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Clinical Characteristics and Treatment Patterns of Tenosynovial Giant Cell Tumor in Japan: An Analysis of the Japanese Bone and Soft Tissue Tumor Registry

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Abstract

Background

Tenosynovial giant cell tumors (TGCTs) are rare proliferative disorders arising from the synovium of the joints, tendon sheaths, and bursae. Despite being generally considered a benign disease, it can cause pain, joint dysfunction, and local recurrence. We investigated TGCT epidemiological characteristics and treatment patterns in Japan using data from the Japanese Bone and Soft Tissue Tumor (BSTT) registry and a nationwide institutional survey.

Methods

A retrospective analysis was performed using the BSTT registry maintained by the Musculoskeletal Tumor Committee of the Japanese Orthopedic Association. Patients diagnosed with TGCT between 2006 and 2019 were included. Demographic characteristics, tumor presentation, diagnostic procedures, and surgical treatments within 1 year of registry entry were analyzed.

Results

Overall, 3,779 patients with TGCT were identified. The mean age at diagnosis was 44.9 years (range, 4–97 years), and 62.1% of patients were women. Most tumors presented as solitary lesions (99.0%). Biopsies were performed in 1,148 patients. Surgical treatment within 1 year of registry entry was recorded in 2,875 patients (76.1%); 888 did not undergo surgery, and surgical status was unknown for 16. Functional outcome assessments using the International Society of Limb Salvage scores were available for 177 patients.

Conclusions

This study overviewed the demographic characteristics and initial treatment patterns of TGCT in Japan. Clinical features were broadly consistent with those reported internationally, and surgery remained the primary management strategy. Longer follow-up and more detailed tumor subtype information are warranted to better characterize the natural history and optimize management strategies.

Mini abstract

Nationwide registry analysis of 3,779 TGCT cases in Japan showed predominance of middle-aged women, mainly solitary lesions, and surgery as the primary treatment, consistent with international findings.

Introduction

Tenosynovial giant cell tumors (TGCT) are a synovial proliferative disorder that, although histologically benign, may result in clinically significant morbidity, including pain, functional limitations, and joint destruction. Historically, this disease has been described using various terms, including pigmented villonodular synovitis and giant cell tumors of the tendon sheath; these entities are now regarded as a spectrum of the same pathological process and collectively referred to as TGCT [1, 2]. According to the current World Health Organization classification of soft tissue and bone tumors, TGCT is categorized as localized or diffuse disease [3]. Localized TGCT usually presents as a well-circumscribed nodular lesion, most often arising in the tendon sheath of the hand, whereas diffuse TGCT involves more extensive synovial proliferation, most commonly in large joints such as the knee, and tends to show more aggressive local behavior [1, 4–6].

Although TGCTs are histologically benign, they can cause considerable morbidity, including pain, swelling, stiffness, mechanical symptoms, joint destruction, and recurrence [4–7]. Epidemiological data remain limited because the disease is rare and historical terminology has been used inconsistently. Recent registry-based studies in Europe have provided important epidemiological insights, suggesting that TGCT may be more prevalent than previously recognized. A nationwide pathology registry study from the Netherlands reported incidence rates of 34 per million person-years for digital disease, 11 per million person-years for localized extremity TGCT, and 5 per million person-years for diffuse-type TGCT, indicating that TGCT is more common than previously recognized [8]. Similarly, a registry-based study from Denmark identified 2,087 localized and 574 diffuse TGCT cases, with incidence rates of 30.3 and 8.4 per million person-years, respectively [9]. Moreover, these studies demonstrated that TGCT typically affects adults in the fourth to fifth decades of life and occurs slightly more frequently in women [8, 9].

Surgical excision has long served as the mainstay of treatment for TGCT [5, 6, 10]. Localized-type lesions are typically managed with marginal excision and generally exhibit favorable local control, whereas diffuse-type TGCT often requires more extensive synovectomy and is associated with a substantially higher risk of recurrence [10–15]. Previous studies have reported recurrence rates ranging from approximately 20% to > 50%, particularly in diffuse disease [10, 12–15].

Recent advances in molecular pathology have clarified the biological basis of TGCT. A translocation involving the *colony-stimulating factor 1* (*CSF1*) gene leads to CSF1 overexpression in a minority of neoplastic cells, which in turn recruits macrophages and other inflammatory cells that constitute most of the tumor mass. This “landscape effect” is a distinctive feature of TGCT and has provided a rationale for targeted systemic treatment [16, 17].

