Introduction

Despite efforts from international communities to support the North Korean tuberculosis (TB) control program, TB is one of the major infectious diseases in North Korea. Lower respiratory tract infections, TB and diarrheal diseases are the major infectious diseases in North Korea. North Korea is one of the 30 countries with the highest burden of TB and rifampin resistant (RR)/multi-drug resistant (MDR)-TB. According to the World Health Organization (WHO), estimated incidence rate of TB has increased from 345/100,000 in 2010 to 513/100,000 in 2018 and estimated incidence of RR/MDR-TB in 2018 was 5200 (20/100,000). North Korea reported 1,782 cases of laboratory-confirmed RR/MDR-TB with initiation of
treatment in 1,487 patient in 2018.

The North Korean health care system has been devastated by natural disasters and the loss of support occasioned by the break-up of the Soviet Union since mid-1990s, making it difficult to respond to poverty- and nutrition-related diseases such as TB. In addition, the tight United Nations sanctions due to the nuclear program of North Korea have made it difficult to maintain the humanitarian assistance operations for the management of TB and MDR-TB in North Korea.

After being divided into separate countries 71 years ago, South Korea and North Korea have shown differences in many health-related statistics, especially with regard to TB. Recently, South Korea and North Korea have initiated discussions about a joint response system for fighting contagious disease, such as TB and malaria; however, data on the incidence and management of TB and MDR-TB in North Korea are scarce. Because of the lack of primary source of data and samples, many South Korean researchers have estimated the circumstances in North Korea on the basis of empirical data collected through testimonies or survey results from North Korean defectors; however, generalizability of these data is limited by the methodology.

Thus, researchers have tried to investigate trends of research on TB or other diseases using North Korean medical journals to supplement for the lack of primary data and to understand the current disease status in North Korea. The analysis of research published in medical journals can provide insights into the current status of research by providing information on the academic interests of a society and on the level of medical development based on the use of technology.

In South Korea, nine medical journals from North Korea are available. This study aimed to perform a comprehensive review of articles related to clinical and laboratory research on TB in North Korean medical journals to understand the medical issues and research trends on the basis of available data.

### Materials and Methods

In South Korea, nine academic journals published by North Korean organizations are available in the Information Center on North Korea maintained by the Ministry of Unification. Researchers can access these journals at the center. The following is the list of these nine medical journals: Yebang ühak (Preventive Medicine), Koryo ühak (Korea Medicine), Choson ühak (Chosun Medicine), Naekwa (Internal Medicine), Soa, sanbuinkwa (Pediatrics, Obstetrics, and Gynecology, Surgery), Úhak (Medicine), Kichó ühak (Basic Medicine), and Choson yakhak (Chosun Pharmacy). We analyzed the articles published from 2006 to 2018 in all these journals, with the exception of two journals, Úhak (Medicine) and Koryo ühak (Korea Medicine). In Úhak (Medicine) and Koryo ühak (Korea Medicine), only articles published during the periods of 2006–2008 and 2016–2018, respectively, were available. Because this study analyzed previously published literature, approval from the institutional review board was not required.

#### 1. Search strategies and data collection

We screened all articles in the nine medical journals to identify those related to TB. All types of articles, except “Introduction of Journal” and “News of Academy,” were included from each journal. Two independent authors (C.J. Lee and S. Lee) initially screened the articles by titles to identify those related to TB; they subsequently assessed the full text of the articles that were preliminarily identified to be relevant. No restrictions were applied regarding study design, patient number, methods of data collection, or article type (case reports, review papers, clinical trials, and basic laboratory research).

#### 2. Data extraction and analysis

Names of authors and journals, titles, and year of publication corresponding to all the included articles were recorded in a Microsoft Excel (Microsoft Corp., Redmond, WA, USA) file. We analyzed the data in included articles on the basis of the classification of disease and field of study. Two researchers (C.J. Lee and S. Lee) conducted all research data extraction and classification, and when differing opinions were presented, consensus was reached by discussion.

