-Mail: y-otaki@med.teikyo-u.ac.jp

This is an open access article distributed under the terms of the Creative Commons Attribution-NonCommercial-ShareAlike 3.0 License, which allows others to remix, tweak, and build upon the work non-commercially, as long as the author is credited and the new creations are licensed under the identical terms.

For reprints contact: reprints@medknow.com

© 2017 Chinese Medical Journal | Produced by Wolters Kluwer - Medknow

Received: 13-03-2017 **Edited by:** Qiang Shi
How to cite this article: Otaki Y, Ishida MD, Saito Y, Oyama Y, Oiso G, Moriyama M. Analysis of Closed Claims in the Clinical Management of Rheumatoid Arthritis in Japan. Chin Med J 2017;130:1454-8.

Access this article online

Quick Response Code:



Website:
www.cmj.org

DOI:
10.4103/0366-6999.207479

malpractice claims provided by insurers in various medical fields.^[10-13] We conducted a retrospective analysis of closed malpractice claim files in collaboration with a leading Japanese malpractice insurer, Sompo Japan Nipponkoa Incorporated (SJNK), which has an approximately 70% market share in Japan and covers various types of hospitals and clinics. With this study, we aimed to increase the understanding of malpractice claims associated with the management of RA or other ACTDs.

METHODS

Closed claims analyzed in this study

The present study evaluated closed claims related to ACTDs that were processed and coded by professional staffers at SJNK according to the International Statistical Classification of Diseases and Related Health Problems, 10th revision between July 2004 and June 2014. This study was conducted in the Tokyo headquarters of SJNK, which handled the highest number of claims within the company. A claim was defined as a written statement demanding compensation for injuries caused by a medical practice.^[14] Claims were classified as closed if they had been dropped, dismissed, or settled by monetary compensation following reconciliation or a judicial decision. Claim files provided by the insurer contained various types of relevant information, including the initial reports from the insured party when the allegations arose, legal reports such as judgment documents, expert opinions, and relevant medical records obtained from medical facilities. A total of 8530 closed claims were processed in the Tokyo headquarters during the study; of these, 38 RA- and other ACTD-related claims were retrieved for this study.

Ethical approval

Japanese law and ethical regulations require maintenance of the anonymity of the parties involved in the study. This anonymity was ensured by applying a contextual de-identification method to the insurer's claim files before transmission to the reviewers. This study complied with Japanese epidemiological study guidelines and was approved by the Ethics Committee of Teikyo University.

Statistical analysis

The background demographics (e.g., diagnosis and patient features), outcomes (e.g., negligence identified), and allegation types (e.g., diagnosis-related and medication-related) from the claim files were subjected to a descriptive statistical analysis. Reviewers identified the most fundamental allegations in each case and categorized them into different allegation types. The term "Medication" was defined as "a problem associated with pharmacotherapy following a diagnosis", whereas "Medical Treatment" referred to "a problem associated with medical treatment other than pharmacotherapy following a diagnosis".^[15] The reviewers also identified the main aspect of the clinical process, in which the breakdown contributing to negligence identified had occurred. 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 reviewers' personal interpretations. Statistical significance (defined as $P < 0.05$) was determined using Fisher's exact test, and IBM SPSS Statistics for Windows, Version 24.0 (IBM Corp., Chicago, IL, USA) was used for calculations.

RESULTS

Background demographics of claim files

The diagnoses of the 38 cases in this study are shown in Table 1. RA was most common, accounting for 20 cases (52.6%). Fifteen (75.0%) of the 20 RA cases were recognized as negligent. Of the 18 non-RA cases (47.4%), 11 (61.1%) were recognized as negligent. The frequency of negligent cases did not differ significantly between the groups.

Background demographic information derived from claim files is shown in Table 2. During the study, a total of 38 (0.04% of 8530 claims at SJNK headquarters) claims related to RA (20 cases) and other ACTDs (non-RA; 18 cases) were identified. Among these, the mean age was 54.7 ± 17.6 years, and the male-to-female ratio was 14:24. Among RA cases, 14 cases (77.8%) involved patients older than 60 years, and the male-to-female ratio was 5:15.