Based on this molecular mechanism, inhibitors of the CSF1/CSF1 receptor pathway have emerged as key therapeutic options for advanced disease. Pexidartinib demonstrated significant antitumor activity in the phase III ENLIVEN trial [18] and has become a key treatment option for patients with advanced TGCT. Additionally, other investigational approaches, including anti-inflammatory agents and molecularly targeted therapies, have been explored in clinical studies [19–21]. Furthermore, recent consensus

recommendations have emphasized the need for individualized, multidisciplinary management of TGCT [22]. Nonetheless, most epidemiological and therapeutic data have been derived from Europe and North America, and large-scale analyses in Asian countries, including Japan, remain limited.

Therefore, this study aimed to investigate the clinical characteristics and treatment patterns of TGCT in Japan using data from the Japanese Bone and Soft Tissue Tumor (BSTT) registry.

Materials and Methods

This retrospective study used the Japanese BSTT Registry, maintained by the Musculoskeletal Tumor Committee of the Japanese Orthopedic Association (JOA). The BSTT registry is a nationwide database that collects clinical information on patients diagnosed with bone and soft-tissue tumors at participating musculoskeletal tumor centers across Japan.

Patients diagnosed with TGCTs between 2006 and 2019 were identified in the registry. Clinical information extracted from the registry included age at diagnosis, sex, tumor multiplicity, diagnostic biopsy status, and surgical treatment performed within 1 year of registry entry. In the BSTT registry, TGCT diagnosis may be recorded based on either histopathological confirmation or clinical and imaging findings. Histopathological confirmation comprised diagnoses based on biopsy specimens, surgical resection specimens, or both. Biopsy procedures were recorded separately in the registry, and some patients underwent multiple biopsies. Functional outcome data, evaluated using the International Society of Limb Salvage (ISOLS) scoring system [23], were also collected when available.

Because the BSTT registry was originally designed for general bone and soft-tissue tumor registration, detailed TGCT subtype classification (localized vs diffuse) was inconsistently recorded in earlier registry entries. In the BSTT registry system, malignant tumors are followed longitudinally for extended periods, whereas benign tumors are generally followed for approximately 1 year after registration. Consequently, the registry primarily provides information on initial diagnostic and treatment patterns rather than long-term oncological outcomes. Thus, recurrence rates and long-term outcomes could not be reliably evaluated in this study.

This retrospective study, based on analysis of the BSTT database, was initially approved by the Musculoskeletal Tumor Committee of the JOA, then by the institutional review board of the principal investigator’s institution (approval number: 2021 – 361), and subsequently by the participating institutions.

Descriptive statistical analyses were performed to summarize demographic characteristics and treatment patterns. Continuous variables are reported as means with ranges, whereas categorical variables are presented as frequencies and percentages.

Results

Overall, 3,779 patients diagnosed with tenosynovial giant cell tumors between 2006 and 2019 were identified in the BSTT registry. The mean age at diagnosis was 44.9 years (range, 4–97 years). This cohort demonstrated a predominance of women. Among registered patients, 2,348 were female (62.1%), and 1,431 were male (37.9%) (Table 1). The anatomical distribution of TGCT lesions is summarized in Table 2. The hand was the most common site (53.1% of cases), followed by the knee (16.6%) and foot (15.6%). Lesions were also frequently observed in the ankles (6.0%) and wrists (3.2%), whereas other anatomical locations were relatively uncommon. Most tumors were solitary. Specifically, 3,741 and 38 patients presented with a single tumor and multiple tumors, respectively. Regarding tumor status at presentation, most cases were primary tumors: 3,630 patients (96.1%) had primary disease, whereas 149 (3.9%) exhibited recurrent tumors at the time of registry entry (Table 1). Histopathological confirmation was available for 3,298 patients (87.3%); in 481 patients (12.7%), the diagnosis was based on clinical and imaging findings without pathological confirmation. Among clinically diagnosed cases, hand involvement was most common, suggesting that a substantial proportion of hand lesions are managed based on typical clinical presentation without preoperative pathological confirmation. Regarding diagnostic procedures, biopsy was performed in 1,148 patients; 2,619 patients did not undergo biopsy, and biopsy status was unknown in 12 patients. Among patients who underwent biopsy, needle biopsy was the most common procedure (45%), followed by incisional biopsy (32%) and excisional biopsy (23%) (Table 3). Some patients underwent multiple biopsies. During the first year after registry entry, 2,875 patients underwent surgical treatment, whereas 888 patients did not undergo surgical intervention; surgical status was unknown in 16 patients (Fig. 1). Among surgically treated patients, complete tumor resection was achieved in 2,409 patients, whereas incomplete resection was reported in 466 patients (Fig. 2).

