ORIGINAL ARTICLE

A Retrospective Comparison of Treatment Response between Short Course (6 months) and Extended Course (9 to 12 months) among Filipino Women with Genital Tract Tuberculosis who underwent Medical Management in a Tertiary Government Hospital from January 2015 to March 2020

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ABSTRACT

Background and Objective. Tuberculosis (TB) remains to be prevalent in the Philippines and globally. Female genital tuberculosis has devastating and permanent consequences, hence, timely and adequate treatment is needed. Since more data regarding optimal duration of treatment of genital tuberculosis are needed, this study compares the treatment response at six months and after at least nine months of treatment, with the intention of determining the most practical management for genital tuberculosis.

Methods. A retrospective chart review was conducted for newly diagnosed cases of genital tuberculosis who met the inclusion criteria. Treatment response was categorized into clinical, microbiologic, histologic, radiologic, and sonographic responses. Responses to treatment were evaluated as either partial or complete at the 6th month and after at least 9 months of treatment, and the proportions were compared.

Results. Out of 140 charts retrieved, only 43 were included. Statistically significant difference was found only in clinical response, primarily due to patients who did not achieve resumption of menstruation within the first six months of treatment. The rest of the treatment responses and adverse drug events are equally the same for both time periods.

Conclusion. Results of this study show that the proportion of patients with microbiologic, histologic, radiologic, and sonographic response to treatment at the 6th month did not significantly differ to the proportion of patients who responded at the 9th or 12th month of treatment. This leads to a conclusion that the 6-month treatment regimen will be more practical in treating genital tuberculosis, except in amenorrheic premenopausal women who may warrant extension of treatment. Further studies on post-treatment rates of relapse and sonographic resolution are needed.

Keywords: abdominopelvic Koch's infection, female genital tuberculosis, pelvic tuberculosis, tuberculosis treatment, Philippines

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INTRODUCTION

Tuberculosis (TB) remains to be a major public health concern in the Philippines. According to the most recent Department of Health (DOH) statistics, there were a total of 444,037 notified cases of tuberculosis in the country as of 2022, giving it an incidence of 554 per 100,000 and a mortality rate of 24 per 100,000.[1] According to the World Health Organization (WHO), tuberculosis is the world's top infectious killer, with 1.25 million people dying from TB in 2023 alone. Despite being a preventable and curable disease, global estimates report approximately 10.8 million people affected by the disease in 2023.[2]

Tuberculosis is an infection caused by the organism *Mycobacterium tuberculosis*, which mostly involves the lungs. Incomplete eradication of the bacilli can result to reactivation or spread to other parts of the body through hematogenous, lymphatic or direct extension to adjacent organs. In cases of genital tuberculosis, infection derived from contact with infected semen have also been reported.[3]

Due to paucibacillary nature of female genital tuberculosis (FGTB), microbiological diagnosis of *M. tuberculosis* is usually difficult.[4] Diagnosis through bacteriologic or histologic confirmation is ideal but this is not always possible, thus, clinical diagnosis is acceptable.[5] However, clinical presentations vary as symptomatology largely depends on the affected site. Hence, a high index of suspicion is needed to make an accurate diagnosis.[6]

Abdominopelvic tuberculosis (AP TB) affects the gut, peritoneum, and solid organs of both the abdomen (liver, pancreas, spleen) and pelvis (uterus, ovaries and bladder). Affected individuals usually present with enlarging abdomen with or without abdominal pain, and constitutional symptoms such as fever and weight loss.[6] Pelvic tuberculosis, on the other hand, is more difficult to diagnose clinically as it may exist only as tuberculous adenitis of the mesenteric or pelvic lymph nodes without affecting the genital tract. In such cases, the patients may be asymptomatic.[3]

The true incidence of genital tuberculosis remains unknown since most affected individuals do not present with any clinical manifestations, and tissues for definitive diagnosis may be difficult to access.[3,7] Since the sequelae may become permanent with insufficient treatment, timely and adequate intervention is of paramount importance in the management of genital tract tuberculosis.