### Results

There were 18,596 articles in those nine journals. After title-based screening and assessment of full-text articles, 106 TB-related articles (0.6%) were included in the final analysis (Figure 1). Among these 106 articles, 75 articles were from two journals: Yebang ühak (Preventive Medicine), 48 articles (45.3%); Naekwa (Internal Medicine), 27 articles (25.5%). After excluding two journals, Úhak (Medicine) and Koryo ühak (Korea Medicine), the number of published articles on TB showed an increasing trend from 2008 to 2015, with the highest number of articles (n=16) published in 2015. All the articles (n=106) were one or two pages in length and were written in Korean. Seven articles published in Choson ühak...
(Chosun Medicine) and one article published in Naekwa (Internal Medicine) had a 2–3 sentence-long summary in English. The articles typically had two authors (74 out of 106 articles) without the contact information of corresponding author and less than five references which were at the end of the article without in-text citation. Articles usually began with citation of the Supreme leaders' instruction and reflection of their ideological views and ideas unique to North Korea. In the articles, tables, graphs, and images were partially illustrated by hand, and some statistics such as percentages and p-values were presented with no specific statistical method. All the experimental and interventional articles showed positive results, and there was no mention of ethical approval for human study.

1. Classification based on field

The articles (n=106) were classified as follows: reviews (n=43), original articles (n=52), and case reports (n=8). Among the 106 articles, 90 involved human studies and 16 involved animal studies. On the basis of the field of study, the articles were classified as follows: articles on diagnosis, 52 (49%); treat-
| Journal             | Year | Title                                                                 | Disease | Subjects | No. | Intervention regimen                                                                 | Control regimen                                                                 | Outcome measure                                                                 |
|---------------------|------|----------------------------------------------------------------------|---------|----------|-----|--------------------------------------------------------------------------------------|----------------------------------------------------------------------------------|--------------------------------------------------------------------------------|
| Naekwa (Internal Medicine) | 2006 | A study on using streptomycin with Lanthanide (le-mycing) for PTB | PTB     | Adults   | Trt 132 Cont 27 | INH 500 mg QD for 4 mo+SM with lanthanide (le-mycing) IM QD for 1 mo, then IM QOD for 2 mo | INH 500 mg QD for 6 mo+SM 1,000,000 U IM QD for 1 mo then IM QOD for 2 mo | Microbiologic, radiographic improvement, adverse events at 6 mo |
| Naekwa (Internal Medicine) | 2006 | Treatment of chronic invasive PTB with intralesional injection of mixed solution of INH/RIF/tuberculins | PTB     | Adults   | Trt 40 Cont 35 | INH 500 mg+RIF 500 mg PO QD+SM 1 g IM QD for 4 mo+INH 500 mg/RIF 500 mg QOD for 2 mo+INH/RIF mixed solution 6 mL+tuberculins diluent 0.1 mL percutaneous intralesional injection BIW for 3 mo | INH 500 mg+RIF 500 mg PO QD+SM 1 g IM QD for 4 mo+INH 500 mg/RIF 500 mg QOD for 2 mo+INH/ RIF mixed solution 6 mL percutaneous intralesional injection twice a week | Microbiologic, clinical improvement, radiographic improvement |