Functional outcomes were evaluated using the ISOLS scoring system in a small subset of patients in the registry. ISOLS evaluations were available for 110 of 2,183 upper limb cases (5.0%) and 67 of 1,492 lower limb cases (4.5%). The mean ISOLS score was 29.1 (range, 19–30) for upper limb tumors and 28.7 (range, 18–30) for lower limb tumors. Because the registry includes both surgically and non-surgically managed patients, these scores do not necessarily represent postoperative outcomes (Table 4).

Discussion

This study provides a large-scale overview of TGCT in Japan, based on data from the Japanese BSTT registry and a nationwide institutional survey. To our knowledge, this is among the largest TGCT analyses in Asia. Overall, 3,779 patients were identified during the study period, offering key insights into the demographic characteristics and treatment patterns of TGCT in Japan. Importantly, this study presents large-scale epidemiological data from Japan, which are scarce in the existing literature.

The demographic characteristics observed in this study were consistent with those reported in previous epidemiological studies. More than half of the lesions occurred in the hand, consistent with the findings of earlier reports indicating that TGCT most commonly arises from the hand tendon sheath.

The mean age at diagnosis in our cohort was 44.9 years, similar to previous reports indicating that TGCT most commonly affects adults in the fourth to fifth decades of life [8, 9]. Female predominance was also observed, with women accounting for approximately 62% of cases. This pattern aligns with findings from European registry-based studies, which reported a modest female predominance among patients with TGCTs [8, 9].

Beyond these demographic features, TGCT is diagnosed primarily on clinical evaluation and imaging findings. Magnetic resonance imaging (MRI) typically demonstrates synovial proliferation with characteristic hemosiderin deposition, [24] although the imaging appearance may vary depending on the anatomical location and extent of the disease. In rare situations, TGCTs arising in unusual anatomical locations may mimic malignant tumors on imaging studies, including positron emission tomography [25].

A key finding of this study was that 481 patients were diagnosed clinically without pathological confirmation. Among these clinically diagnosed cases, the hand was the most commonly involved site. This pattern likely reflects the well-recognized clinical features of TGCT of the hand, in which localized lesions are often small, well-circumscribed, and arise from the tendon sheath. In such settings, surgeons frequently proceed directly to excision without prior biopsy because the presentation is typical, and excision serves both diagnostic and therapeutic purposes[6, 26]. The relatively low preoperative biopsy rate observed here does not necessarily indicate a low overall histological confirmation rate. Conversely, TGCT involving large joints, such as the knee, may exhibit characteristic MRI findings, allowing clinical diagnosis in selected cases even without preoperative pathological confirmation.

Recent population-based registry studies have substantially advanced our understanding of TGCT epidemiology. A nationwide pathology registry study from the Netherlands reported incidence rates of approximately 34, 11, and 5 per million person-years for digital, localized-extremity, and diffuse-type TGCT, respectively [8]. Similarly, a registry-based cohort study in Denmark reported incidence rates of 30.3 per million person-years for localized TGCT and 8.4 per million person-years for diffuse-type TGCT [9]. These studies demonstrated that TGCTs are more common than previously recognized and provide valuable epidemiological benchmarks. Although the present research was not population-based and therefore cannot be used to calculate precise incidence rates, the demographic patterns observed in our cohort appear broadly consistent with those reported in these European registry studies. Thus, the overall clinical profile of TGCT in Japan may be similar to that observed in Western populations.

Surgical treatment is the cornerstone of TGCT management. Here, most patients underwent surgery within 1 year of registry entry. This finding aligns with those of prior reports indicating that surgery remains the standard treatment for TGCT [5, 6, 10]. For localized disease, marginal excision is generally sufficient and is associated with relatively low recurrence rates. Conversely, diffuse-type TGCT often requires extensive synovectomy, and recurrence remains a significant clinical problem [10, 12–15].

Previous research has reported recurrence rates of approximately 20% to > 50% in diffuse-type TGCT [10, 12–15]. Nevertheless, recurrence rates could not be reliably evaluated in this study because the BSTT

registry followed benign tumors for only a limited period, generally about 1 year after registration. Consequently, the registry largely captures initial treatment patterns rather than long-term outcomes, which likely explains the relatively low recurrence rates observed in our dataset.

Advances in understanding the molecular mechanisms of TGCT have driven the development of targeted therapies targeting the CSF1/CSF1 receptor pathway. Pexidartinib, a selective CSF1 receptor inhibitor, demonstrated significant clinical efficacy in the phase III ENLIVEN trial and has become an important therapeutic option for patients with advanced TGCT [18]. Other systemic agents targeting the same pathway have also been investigated, including nilotinib and pimicotinib [20, 21].