Twenty-six (68.4%) of the 38 claims were recognized as negligent cases and were resolved by monetary compensation. Of the 20 claims (52.6%) related to fatalities, 14 (70.0%) were identified as negligent cases and were resolved by monetary compensation. There was no statistically significant difference in the frequency of fatalities ($P = 0.35$) or in the frequency of negligence associated with fatalities between RA and non-RA cases.

The median (interquartile range) interval between the receipt and closure of a claim was 23 (5, 55) months in all cases. There was statistically significant difference in the duration required for closure between RA and non-RA cases ($P = 0.03$). Twenty-three claims (60.5%) involving 31 physicians included the number of years of experience held by physicians (mean: 17.0 ± 11.3 years). Of 31 physicians, 6 (19.4%) had less than 5 years of experience, whereas only 3 of 31 physicians (9.7%) had less than 2 years of experience.

Allegation types

Table 3 lists the number of closed claims per the type of allegation made by patients. Overall, the most common allegation type was medication related, which accounted for 14 cases (36.8%). Of these, 8 cases (57.1%) were recognized as negligent. Diagnosis- and management-related allegations each accounted for 6 cases. Among RA cases, more than half of the allegations were medication related (11 cases, 55.5%). However, no diagnosis-related allegations were made regarding RA cases, in contrast to 6 non-RA cases. The frequencies of medication- and diagnosis-related

Table 1: Number of closed claims of patients with autoimmune connective tissue disease in this study according to diagnosis

Diagnosis	Number of cases, <i>n</i>	Number of negligent cases, <i>n</i>	Percentage of negligent cases (%)
RA	20	15	75.0
Other ACTDs (non-RA cases)	18	11	61.1
Systemic lupus erythematosus	3	1	33.3
Polymyositis and dermatomyositis	2	2	100
Sjögren's syndrome	2	2	75.0
Systemic vasculitis	5	3	60.0
Others	6	3	50.0

RA: Rheumatoid arthritis; ACTD: Autoimmune connective tissue disease.

Table 2: Background information of patients with autoimmune connective tissue disease from claim files

Items	RA cases, <i>n</i>	Non-RA cases, <i>n</i>	All cases, <i>n</i>
Age groups			
<20 years	0	1	1
20–39 years	2	5	7
40–59 years	4	6	10
≥60 years	14	6	20
Sex			
Male	5	9	14
Female	15	9	24
Characteristics of cases*			
Death (negligent cases)	9 (7)	11 (7)	20 (14)
Nondeath (negligent cases)	11 (8)	7 (4)	18 (12)
Total	20	18	38
Duration required for closure ^{†‡}			
<1 year	9	2	11
1–2 years	5	6	11
3–4 years	1	6	7
≥5 years	3	3	6
Total	18	17	35

*The frequency of cases involving death did not differ significantly between RA and non-RA cases (Fisher's exact test, $P = 0.35$). †Two cases of RA and 1 case of non-RA were not available for analysis; ‡The distribution of duration required for closure (<1 year) differed significantly between RA and non-RA cases (Fisher's exact test, $P = 0.03$). RA: Rheumatoid arthritis.

allegations differed significantly between RA cases and non-RA cases (Fisher's exact test, $P = 0.02$ and $P < 0.01$, respectively).

Breakdowns that contributed to negligence

Table 4 shows the clinical processes that suffered breakdowns leading to negligence. Overall, the assessment process was most commonly affected, accounting for 13 cases involving breakdowns (50.0%). Assessment process was also the most common among RA cases, affecting 9 cases (50.0%), and was followed by patient management process in 3 cases (20.0%). In 5 cases (55.5%) involving assessment process breakdowns, adverse drug-related events were caused by anti-rheumatic drugs. The frequency of assessment process breakdowns did not

differ significantly between RA and non-RA cases (Fisher's exact test, $P = 0.43$).

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.^[9,16] The rate of negligence identified in this study, 68.4%, was much higher than the rate publicized by the Japanese Supreme Court in 2014, 20.6%, which was based on a malpractice lawsuit closed by a judicial decision.^[17] This discrepancy can be attributed to the basis of the publicized rate only on litigation closed by judicial decisions and not on lawsuits closed by reconciliation or claims treated by insurers. 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.

