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# Clear cell sarcoma in Japan: an analysis of the population-based cancer registry in Japan

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## Abstract

**Background:** Clear cell sarcoma is rare, so no reports have previously characterized its national profiles. We examined the nationwide epidemiology and clinical outcomes of patients with clear cell sarcoma based on the National Cancer Registry in Japan.

**Methods:** Overall, 23 522 patients with soft tissue sarcoma—entered in the National Cancer Registry in 2016–2019 using the International Classification of Diseases for Oncology, Third Edition cancer topography and morphology codes—were enrolled in either the clear cell or the non-clear cell sarcoma group. Data extracted included: demographics (sex and age), tumor details (reason for diagnosis, tumor location, histology and stage), hospital volume and facility type, treatment and prognosis for each patient.

**Results:** Of 23 522 soft tissue sarcoma patients, 122 were enrolled in the clear cell sarcoma group and 23 400 in the non-clear cell sarcoma group. The incidence of clear cell sarcoma was 0.52% of all soft tissue sarcoma, with an age-adjusted incidence of 0.024/100 000/year. The age at diagnosis was significantly younger, and more tumors were at the localized stage in the clear cell than the non-clear cell sarcoma group. In addition, the overall survival in the clear cell group was worse than in the non-clear cell group ($P < 0.001$). Of 122 patients with clear cell sarcoma, the localized stage, surgical treatment and treatment without chemotherapy were associated with better overall survival in the univariate analyses.

**Conclusions:** The present study is the first to have clarified the epidemiology, clinical features, treatment, prognosis and significant factors affecting the prognosis of patients with clear cell sarcoma in Japan.

**Key words:** clear cell sarcoma, National Cancer Registry, epidemiology, clinical outcome, prognostic factors

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## Introduction

Clear cell sarcoma (CCS) is an extremely rare melanocytic soft tissue sarcoma (STS) (1). The most common site of CCS is in the deep layer of the distal extremities, often adjacent to tendons and fascial structures. Most CCS have a recurrent chromosomal translocation t(12;22) (q13;q12) or t(2;22) (q34;q12), which is associated with the *EWSR1-ATF1/CREB1* fusion genes (2), and the use of fluorescence *in situ* hybridization or reverse transcription polymerase chain reaction is essential for diagnosis and distinguishing CCS from primary and/or metastatic melanoma (1). Although the standard treatment for localized CCS is believed to be complete resection with a negative surgical margin, the roles of radiotherapy and chemotherapy are still controversial due to the rarity of CCS. This rarity also poses major challenges for accurate diagnosis, understanding disease biology and generating clinical evidence to support new drug development. However, epidemiological data, such as information on the number of cancer diagnoses and stage at presentation, is essential for a rational approach to the Cancer Control Act.

A few previous reports have focused on the epidemiology of CCS using the Surveillance, Epidemiology, and End Results (SEER) database and the National Cancer Database in the United States (3–5). However, to our knowledge, there have been no reports characterizing population-based overall profiles of CCS at the national level.

Therefore, in the present study, we attempted to clarify the nationwide statistics for CCS in Japan by analyzing data from Japan's National Cancer Registry (NCR), which is a nationwide population-based cancer registry that was launched in 2016. This study is the first to have used the NCR for CCS since it became available for the purpose of clinical research in 2019.

## Patients and methods

### Data source

The NCR was developed as a reliable cancer surveillance system on the legal basis of the Cancer Registry Promotion Act of 2013, for the purpose of promoting cancer control. The NCR was transitioned from prefectural, population-based cancer registries and the data of cancer patients diagnosed since January 2016 has been collected.

All hospitals in Japan are obliged to submit basic data to prefectures when they diagnose new patients with cancer. Therefore, the NCR is a population-based cancer registry that corresponds to the SEER database in the United States but has a unique advantage in terms of registry completeness. The unique advantage of the NCR is that it represents almost all newly diagnosed cancer cases in Japan.

The data collected include cancer type and stage; treatment; circumstances of cancer detection, diagnosis and treatment; survival; etc. The collected data were thoroughly filtered by the government and have been available to researchers since 2019. This study conducted investigative research based on the Cancer Registry Act. According to the procedure stipulated by the law, the protocol was reviewed by the Data Utilization Committee of the National Cancer Registration Office. As per the research ethics guidelines in Japan, our study was exempted from an ethics review by our institutional review board.