More recently, the phase III MANEUVER trial demonstrated that pimicotinib significantly improved tumor response and patient-reported outcomes in patients with advanced TGCT [21]. These findings reflect a rapidly evolving therapeutic landscape for TGCT. Although systemic therapies are increasingly recognized as important treatment options, access to these agents remains limited in some countries, and surgery continues to play a central role in disease management.

In addition to CSF1R inhibitors, other pharmacologic approaches have been investigated. For example, a randomized, placebo-controlled phase II trial assessed the efficacy of the nonsteroidal anti-inflammatory drug zaltoprofen in patients with diffuse TGCT or unresectable localized TGCT. Although no significant tumor response was observed, this study provided valuable insights into potential anti-inflammatory treatment strategies for TGCT [27].

Another key aspect of TGCTs is their impact on patients' symptoms and quality of life. Previous studies have demonstrated that patients with TGCT often experience pain, stiffness, swelling, and functional limitations, which may substantially affect daily activities [7]. Furthermore, prospective registry studies, including the Tenosynovial Giant Cell Tumor Observational Platform Project, have documented the considerable disease burden and reinforced the value of incorporating patient-reported outcomes into clinical decision-making [28]. Recent studies have suggested that active surveillance may be an appropriate management strategy for selected patients with diffuse-type TGCT who have stable disease and minimal symptoms [29].

Collectively, these findings suggest that TGCT management is shifting toward a more individualized, multidisciplinary approach that balances disease control with the preservation of joint function and quality of life [22].

This study had some limitations. First, the BSTT registry primarily includes data from specialized musculoskeletal tumor centers and is not population-based. Therefore, referral bias may be present, and the dataset may not fully reflect the nationwide incidence of TGCT in Japan. Second, detailed clinical variables, including tumor subtype (localized versus diffuse), tumor size, surgical techniques, and recurrence data, were not consistently available in the registry. Specifically, the distinction between localized- and diffuse-type TGCT could not be reliably analyzed, although these subtypes differ substantially in clinical behavior and risk of recurrence. Third, the follow-up period for benign tumors in

the registry was relatively short. In the BSTT registry system, malignant tumors are followed up for extended periods, whereas benign tumors are generally followed up for approximately 1 year following registration. Consequently, long-term outcomes, such as recurrence, disease progression, and functional recovery, could not be adequately evaluated in this study.

Nevertheless, the large case volume and nationwide coverage of the participating institutions provide valuable insights into the current clinical characteristics and treatment patterns of TGCTs in Japan.

In conclusion, this nationwide, registry-based analysis provides a detailed overview of the demographic characteristics and initial treatment patterns of TGCT in Japan. In this large cohort, the demographic profile was broadly consistent with that reported in previous international studies, with a predominance of middle-aged adults and a slight female predominance. Surgical treatment remains the primary management strategy during the initial treatment period. Although this registry provides valuable insights into the clinical characteristics of TGCT in Japan, longer follow-up and more detailed clinical information, including tumor subtype classification and patient-reported outcomes, are required to further clarify the natural history and optimal management strategies for this rare disease.

Declarations

Conflict of interest:

The authors declare no conflicts of interest regarding this study.

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Data availability

The data that support the findings of this study are derived from the Japanese Bone and Soft Tissue Tumor registry. Restrictions apply to the availability of these data, which were used under license for the current study and are not publicly available.

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Tables

Table 1 to 4 are available in the Supplementary Files section.