The Tokyo headquarters office of SJNK, a leading medical malpractice insurer in Japan, collects and analyzes up to 60% of all claims handled by the company. Therefore, the closed claims analyzed in the present study provide a representative nationwide sample of insurer claims associated with RA and other ACTDs. While processing all claims, SJNK considered the opinion of at least one expert physician, unless negligence was obvious. The number of closed claims related to patients with RA and other ACTDs was limited to 38 cases (from a total of 8530 cases) in the present study. This small sample size is mainly attributable to the nature of the relatively low prevalence of ACTDs compared to those of other conditions, such as cardiovascular diseases or malignant neoplasms.^[15,18] This also accounts for chronic diseases, which are generally less emergent than diseases requiring urgent medical intervention, such as acute myocardial infarction.^[19] RA was the most common ACTD assessed in this study, accounting for 20 cases. This confirms that status of RA as the most common ACTD encountered in this research.

Among RA cases, the male-to-female ratio was 5:15, in accordance with the general demographic distribution of RA; however, the frequency of patients older than 60 years was relatively high when compared with the usual age range of RA susceptibility (30–50 years). In addition to the finding,

Table 3: Number of closed claims of patients with autoimmune connective tissue disease by allegation type

Allegation type	RA cases (negligent cases), <i>n</i>	Non-RA cases (negligent cases), <i>n</i>	All cases (negligent cases), <i>n</i>
Diagnosis related*	0	6 (3)	6 (3)
Medication related†	11 (7)	3 (1)	14 (8)
Surgery related	3 (3)	1 (0)	4 (3)
Medical treatment related	1 (1)	2 (1)	3 (2)
Follow-up related	2 (1)	2 (2)	4 (3)
Management/nursing related	3 (3)	3 (3)	6 (6)
Accountability related	0	1 (1)	1 (1)
Total number of claims	20 (15)	18 (11)	38 (26)

*†The frequencies of medication- and diagnosis-related allegations differed significantly between RA and non-RA cases (Fisher's exact test, $P = 0.02$ and $P < 0.01$, respectively). RA: Rheumatoid arthritis.

Table 4: Breakdowns in care process of patients with autoimmune connective tissue disease that contributed to negligence

Breakdown point	RA cases, <i>n</i> (%)	Non-RA cases, <i>n</i> (%)	All cases, <i>n</i> (%)
Assessment process* (including physical examination, test ordering and performance, consideration of available clinical information, addressing of abnormal findings)	9 (60.0)	4 (36.3)	13 (50.0)
Planning and ordering treatment (including selection/management of invasive/surgical procedures, medical treatments, and medication)	1 (6.7)	3 (27.3)	4 (15.4)
Performance of treatment (including poor technique and misidentification of anatomic structures)	2 (13.3)	1 (9.1)	3 (11.5)
Patient management (including nursing, monitoring, and facility safety management)	3 (20.0)	2 (18.2)	5 (19.2)
Medical advice and consent	0	1 (9.1)	1 (3.8)
Total number	15 (100.0)	11 (100.0)	26 (100.0)

*The frequency of breakdowns in the assessment process did not differ significantly between RA and non-RA cases (Fisher's exact test, $P = 0.43$). RA: Rheumatoid arthritis.

the much higher frequency of medication-related allegations relative to other allegations among RA cases may support that severe adverse effects of immunosuppressant agents, such as methotrexate or biologics, more readily appear in older patients. The duration required for closure was shorter for RA cases than for non-RA cases, which might suggest that negligence was more easily identified in the former. However, the groups did not differ significantly with regard to cases involving fatalities and identified negligence. In other words, the unfortunate outcome of death did not correlate with the identification of negligence.

The allegation type analysis revealed two key findings of RA cases: diagnosis-related allegations were absent, whereas medication-related allegations were distinctively common. In Japan, the rapid dissemination of innovative clinical information has led to a drastic paradigm shift in RA practices that affect various clinical settings.^[1-4] The increasing awareness of RA among Japanese physicians might have contributed to the lack of diagnosis-related allegations in the present study, whereas the heavily pharmacologic nature of clinical RA management may have contributed to the higher number of medication-related allegations. Diagnosis-related allegations were most common in non-RA cases. The finding is likely associated with the nature of other ACTDs. In clinical practice, other ACTDs may be difficult to diagnose accurately, especially

when the patient is seen by nonmedical specialists who are unfamiliar with these diseases.