### Data extraction

We received the registry information in accordance with the law, and the data in this study were independently created and processed in accordance with relevant data-sharing laws. The protocol was reviewed by the Data Utilization Committee of the National Cancer Registration Office according to the procedure stipulated by law.

Patients eligible for study inclusion were diagnosed with CCS in 2016–2019 and entered in the NCR under the cancer morphology code (9044) based on the International Classification of Diseases for Oncology, Third Edition (ICD-O-3) (6). The final cohort was composed of 122 patients with CCS. For comparison, we extracted all STS cases as defined by the cancer morphology codes (8710–8714, 8800–8934, 8940–9138 and 9141–9582) of the ICD-O-3 and categorized patients into either the CCS or non-CCS group. Tumor location was categorized according to topography codes into 'soft tissue and skin', 'head and neck', 'retroperitoneum' and 'visceral'. The extent of disease was categorized into 'localized' (confined to the organ of origin and not spread to other parts of the body), 'regional' (the spread of cancer from its original site to nearby areas such as regional lymph nodes and adjacent organs, but not to distant sites), or 'distant' (spread to organs or tissues that are farther away) stages. The type of facility was categorized based on Japanese Orthopedic Association (JOA) certification. The number of patients with bone and STS for each hospital was assessed, and the hospital volumes were determined using their unique identifier. The hospitals were then categorized by patient tertiles into 'low-' (<49 cases/4 years), 'medium-' (50–158 cases/4 years) or 'high-volume' (≥159 cases/4 years).

### Statistical analyses

An age-adjusted rate is a measure that controls for the effects of age differences on the rate of health events. In this study, we used direct age adjustment for calculating incidence, where the sum of the products of age-specific rates observed in a population, multiplied by the proportion of each age group in a standard population, was the age-adjusted incidence. The 1985 model population of Japan was used for this purpose. The incidences were described per 100 000 population.

Differences between the groups were evaluated using the Mann–Whitney U test and the chi-squared test. Overall survival (OAS) was defined as the duration between the date of the diagnosis and the date on which the patient was last contacted or died. OAS was estimated using the Kaplan–Meier method, and the log-rank test was used to assess the differences in survival. Differences and correlations were considered statistically significant at $P < 0.05$. All statistical analyses were conducted using IBM SPSS version 19.0 (IBM SPSS, Armonk, NY, USA).

## Results

### Patients

During 2016–2019, we identified the records of 23 522 patients with STS. Approximately 30 new cases were diagnosed as CCS per year, representing 0.52% of all STS. The age-adjusted incidence of CCS was 0.024/100 000/year, which meets the criteria for a rare cancer (<6/100 000/year) (Fig. 1) (7). Table 1 shows the patient characteristics of the CCS ($N = 122$) and non-CCS groups ($N = 23\,400$). The age at diagnosis was younger in the CCS group than in the non-CCS group ($P < 0.001$). The most common location in the CCS group was the soft tissue and skin ($N = 110$, 91.7%). On the other hand, no retroperitoneal cases were observed in the CCS group. Only a small proportion of patients were diagnosed with CCS by cancer screening or routine health check-up. At the time of diagnosis, in the CCS group there were 48 localized cases (51.1%), 23 regional cases