Historically, anti-tubercular therapy took 12 to 18 months before completion. Both local and international guidelines advocate a short course (6-month treatment) for cases of extra-pulmonary tuberculosis, excluding central nervous system (CNS) and bone tuberculosis. Local guidelines currently recommend treatment of abdominal and genitourinary tuberculosis with a regimen consisting of two months of Isoniazid, Rifampicin, Pyrazinamide and Ethambutol (HRZE) followed by four months of maintenance with Isoniazid and Rifampicin (HR).[5]

Several studies have shown that a 6-month course of anti-tuberculosis therapy has the same efficacy as a 9-month course. A randomized controlled trial done by Sharma et al. showed no significant difference in the clinical response rate of women with female genital tuberculosis treated for six months and nine months.[8] A review by Jullien et al. supported the adequacy of a 6-month anti-tuberculosis therapy for intestinal and peritoneal tuberculosis when compared to a 9-month therapy.[6]

However, there is still reluctance among physicians, especially in low and middle-income countries, regarding the adequacy of a 6-month regimen because of tolerance of the tubercle bacilli to some drugs. In addition, the recommendations for the duration of treatment for extrapulmonary tuberculosis (EPTB) are not based on studies as robust as those for pulmonary tuberculosis (PTB).[7] There is very limited literature available regarding randomized clinical trials which have investigated the optimal drugs and the duration of treatment for genital TB.[9] Studies have also shown that some risk factors may require longer treatment duration.[10,11] Hence, a standardized treatment approach may result to undertreatment of some patients and increased risk of relapse.[7]

In our division, abdominopelvic tuberculosis cases have consistently been one of the most common referrals. The division uses a 12-month treatment regimen (2HRZE/10HR) due to doubts on the sufficiency of the short course treatment in achieving complete resolution and preventing relapse of the disease. However, this reluctance is based only on previous clinical experience and more research supporting this 12-month treatment course are still needed.

Adverse drug reactions (ADR) are any appreciably harmful or unpleasant reaction resulting from an intervention related to the use of a medicinal product.[12] Commonly reported ADRs associated with anti-tuberculosis medications include hepatotoxicity (presenting as jaundice and/or more than 2x elevated liver transaminases), gastrointestinal symptoms (anorexia, loss of appetite, nausea, vomiting, abdominal pain), and cutaneous reactions (generalized or localized erythematous rashes, petechial rashes).[6] Although anti-tuberculosis drugs are known to be relatively safe, there is still the risk of developing side effects when used over a long period of time. Even though a longer duration of therapy may ensure more adequate treatment, it can also predispose to problems with toxicity, cost, and compliance. A study done by Lee showed that incomplete adherence to therapy might increase the two-year recurrence rate.[13]

Significance of the Study

Despite the heavy burden globally and locally, the efficacy of the currently recommended treatment courses for extra-pulmonary tuberculosis remain debatable, especially in the local setting. Due to the lack of robust data on the effectiveness of the short-course regimen on cases of extrapulmonary TB,

as well as very few proper randomized controlled trials on treatment of female genital tuberculosis for six months or longer treatment, the duration of treatment for female genital TB remains controversial.[14]

In the Philippines, majority of patients with tuberculosis belong to the lower socioeconomic bracket. It is therefore essential to establish a cost-effective treatment for an important health threat. This study compares the treatment response at six months and after at least nine months of treatment, with the intention of determining the most practical management for pelvic tuberculosis.

OBJECTIVES

The general objective of this study is to compare the treatment response of patients with female genital tuberculosis at the 6th month and at the end (9th to 12th month) of treatment.

The specific objectives are to determine and compare the proportion of patients who were successfully treated—in terms of clinical, microbiologic, histologic, radiologic, and sonographic improvement—at the 6th month and at the end of treatment (9th or 12th month), as well as to determine and compare the proportions of patients who had adverse drug reactions at the 6th month and at the end of treatment.