The findings of the present study indicate that clinical processes related to the assessment process were most vulnerable to breakdowns, particularly among in RA cases; in this group, five of the nine breakdowns in the assessment process were related to medication, and all five involved medication-related allegations with responses to adverse anti-rheumatic drug reactions during follow-up. The rulings in all five cases favored the plaintiff, suggesting the difficulty of defending against medication-related allegations during the follow-up phase. The careful monitoring of adverse events related to anti-rheumatic pharmacotherapy is known to be crucial when following up with existing RA patients, especially old patients. However, our findings suggest that this point requires reiteration from the viewpoint of malpractice.

This study had several limitations of note. First, this was a retrospective review of closed claims provided by a malpractice insurer and did not represent all claims of medical errors associated with the diseases analyzed in this research. Therefore, the results might only be applicable to a single aspect of malpractice claims. Further analysis, including an analysis of closed claims, is needed to further our understanding of medical errors. Second, nationwide

and long-term analyses conducted in collaboration with malpractice insurers are needed to further improve the quality of closed claim analyses. Despite these limitations, however, this was the first study to analyze malpractice claims associated with RA and other ACTDs in Japan. The clinical management of these diseases is expected to increase in specialization and complexity in the future. We hope that the findings of the present study will help physicians who manage these ACTDs to better understand claim patterns or clinical processes vulnerable to breakdown in the practice.

Acknowledgment

We would like to thank Tomomi Katayama, Kanako Arai, Mizue Kurosawa, Atsuko Murohashi, and other SJNK staff members for their invaluable assistance.

Financial support and sponsorship

This study was supported by a grant from the Japan Society for the Promotion of Science KAKENHI (No. 15K21382).

Conflicts of interest

There are conflicts of interest to declare that Yuichi Saito and Yasuaki Oyama are employees of Sompo Japan Nipponkoa Insurance Incorporated, which provided the claim files for the analysis in the present study. Yasuhiro Otaki serves independently as a medical and legal consultant for Sompo Japan Nipponkoa Insurance Incorporated on an as-needed basis receiving appropriate fees.