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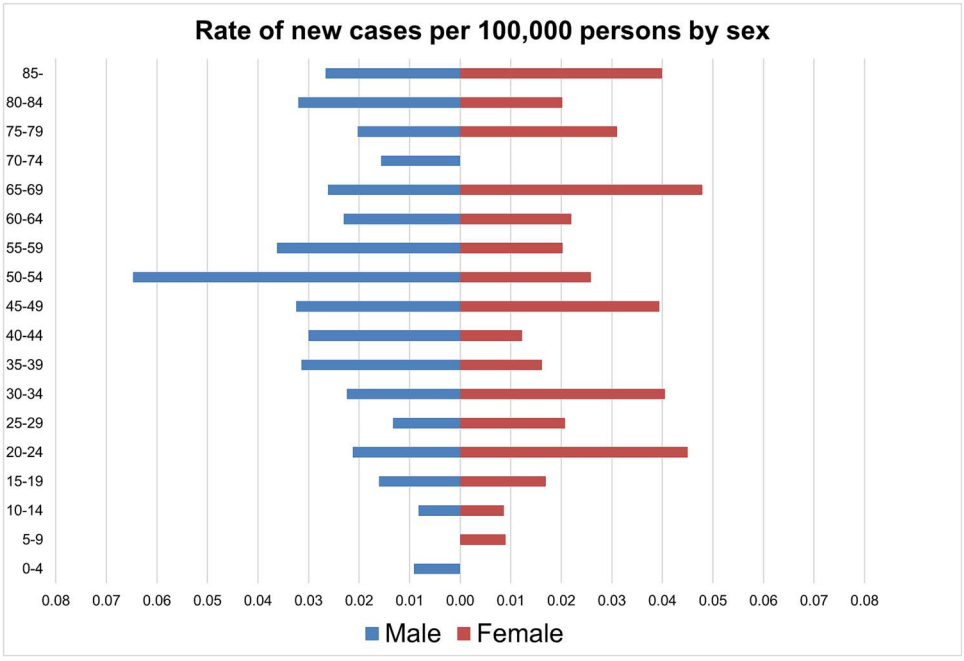


**Figure 1.** Rate of new cases per 100 000 persons by sex.

(24.5%) and 23 distant metastasis cases (24.5%); in the non-CCS group, there were 7260 localized cases (38.5%), 9049 regional cases (48.0%) and 2543 distant metastasis cases (13.5%). The patients were more frequently diagnosed with CCS in JOA-certified hospitals ($P = 0.032$).

### Treatment

In the CCS group, 60 patients (65.9%) underwent surgical treatment, 23 patients (25.3%) underwent chemotherapy and 14 patients (15.4%) underwent radiotherapy. No significant differences in the rate of treatment options between the CCS and non-CCS groups were observed.

### Survival and prognostic factors

The OAS estimated by the Kaplan–Meier method is shown in Fig. 2. The 3-year OAS was 41.1% and 64.0% in the CCS and non-CCS groups, respectively, a significant difference favoring the non-CCS group ($P < 0.001$).

Among the 122 patients with CCS, the unadjusted associations of various factors with the OAS rate determined using Kaplan–Meier plots are shown in Fig. 3 and Table 2. The log-rank test revealed that regional or distant stages, treatment without surgery and treatment with chemotherapy were significantly associated with a worse OAS.

## Discussion

In the present study, we retrospectively demonstrated the characteristics, treatment modality and clinical outcomes of CCS, and identified factors associated with the OAS of 122 patients with CCS registered in the NCR between 2016 and 2019. This study is the first to have characterized the profiles of CCS on a national basis in a population-based manner in Japan.

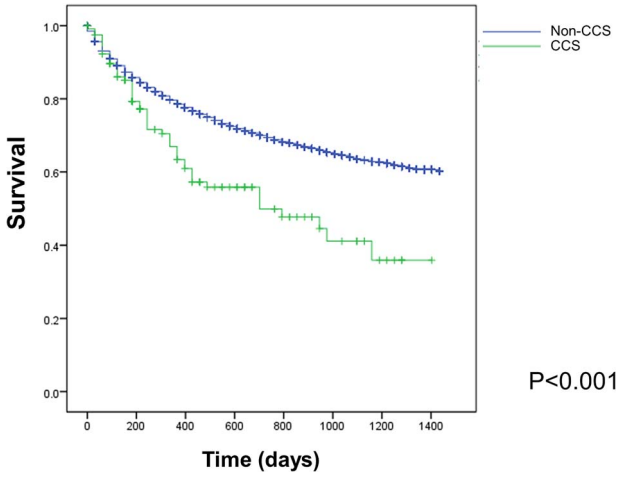


**Figure 2.** Kaplan–Meier survival plots of OAS for CCS and non-CCS.

Notably, although CCS is known to be extremely rare, nobody knows the actual incidence of CCS in Japan. The present study first identified the age-adjusted incidence of CCS as 0.024/100 000/year and demonstrated CCS meets the criteria for ultra-rare sarcoma (<0.1/100 000/year) (8), as well as that for rare cancer (7). We also revealed that CCS accounted for only 0.52% of STS, which is less than the previously reported incidence of 1% of STS (1).