| Naekwa (Internal Medicine) | 2006 | Clinical study for the treatment of tuberculous exudative meningitis with DC magnetic field and anti-TB drug | TB pleurisy | Adults   | Trt 50 Cont 50 | INH+SM+thoracentesis+DC magnetic field therapy for 20 min, not specified further for the treatment | DOTS III category, not specified further for the treatment | Subjective symptoms (fever, dyspnea, chest pain etc.), body temperature, ESR in peripheral blood, pleural adhesion |
| Naekwa (Internal Medicine) | 2006 | Treatment of epididymal tuberculosis with a combination of snake venom and anti-TB chemotherapy | TB epididymitis | Adults   | Trt 80 Cont 40 | 0.0005% Snakes venom 1.0 mL local injection BIW or ITW+DOTS III, not specified further for the treatment | DOTS III category, not specified further for the treatment | Subjective symptoms (pain, tenderness), size of induration, volume of semen |
| Naekwa (Internal Medicine) | 2007 | Treatment of PTB with intralesional injection of mixed solution of snake venom and INH/RIF | PTB     | Children | Trt 50 Cont 25 | Added mixed solution of 3 mL of INH (250 mg)/RIF (150 mg) and 2 mL 0.005% snake venom percutaneous intralesional injection BW for 6 mo | INH 500 mg QD/RIF 500 mg PO QD/SM 1,000,000 U IM QD for 2 mo+INH 500 mg QD/RIF 500 mg QD/PZA 1,500 mg QOD for 2 mo+INH 500 mg QOD/RIF 500 mg QOD/KM 1,000,000 U IM QOD | Microbiologic, radiographic improvement |
| Soa, sanbuinkwa (Pediatrics, OBGYN, Surgery) | 2007 | TB drug inhalation and magnet application for pediatric PTB | PTB     | Children | Trt 50 Cont 35 | INH and RIF inhalation treatment and magnet application to the chest for 1 hour QD, no detailed information | INH and RIF inhalation treatment, no detailed information | Radiographic improvement, change of ESR and lymphocyte count in peripheral blood |
| Journal                  | Year | Title                                                                 | Disease | Subjects                  | No. | Intervention regimen                                                                 | Control regimen                                                                 | Outcome measure                                                                 |
|-------------------------|------|----------------------------------------------------------------------|---------|---------------------------|-----|--------------------------------------------------------------------------------------|---------------------------------------------------------------------------------|----------------------------------------------------------------------------------|
| Soa, sanbuinkwa (Pediatrics, OBGYN, Surgery) | 2007 | CSF drainage and intrathecal injection of anti-TB drug for the treatment of pediatric TBM | TBM     | Children                  | Trt 30 Cont 49 | CSF drainage and intrathecal injection of mixed solution of INH/RIF/hydrocortisone QD or QOD or QW | Anti-TB medication no detailed information | Subjective symptoms (fever, pain, weakness, etc.), meningal symptoms, CSF profile, CT change |
| Soa, sanbuinkwa (Pediatrics, OBGYN, Surgery) | 2010 | CSF drainage and intrathecal injection of mixed solution of RIF/hydrocortisone for the treatment of pediatric TBM | TBM     | Children                  | Trt 60 Cont 70 | CSF drainage and intrathecal injection of mixed solution of RIF/hydrocortisone TIW+DOTS, no detailed information | DOTS, no detailed information | Subjective symptoms (fever, pain, weakness, etc.), meningal symptoms, CSF profile |
| Chosŏn ŭhak (Chosun Medicine) | 2014 | Treatment of exudative pleurisy with combination of Hojanggun and anti-TB drugs | TB pleurisy | Not specified | Trt 15 Cont 12 | Hojanggun (60 g)+INH 500 mg+mycing 1,000,000 U IM for 1 mo | INH 500 mg+mycing 10,000,000 U IM for 1 mo | Subjective symptom (fever, dyspnea, chest pain, etc.), radiographic improvement |