MATERIALS AND METHODS

A retrospective chart review was conducted for all newly diagnosed cases of pelvic tuberculosis referred to the division from January 2015 to June 2019. All cases who met the following criteria were included: (i) Filipino women aged 18 years and above, (ii) newly diagnosed case of pelvic, abdominopelvic, or disseminated tuberculosis (with involvement of the genital tract) with no previous treatment for TB, and (iii) able to complete at least nine months of TB treatment by March 2020, with good compliance. Excluded from the study were: pregnant patients, immunocompromised patients, retreatment cases, those with multi-drug resistant tuberculosis (MDRTB) or given a different treatment regimen, patients with bone/joint/CNS tuberculosis, those with incomplete chart or diagnostics, and patients who were unable to comply and finish at least nine months of treatment. The study protocol was approved by the hospital's Research Ethics Board.

Basic demographic data and physical examination findings (weight, abdominal girth, rashes, jaundice, ascites) documented in the charts were obtained. The specific signs and symptoms associated with tuberculosis that were noted are: fever, anorexia, weight loss, cough, nausea, vomiting, abdominal enlargement, abdominal pain, and amenorrhea.

Diagnostics included were microscopy for Acid-Fast Bacilli (AFB) of sputum, urine, stool, and menstrual samples, endometrial biopsy, chest radiograph, transvaginal sonography, and liver function tests. Only those with available results were recorded. All patients were given the same treatment regimen consisting of two months intensive phase (HRZE) and seven to 10 months maintenance phase (HR). Clinical and laboratory data were obtained at diagnosis, at the 6th month of treatment, and at the end of treatment.

Outcome Measures

Data obtained at six months and at 9-12 months were interpreted and compared. Response to treatment were categorized into clinical, microbiologic, histologic, radiologic, and sonologic. At the 6th month and at end of treatment, treatment responses were evaluated. Complete response was defined as absence of any abnormal clinical and laboratory findings compared to baseline. Partial response was defined as clinical and laboratory improvement from baseline but without achievement of a complete response. Absent or incomplete diagnostics which preclude interpretation of response were classified as indeterminate.

Statistical tools used for data analysis were proportion and test on the difference of population proportion. Means, standard deviation and chi square tests were not applicable.

RESULTS

A total of 140 charts of new referrals were retrieved. Out of these, 81 did not meet the inclusion criteria and an additional 16 were excluded. Only 43 charts were included for evaluation at the 6th month and end of treatment (Figure1).

Of the 43 evaluated cases, majority (69.7%) were cases of disseminated tuberculosis with involvement of the genital tract, while 10 (23.3%) were abdominopelvic Koch's and three (7%) were isolated genital tuberculosis. All 43 were

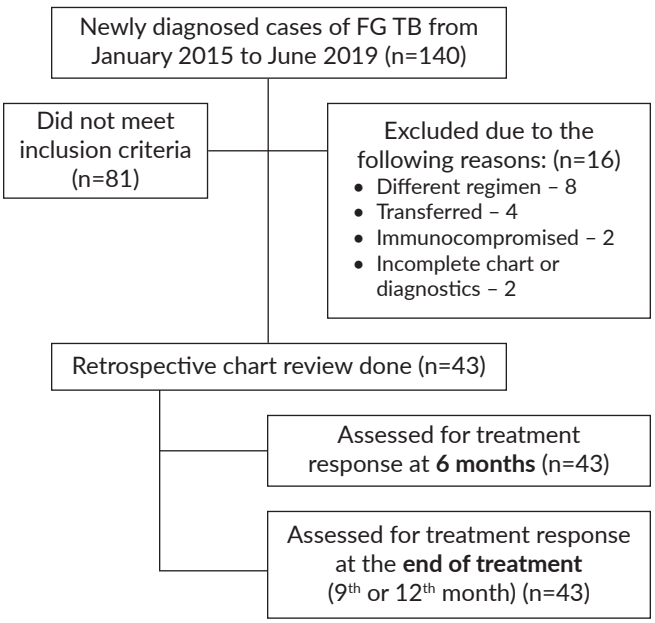

Figure 1. Diagrammatic presentation of how the study was conducted.

given two months of intensive phase (HRZE) and at least seven months of maintenance phase (HR).

For those whose response to treatment can be evaluated, Table 1 shows the proportion of patients who were successfully treated at the 6th month interval and at the end of treatment. The only statistically significant difference exists in the clinical treatment response.