Traditionally, cancer-surveillance data of sarcoma in Japan have been captured primarily from the Bone and Soft Tissue Tumor (BSTT) Registry (9,10), which is the organ-specific cancer registry of sarcoma organized and funded by the JOA and promoted by the National Cancer Center. However, in terms of capturing cancer-surveillance data, one of the shortcomings of the BSTT Registry

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**Table 1.** Characteristics of the study population

| | Overall ($N = 23\,522$) | | Clear cell sarcoma ($N = 122$) | | Non clear cell sarcoma ($N = 23\,400$) | | |
|---|---|---|---|---|---|---|---|
| | No. of patients | % | No. of patients | % | No. of patients | % | *P* value |
| **Year of diagnosis** | | | | | | | |
| 2016 | 5695 | 24.2 | 28 | 23.0 | 5667 | 24.2 | 0.821 |
| 2017 | 5800 | 24.7 | 28 | 23.0 | 5772 | 24.7 | |
| 2018 | 5966 | 25.4 | 30 | 24.6 | 5936 | 25.4 | |
| 2019 | 6061 | 25.8 | 36 | 29.5 | 6025 | 25.7 | |
| **Sex** | | | | | | | |
| Male | 12 927 | 55.0 | 61 | 50.0 | 12 866 | 55.0 | 0.269 |
| Female | 10 592 | 45.0 | 61 | 50.0 | 10 531 | 45.0 | |
| **Age (y)** | | | | | | | |
| 0–14 | 521 | 2.2 | 1–10 | – | 511–520 | – | <0.001 |
| 15–39 | 2577 | 11.0 | 38 | 31.1 | 2539 | 10.9 | |
| 40–59 | 5621 | 23.9 | 43 | 35.2 | 5578 | 23.8 | |
| 60–74 | 7882 | 33.5 | 22 | 18.0 | 7860 | 33.6 | |
| 75- | 6921 | 29.4 | 11–20 | – | 6901–6910 | – | |
| **Tumor location** | | | | | | | |
| Soft tissue and skin | 16 107 | 69.1 | 110 | 91.7 | 15 997 | 68.9 | <0.001 |
| Head and neck | 661 | 2.8 | 1–10 | – | 651–660 | – | |
| Retroperitoneum | 3311 | 14.2 | 0 | 0.0 | 3311 | 14.3 | |
| Visceral | 3245 | 13.9 | 1–10 | – | 3231–3240 | – | |
| **Reason for diagnosis** | | | | | | | |
| Cancer/health screening | 822 | 3.7 | 1–10 | – | 811–820 | – | 0.449 |
| Others | 21 617 | 96.3 | 111–120 | – | 21 501–21 510 | – | |
| **Stage** | | | | | | | |
| Localized | 7308 | 38.6 | 48 | 51.1 | 7260 | 38.5 | <0.001 |
| Regional (spread outside the bone to nearby structures or lymph nodes | 9072 | 47.9 | 23 | 24.5 | 9049 | 48.0 | |
| Distant | 2566 | 13.5 | 23 | 24.5 | 2543 | 13.5 | |
| **JOA certified hospital** | | | | | | | |
| Yes | 5832 | 32.7 | 37 | 43.5 | 5795 | 32.6 | 0.032 |
| No | 12 025 | 67.3 | 48 | 56.5 | 11 977 | 67.4 | |
| **Hospital volume** | | | | | | | |
| High | 5972 | 33.4 | 36 | 42.4 | 5936 | 33.4 | 0.181 |
| Medium | 5893 | 33.0 | 22 | 25.9 | 5871 | 33.0 | |
| Low | 5992 | 33.6 | 27 | 31.8 | 5965 | 33.6 | |
| **Surgery** | | | | | | | |
| Yes | 14 477 | 73.4 | 60 | 65.9 | 14 417 | 73.4 | 0.108 |
| No | 5256 | 26.6 | 31 | 34.1 | 5225 | 26.6 | |
| **Chemotherapy** | | | | | | | |
| Yes | 4364 | 22.1 | 23 | 25.3 | 4341 | 22.1 | 0.467 |
| No | 15 370 | 77.9 | 68 | 74.7 | 15 302 | 77.9 | |
| **Radiotherapy** | | | | | | | |
| Yes | 3126 | 15.8 | 14 | 15.4 | 3112 | 15.8 | 0.905 |
| No | 16 607 | 84.2 | 77 | 84.6 | 16 530 | 84.2 | |