| Naekwa (Internal Medicine) | 2015 | Treatment of mesenteric TB lymphadenitis with laparoscopic ultraviolet irradiation | TB lymphadenitis | Not specified | Trt 12 Cont 9 | laparoscopic UV radiation for 2 min+INH+RIF 450 mg+SM 1,000,000 IU IM for 3 mo | INH+RIF 450 mg+SM 1,000,000 IU IM for 3 mo | Subjective symptom (fever, abdominal pain, abnormal bowel sound, etc.), ESR in peripheral blood, ultrasonic improvement for LN |
| Naekwa (Internal Medicine) | 2015 | Clinical study for the treatment of TBM by intrathecal injection | TBM     | Not specified             | Trt 12 Cont 9 | Intrathecal injection of mixed solution of isotubo 3–4 mL, dexamethasone 0.5–1.0 mL, and 0.2% levofloxacin 2 mL QD for 5–7 days; then, QW or BIW for 2–3 mo+anti-TB medication QOD; duration not specified | Anti-TB medication every other day no detailed information | Subjective symptoms (fever, headache, vomiting, etc.), degree of meningeal irritation sign, ESR in blood, CSF profile |
| Yebang ŭhak (Preventive medicine) | 2016 | Treatment of TBM by CSF exchange and intrathecal injection | TBM     | Adults and children       | Trt 29 Cont 20 | Combination of INH/RIF/EMB/PZA/SM+exchange of CSF/saline and intrathecal injection of mixed solution of INH/RIF/hydrocortisone 25 mg QD or QOD; duration not specified | DOTS, no detailed information | CSF profile |
| Journal          | Year | Title                                                                 | Disease                      | Subjects | No. | Intervention regimen                                                                 | Control regimen                                                                 | Outcome measure                                                                 |
|------------------|------|----------------------------------------------------------------------|------------------------------|----------|-----|---------------------------------------------------------------------------------------|---------------------------------------------------------------------------------|--------------------------------------------------------------------------------|
| Koryo ŭihak (Korea Medicine) | 2016 | Treatment of pediatric TB lymphadenitis with haneultali neosam tablet | TB lymphadenitis              | Children | Trt 53 Cont 43 | INH 5 mg/kg/RIF 10 mg/kg/haneultali neosam tablet 500–1,000 mg TID for 2 mo+INH/RIF TIW/ haneultali neosam tablet 500 mg TID for 4 mo | INH/RIF/EMB/PZA for 2 mo+INH 10 mg/kg/RIF 10 mg/kg for 4 mo | Subjective symptoms (sweating size of lymph node, ESR in peripheral blood, AFB smear of lymph node aspirate) |
| Yebang ŭihak (Preventive medicine) | 2018 | Treatment of TBM sequelae with sacral epidural injection              | TBM                          | Adults   | Trt 19 Cont 10 | Epidural injection of hydrocortisone 30 mg/5% vitamin B 4.0 mL/vitamin B12 1.000 r 1.0 mL+saline 10.0 mL Q3D, 5 times at sacral level | Hydrocortisone 30 mg/vitamin B 4.0 mL/saline 500 mL intravenous injection+vitamin B12 1000 r 1.0 mL IM injection Q3D for 1 mo | Subjective symptoms (pain, weakness), degree of peripheral paralysis, functional disability scale |
| Yebang ŭihak (Preventive Medicine) | 2018 | Treatment of TBM with combination of milk vetch root drug and anti-TB drugs | TBM                          | Adults   | Trt 16 Cont 14 | INH/RIF/SM QD+milk vetch root drug 2 mLIM QD; duration not specified | INH/RIF/SM QD; duration not specified | Body temperature, meningeal symptoms, ESR in peripheral blood |