At the 6th month interval, all categories except for sonographic response had higher proportions of complete resolution compared to partial response. In the microbiologic response category, all cases where response to treatment can be evaluated had normal/complete resolution by the 6th month of treatment. At the end of extended treatment, all cases had complete microbiologic and histologic resolution. However, there is note of decrease in the proportion of those who responded in terms of radiologic findings. This is due to cases who developed abnormal chest Xray results, not necessarily implicative of worsening or progressive disease.

Figure 2 is a graphical representation of the comparison of treatment responses at the 6th month interval and at the end of treatment. The greatest overall response can be seen in the clinical and microbiological responses.

Table 2 shows the comparison in the incidence of adverse drug reactions. The proportion of patients with adverse drug reactions after six months of treatment and at the end of treatment are statistically the same since the p-value of the difference in proportion is greater than 0.05 (p value 0.16452).

Table 1. Treatment Response (in Proportions) at the 6th Month and at the End (9th or 12th Month) of Treatment

	6th month	9th or 12th month	*p*-value	Interpretation
Clinical response				
Partial improvement	0.4651	0.1395	0.001	Significant
Normal/complete	0.5349	0.8605	0.001	Significant
Microbiologic response				
Normal/complete	0.6744	0.7442	0.4777	Not Significant
Histologic response				
Partial improvement	0.0233	0.0000	0.3125	Not Significant
Normal/complete	0.2093	0.2326	0.79486	Not Significant
Radiologic response				
Partial improvement	0.2093	0.2791	0.45326	Not Significant
Normal/complete	0.2791	0.1860	0.23014	Not Significant
Sonological response				
Partial improvement	0.3256	0.3488	0.8181	Not Significant
Normal/complete	0.3023	0.4884	0.0784	Not Significant

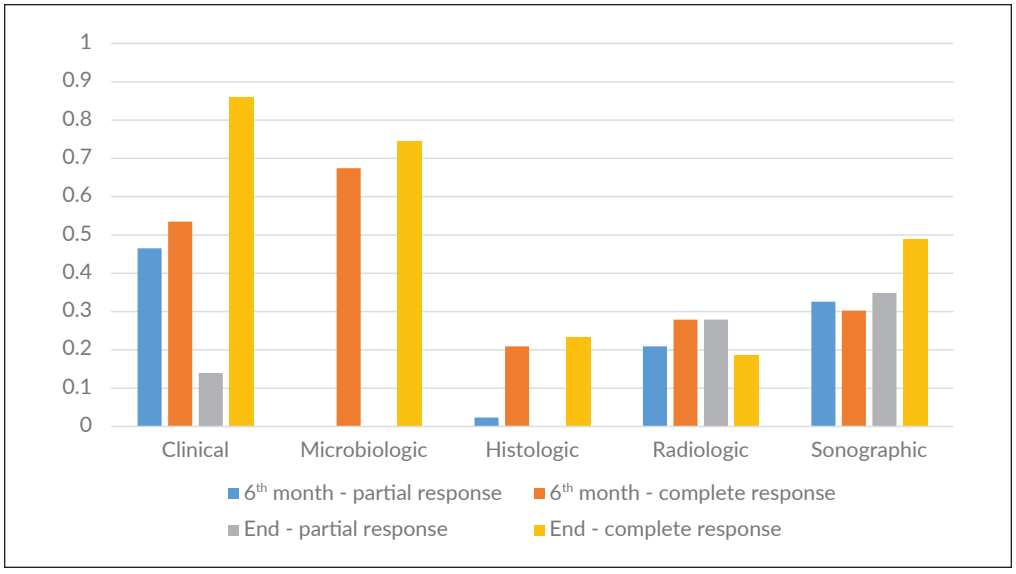

Figure 2. Treatment response (in proportions) at the 6th month and end of treatment.