is the underreporting and bias of the cases treated by physicians of different specialties other than orthopedic oncologists. This background makes it difficult for the BSTT Registry to capture the actual number of cases with sarcoma that were not treated by orthopedic oncologists. In fact, the capture rate of CCS in the BSTT Registry, estimated by the number of cases with CCS in the BSTT Registry in 2016–2019, divided by those in the NCR in 2016–2019, was only 54%, whereas the capture rate of osteosarcoma was much higher: 64% https://pubmed.ncbi.nlm.nih.gov/38858229/).

CCS is known to produce more lymph node metastases compared to other STS (11,12). However, in this study, the exact proportion of lymph node metastases could not be estimated because lymph node metastases were included in the regional stage, defined as the spread of cancer from its original site to nearby areas, such as regional lymph nodes and adjacent organs.

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**Table 2.** Univariate analyses of OAS among the 122 patients with CCS

| | No. of patients ($N = 122$) | 3-year OAS (%) | *P* value |
|---|---|---|---|
| **Year of diagnosis** | | | 0.498 |
| 2016 | 28 | 38.3 | |
| 2017 | 28 | 28.1 | |
| 2018 | 30 | 65.8 | |
| 2019 | 36 | 61.1 | |
| **Sex** | | | 0.304 |
| Male | 61 | 43.7 | |
| Female | 61 | 40.7 | |
| **Age (y)** | | | 0.269 |
| 0–14 | 1–10 | 75.0 | |
| 15–39 | 38 | 48.1 | |
| 40–59 | 43 | 45.3 | |
| 60–74 | 22 | 51.1 | |
| 75- | 11–20 | 18.2 | |
| **Reason for diagnosis** | | | 0.646 |
| Cancer/health screening | 1–10 | 50.0 | |
| Others | 111–120 | 42.1 | |
| **Stage** | | | <0.001 |
| Localized | 48 | 80.3 | |
| Regional (spread outside the bone to nearby structures or lymph nodes | 23 | 24.3 | |
| Distant | 23 | 8.7 | |
| **JOA certified hospital** | | | 0.335 |
| Yes | 37 | 37.4 | |
| No | 48 | 38.8 | |
| **Hospital volume** | | | 0.170 |
| High | 36 | 42.0 | |
| Medium | 22 | 31.1 | |
| Low | 27 | 39.0 | |
| **Surgery** | | | <0.001 |
| Yes | 60 | 77.1 | |
| No | 31 | 10.1 | |
| **Chemotherapy** | | | <0.001 |
| Yes | 23 | 0 | |
| No | 68 | 64.8 | |
| **Radiotherapy** | | | 0.107 |
| Yes | 14 | 21.6 | |
| No | 77 | 48.0 | |

CCS is known to produce more late lymph node or distant metastasis, as well as metastasis at diagnosis (13–15), and finally results in systemic spread and tumor-related death in the long term. In the NCR data, CCS had significantly poorer OAS than non-CCS (Fig. 1), despite the fact that more patients with CCS were at the localized disease stage at presentation compared with non-CCS patients (Table 1). This suggests a significant impact of late lymph node or distant metastasis on survival in CCS. Although the follow-up period of the current study is relatively short, this trend will become more evident with longer follow-ups in future studies.

Since CCS is extremely rare, information on the prognostic factors has been limited, including tumor location (16), stage (3–5), tumor size (3,14,15,17) and treatment (15). Our study identified significant negative prognostic factors, including advanced stage and treatment without surgery, which were concordant with previous reports.