PTB: pulmonary tuberculosis; Trt: treatment group; Cont: control group; INH: isoniazid; SM: streptomycin; QD: every day; IM: intramuscular injection; QOD: every other day; RIF: rifampin; PO: per oral; BIW: twice in a week; DC: direct current; TB: tuberculosis; ESR: erythrocyte sediment rate; TIW: thrice a week; DOTS: Directed observed treatment strategy; PZA: pyrazinamide; KM: kanamycin; OBGYN: Obstetrics and Gynecology; CSF: cerebrospinal fluid; TBM: tuberculosis meningitis; QW: once in a week; CT: computed tomography; LN: lymph node; EMB: ethambutol; TID: thrice a day; AFB: acid-fast Bacilli; Q3D: every three days.
ment, 39 (37%); epidemiology, 3 (3%); pathogenesis, 2 (2%); vaccines, 3 (3%); diagnosis+treatment, 5 (5%); and others, 2 (2%).

Among the 52 articles on the diagnosis of TB, 26 were original articles with 24 involving human subjects (Figure 2). These 24 articles corresponded to different methods of TB diagnosis: molecular diagnosis (n=9), biochemical diagnosis (n=3), acid-fast Bacilli (AFB) smear-based diagnosis (n=2), mycobacterial culture-based diagnosis (n=2), immunologic diagnosis (n=2), and radiological diagnosis (n=1). Among the nine articles on molecular diagnosis, five corresponded to molecular diagnosis of TB, three corresponded to molecular diagnosis of drug-resistant TB, and one corresponded to the diagnosis of nontuberculous mycobacteria (NTM). None of the studies investigated any aspect of the commercialized molecular diagnosis systems such as Gene Xpert MTB/RIF assay (Cepheid, Sunnyvale, CA, USA) or GenoType MTBDRplus assay (Hain Lifescience, Nehren, Germany). In addition, there was no detailed description of molecular diagnostic procedures such as polymerase chain reaction or microarray analysis used for the detection of TB or rpoB gene mutation.

Among the 39 articles on the treatment of TB, 17 corresponded to interventional trials (Figure 3). Among these 17 interventional studies, four and 11 articles were related to the treatment of pulmonary TB and extra-pulmonary TB, respectively, in humans. In Table 1, the detailed treatment regimens for 15 human trials are summarized. The non-standardized regimen and intermittent treatment were common in these 15 trials. In six studies, Korean traditional medicine was used for the treatment of TB; one of these medicines involved the use of snake venom. There were no studies on interventional treatment for drug-resistant TB.

2. Classification based on topic

We found 13 articles on drug resistant TB, two articles/year in 2007, 2012, 2013, 2014, 2015, and 2017 and one in 2018. Among them, five were reviews and eight were original articles. A review article published in 2013 summarized the “Guidelines for the programmatic management of drug-resistant TB, 2008 WHO”11, and a review article published in 2014 mentioned about Gene Xpert/MTB RIF assay. In the latter review, the author mentioned Xpert MTB/RIF assay and nitrate reductase assay for rapid drug susceptibility test for TB; they discussed more positive points of views on the nitrate reductase assay. All the original articles on drug resistant TB in humans were about the diagnosis of drug resistance: molecular diagnosis (n=3), smear morphology-based diagnosis (n=1), biochemical assay-based diagnosis (n=1), and culture-based drug susceptibility test-based diagnosis (n=1) (Figure 4). In one study involving analysis of the frequency of drug resistance using a culture-based drug susceptibility test, the authors assessed the resistance of 246 culture isolates to isoniazid (INH), streptomycin (SM), rifampin (RIF), ethambutol (EMB), and pyrazinamide (PZA). Among 33 treatment naïve TB isolates, five (15.1%) showed resistance to INH and six (18.1%) showed resistance to RIF according to the report. Among 53 isolates after over 6 months of treatment, 47 (88.6%) were resistant to INH and 36 (67.9%) were resistant to RIF12.

One review article and one case report were about latent tuberculosis infection (LTBI). In the case report, the authors diagnosed LTBI using tuberculin skin test (30 mm of induration) and QuantiFERON TB Gold 2G (Cellestis, Melbourne, Australia) in a female patient with systemic lupus erythematosus. There were four articles on the molecular diagnosis of NTM; two case reports, one review, and one original article.

Among the 106 articles, 37 articles (34.6%) covered extra-pulmonary TB. TB meningitis was the most common form of.
extra-pulmonary TB (18 articles, 49%). Especially, five studies focused on investigating the effect of intrathecal anti-TB drug injection for the treatment of TB meningitis and four studies focused on investigating the synergistic effect of anti-TB medicines and traditional Korean medicines for the treatment of extra-pulmonary TB (Table 1). In these studies, the additional effect of traditional medicine in relieving meningitis symptoms or improving treatment outcome of pleural TB and epididymal TB were assessed.

3. Diagnosis and treatment of TB in North Korea

According to a review article, AFB smear is the mainstay for diagnosing TB and monitoring treatment response in North Korea. In one paper published in 2007, the author emphasized that AFB smear should be performed at least 3 times for the diagnosis of TB and that when the AFB smear is negative, TB could be diagnosed by imaging-based studies and expert opinion. For the treatment of TB, Directly Observed Treatment, Short-course (DOTS) was described as a basic approach and INH, RIF, EMB, PZA, and SM were mentioned as the drugs used. Category I and II TB treatment regimens were the standard treatment regimens used.