REFERENCES

- Schellekens GA, Visser H, de Jong BA, van den Hoogen FH, Hazes JM, Breedveld FC, *et al.* The diagnostic properties of rheumatoid arthritis antibodies recognizing a cyclic citrullinated peptide. *Arthritis Rheum* 2000;43:155-63. doi: 10.1002/1529-0131(200001)43:1<155:AID-A NR20>3.0.CO;2-3.
- Aletaha D, Neogi T, Silman AJ, Funovits J, Felson DT, Bingham CO 3rd, *et al.* 2010 Rheumatoid arthritis classification criteria: An American College of Rheumatology/European League Against Rheumatism collaborative initiative. *Arthritis Rheum* 2010;62:2569-81. doi: 10.1002/art.27584.
- Lipsky PE, van der Heijde DM, St Clair EW, Furst DE, Breedveld FC, Kalden JR, *et al.* Infliximab and methotrexate in the treatment of rheumatoid arthritis. Anti-Tumor Necrosis Factor Trial in Rheumatoid Arthritis with Concomitant Therapy Study Group. *N Engl J Med* 2000;343:1594-602. doi: 10.1056/NEJM200011303432202.
- St Clair EW, van der Heijde DM, Smolen JS, Maini RN, Bathon JM, Emery P, *et al.* Combination of infliximab and methotrexate therapy for early rheumatoid arthritis: A randomized, controlled trial. *Arthritis Rheum* 2004;50:3432-43. doi: 10.1002/art.20568.
- Singh JA, Cameron C, Noorbaloochi S, Cullis T, Tucker M, Christensen R, *et al.* Risk of serious infection in biological treatment of patients with rheumatoid arthritis: A systematic review and meta-analysis. *Lancet* 2015;386:258-65. doi: 10.1016/S0140-6736(14)61704-9.
- Nard FD, Todoerti M, Grosso V, Monti S, Breda S, Rossi S, *et al.* Risk of hepatitis B virus reactivation in rheumatoid arthritis patients undergoing biologic treatment: Extending perspective from old to newer drugs. *World J Hepatol* 2015;7:344-61. doi: 10.4254/wjh.v7.i3.344.
- Conway R, Low C, Coughlan RJ, O'Donnell MJ, Carey JJ. Methotrexate and lung disease in rheumatoid arthritis: A meta-analysis of randomized controlled trials. *Arthritis Rheumatol* 2014;66:803-12. doi: 10.1002/art.38322.
- Kiuchi A, Matsumura Y, Makino Y, Kyakuno M, Ehara K. Analysis of lawsuits on malpractice related to spinal anesthesia in Japan – Change in the causes of anesthetic malpractice related to judicial precedents. *Leg Med (Tokyo)* 2009;11:S370-1. doi: 10.1016/j.legalmed.2009.02.036.
- Maeda S, Sakamoto N, Nobutomo K. The problems of medical malpractice litigation in Japan: The significant factors responsible for the tendency of patients to avoid litigation. *Leg Med (Tokyo)* 2001;3:56-62. doi: 10.1016/S1344-6223(01)00007-4.
- Rogers SO Jr., Gawande AA, Kwaan M, Puopolo AL, Yoon C, Brennan TA, *et al.* Analysis of surgical errors in closed malpractice claims at 4 liability insurers. *Surgery* 2006;140:25-33. doi: 10.1016/j.surg.2006.01.008.
- Gandhi TK, Kachalia A, Thomas EJ, Puopolo AL, Yoon C, Brennan TA, *et al.* Missed and delayed diagnoses in the ambulatory setting: A study of closed malpractice claims. *Ann Intern Med* 2006;145:488-96. doi: 10.7326/0003-4819-145-7-200610030-00006.
- Matsen FA 3rd, Stephens L, Jette JL, Warme WJ, Posner KL. Lessons regarding the safety of orthopaedic patient care: An analysis of four hundred and sixty-four closed malpractice claims. *J Bone Joint Surg Am* 2013;95:e201-8. doi: 10.2106/JBJS.K.01272.
- Zengerink I, Reijman M, Mathijssen NM, Eikens-Jansen MP, Bos PK. Hip arthroplasty malpractice claims in the Netherlands: Closed Claim Study 2000-2012. *J Arthroplasty* 2016;31:1890-3.e4. doi: 10.1016/j.arth.2016.02.055.
- Singh H, Thomas EJ, Petersen LA, Studdert DM. Medical errors involving trainees: A study of closed malpractice claims from 5 insurers. *Arch Intern Med* 2007;167:2030-6. doi: 10.1001/archinte.167.19.2030.
- Schiff GD, Puopolo AL, Huben-Kearney A, Yu W, Keohane C, McDonough P, *et al.* Primary care closed claims experience of Massachusetts malpractice insurers. *JAMA Intern Med* 2013;173:2063-8. doi: 10.1001/jamainternmed.2013.11070.
- Yoshikawa K. Litigation action in medical malpractice litigation. In: Asai T, Sonoo K, editors. *A Survey of Contemporary Litigation Law*. Vol. 7. Tokyo: Sinnihonhouki; 1998. p. 15-30.
- Japanese Supreme Court. The present conditions of the medical lawsuits (in Japanese). Available from: http://www.courts.go.jp/saikosai/vcms_lf/2016053103ijikankei.pdf. [Last accessed on 2017 Mar 31].
- Brown TW, McCarthy ML, Kelen GD, Levy F. An epidemiologic study of closed emergency department malpractice claims in a national database of physician malpractice insurers. *Acad Emerg Med* 2010;17:553-60. doi: 10.1111/j.1553-2712.2010.00729.x.
- Andersen PO, Maaløe R, Andersen HB. Critical incidents related to cardiac arrests reported to the Danish patient safety database. *Resuscitation* 2010;81:312-6. doi: 10.1016/j.resuscitation.2009.10.018.