The present study has several limitations. First, database studies usually have incomplete or inaccurate data that can bias the results; there may be an underestimation or overestimation of the data due to incomplete reporting. Second, the important factors affecting OAS, including tumor size, the severity of preoperative comorbidities, response to chemotherapy, surgery type and surgical margin status, were not evaluated because the NCR does not collect this information. Third, the follow-up period was relatively short since the NCR only started in January 2016. Therefore, we hope to continue the observation of these patients and to report on their follow-ups in future studies.

In conclusion, the current study clarified the epidemiology, clinical features, treatment and prognosis of patients with CCS in Japan based on the NCR. This study is the first to have characterized the profiles of CCS on a national basis in a population-based manner in Japan and may be useful in predicting appropriate prognoses and planning treatments for patients with CCS.

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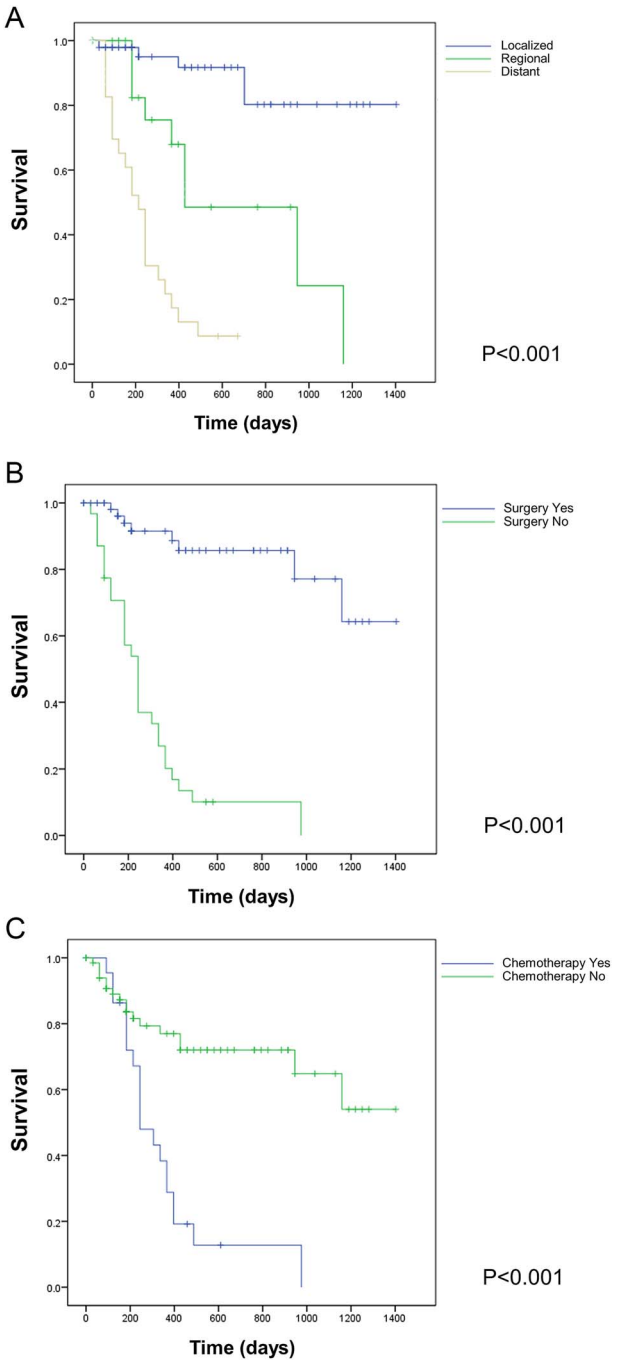


**Figure 3.** Kaplan–Meier survival plots of OAS stratified by predictor variables: (A) stage, (B) surgical treatment, (C) radiotherapy.

## Author contributions

TT, KO, TH and AK conceived of and designed the study. TT, KO, CM, TS, SI, YT, SM, HK and EK acquired and analyzed data. All authors read, critically revised, and approved the final version of the manuscript.

Conflict of interest: None declared.

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## Ethics statement

Approval of the research protocol by an Institutional Reviewer Board: According to the procedure stipulated by the law, the protocol was reviewed by the Data Utilization Committee of the National Cancer Registration Office. As per the research ethics guidelines in Japan, our study was exempted from an ethics review by our institutional review board.

Informed consent: N/A
Registry and the Registration No. of the study/trial: N/A
Animal studies: N/A

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