Discussion

We analyzed 106 articles dealing with TB in North Korea. This can be a starting point for evaluating the status of TB burden and research infrastructure in North Korea.

Articles on TB have been increasing since 2010. About half of these articles were published in one journal, Yebang üıhak (Preventive Medicine); this possibly implies the importance of prevention, with regard to public health-related aspects of TB in North Korea.

For the diagnosis of TB, research on new technologies—such as molecular diagnostics—has increased since 2012. Studies focusing on the molecular diagnosis of resistance have also been conducted, but no research was conducted on commercialized kits that can be used for actual patient care. In particular, studies on Gene Xpert MTB/RIF assay, which is highly recommended for the rapid diagnosis of TB and MDR-TB by WHO, have not been reported in any of the analyzed articles. This could be a result of relatively recent introduction of Gene Xpert MTB/RIF in North Korea. According to the Joint Monitoring Mission Tuberculosis Control Programme report, GeneXpert system was first set up in North Korea in the national reference laboratory in 2013 and 2016. Four more GeneXpert machines were procured for provincial level laboratories under Global Fund support. However, a shortage of cartridges is hindering the use of these machines.

The proportion of research focused on culture-based diagnosis of TB and drug resistance was also small, which could indicate that it was difficult to establish a proper culture system in North Korea. The drug susceptibility test for TB was performed in the National TB Reference laboratory in Pyongyang. An effort to build a National TB reference laboratory with facilities for diagnosing drug resistant TB in North Korea was led by the Bay Area TB Consortium, a network of experts from Stanford university, state’s TB program, and Christian Friends of Korea in 2009. However, the maintenance and actual capacity of that laboratory might currently be under-supported because of economic sanctions from the UN. This suggests the insufficiency of infrastructure and resources of a national program for the diagnosis and treatment of drug-resistant TB in North Korea.

For the treatment of TB, the Ministry of Public Health (MOPH) of North Korea adopted DOTS, the WHO-recommended approach for TB control in resource-limited setting in 1998. North Korea began procurement of TB drugs from the Global Drug Facility, a WHO-led initiative that has supplied quality assured drugs to over 90 countries from 2003. In 2010, the Global Fund to Fight AIDS, TB, and Malaria (GFATM) began a major project to strengthen TB control in North Korea, and this investment enabled the national TB program to undergo a much-needed modernization, including the introduction of new diagnostic and treatment protocols. However, a small portion of this international aid was allocated for the treatment of drug-resistant TB. The MOPH of North Korea first began diagnosing and treating MDR-TB in 2008 with support from the Eugene Bell Foundation (EBF), a US- and South Korea–based nongovernmental organization. However, this EBF program did not cover North Korea in entirety.

Based on the analysis of articles on TB from the nine North Korean journals, the procurement of first line TB drugs was estimated to be insufficient. Although category I standard regimen with daily INH/RIF/EMB/PZA administration for 2 months and daily INH/RIF administration for 4 months for new smear positive or extensive smear negative pulmonary TB and DOTS for severe forms of extra-pulmonary TB appear to be similar to the basic treatment prescription, in some studies, patients were treated with 3 drugs—INH, RIF and SM or PZA—every other day. Intermittent treatment, which is no longer recommended by WHO, is still provided in the continuation phase for drug-sensitive TB in North Korea, according to the articles. In addition, category II treatment is still in use with SM; however, this regimen is contra-indicated by WHO. In other studies, patients were treated with two anti-TB medicines combined with Korean traditional medicine for 2 or 3 months. Five articles investigated the effects of Korean traditional medicine for the treatment of TB. This may imply two things: (1) North Korea is continuing its efforts to develop new treatments for TB using Korean traditional medicines and (2) the lack of reliable supply of anti-TB drugs has led to exploration of traditional options.

With regard to the prevalence of drug resistance, consider-
TB-related issues in North Korean literature

Conflicts of Interest
No potential conflict of interest relevant to this article was reported.

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