Figures

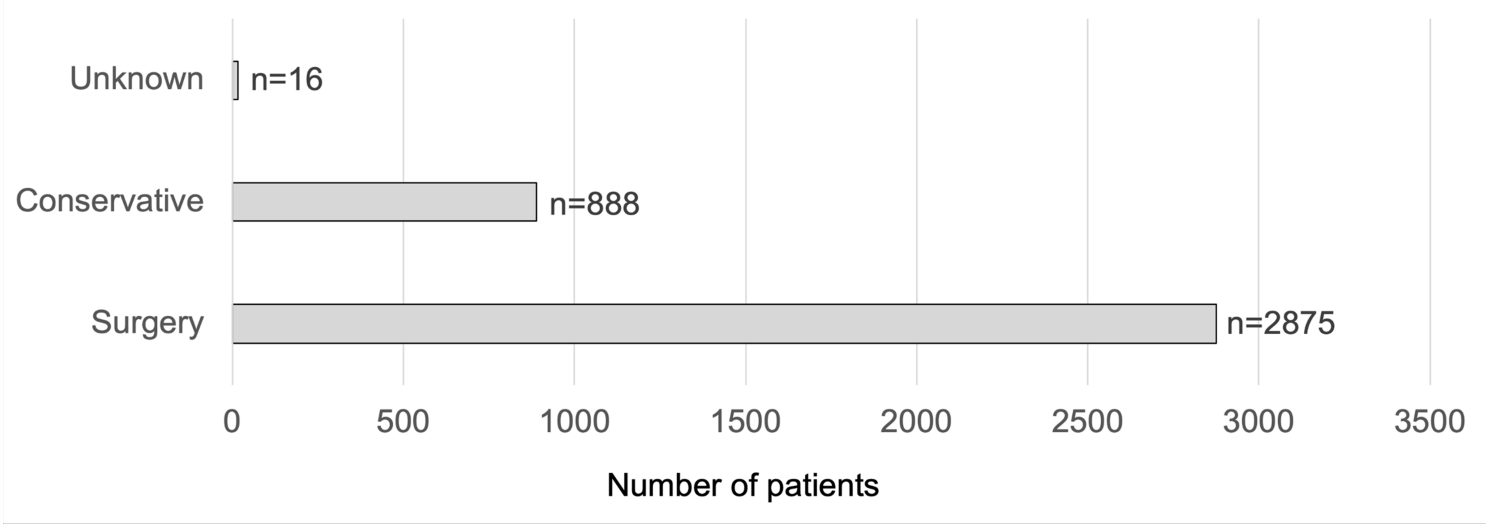


Figure 1

Initial treatment strategy recorded in the registry.

Surgical treatment was performed in 2,875 patients (76.1%), 888 patients (23.5%) did not undergo surgery, and the surgical status was unknown in 16 patients (0.4%).

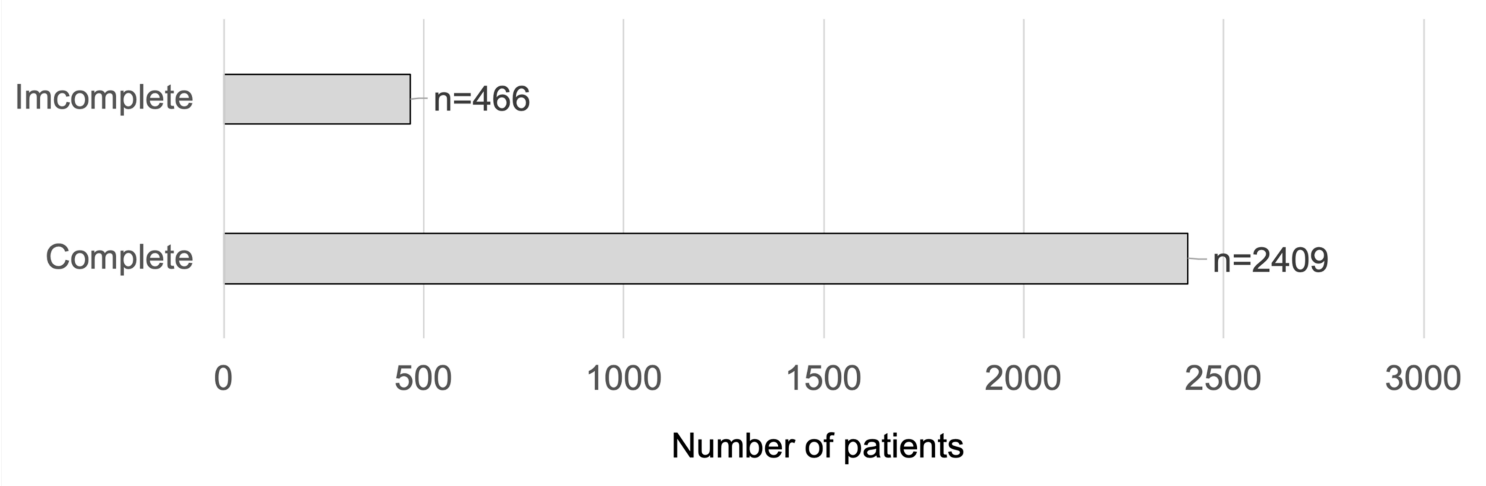


Figure 2

Surgical margin status among surgically treated patients.

Complete tumor resection was recorded in 2,409 patients (83.8%), whereas incomplete resection was reported in 466 patients (16.2%).

Supplementary Files

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- TableTGCT032926.pptx