Table 2. Comparison of Adverse Drug Reactions after Six Months and at the End of Treatment

Proportion	6th month	12th month	*p*-value	Interpretation
ADE	0.093	0.023	0.16452	Not Significant

DISCUSSION

Despite advances in immunization and national advocacies, the Philippines has remained to be one of the countries still with the highest burden of tuberculosis. National statistics states that the incidence of tuberculosis in 2019 is 554 per 100,000, with treatment coverage only at 63%.[1] In spite of the high incidence of TB in the country, female genital tract tuberculosis remains underreported, owing mostly to its subtle symptomatology. A study done by Melkamu et al. estimates the prevalence of FGTB to be at 0.32% to 1.8%.[15] Genital TB alone is reported to account for 9% of all extrapulmonary tuberculosis cases.[9] The local incidence of female genital tuberculosis is difficult to determine because of the following reasons: (1) involvement of the female genital tract is uncommon, (2) difficulty in obtaining bacteriologic or histologic diagnosis, and (3) its subtle symptomatology warrants a high index of suspicion.[3] However, because the consequences of untreated genital tract tuberculosis could be devastating and permanent, timely and adequate treatment is necessary.

Genital tuberculosis is often associated with involvement of other organs. As mentioned in the results, only 7% were isolated cases of genital tuberculosis while majority were associated with disseminated TB. Because of this, the clinical presentation of patients was mostly nonspecific, such as weight loss, abdominal enlargement, and abdominal pain, while only a minority presented with abnormal vaginal discharge and amenorrhea.

An estimate of 10-75% of patients with genital TB may have abnormal findings on chest radiograph. However, a negative chest x-ray does not rule out the possibility of extrapulmonary TB.[9] The gold standards for diagnosis of genital tuberculosis are: (1) detection of acid-fast bacilli on microscopy or culture on endometrial sampling, or (2) demonstration of epithelioid granuloma on endometrial or peritoneal biopsy.[8] However, access to these tissues may not be readily available and given the paucibacillary nature of the disease, there may be a low rate of positivity.

Since endpoints to monitor treatment response in EPTB are not easy if access to tissue repeatedly cannot be done, clinical evaluation remains an important tool in monitoring treatment response.[7] In our study, the last symptom to resolve was amenorrhea, and this accounted for the statistical difference in the clinical response category. The rest of the initial symptoms had apparent improvement with treatment at the 6th month. However, in a few cases, it took as long as 12 months before the amenorrhea was resolved.

Histologic response consistently had the smallest proportion of response to treatment. However, this does not imply inadequacy of treatment, as demonstrated by complete histologic resolution of all cases where treatment response can be evaluated. The lack of a repeat biopsy and the difficulty in obtaining biopsy specimens are the foremost reasons explaining the small proportion of those with treatment response.

A study on histopathologic patterns of FGTB showed that endometrium is the most commonly affected part of the female genital tract, and this correlates with symptoms of menstrual disturbances. However, that study also noted that the staging of the granulomas found in the endometrium did not necessarily correlate with severity of symptoms.[15]

The high microbiologic response seen at the 6th month of treatment may be indicative of the effectiveness of the treatment. However, it may be observed that the rate of microbiologic resolution does not necessarily correspond to the rate of radiographic and sonographic resolutions.

The small proportion of patients with radiologic resolution may be attributed to persistence of and, in some cases, delay in the development of radiologic findings for this condition. There were two cases which had normal baseline chest radiographs but subsequently showed findings of pulmonary tuberculosis after the 6th month of treatment despite negative sputum microscopy results. These findings may be indicative of pulmonary fibrosis and not necessarily of disease activity. Note also that these radiologic findings pertain to chest radiographs and do not demonstrate treatment response of the pelvic organs. However, radiologic response was included in the study as part of the overall response to anti-tuberculosis treatment.

Ultrasonography (USG) is often the gynecologist's imaging of choice when diagnosing pelvic tuberculosis as it allows simultaneous evaluation for ovarian, uterine and extrapelvic involvement.[9] On USG, the tubes may appear thickened and dilated with the presence of clear fluid (hydrosalpinx) or fluid with thick echoes and echogenic debris (pyosalpinx). In later stages, adhesions may occur between ovaries and adjacent pelvic organs resulting in an adnexal mass.[9] A tubo-ovarian complex is formed when the ovary merges with the fallopian tube but can be still distinguished separately. A tubo-ovarian abscess forms when there is no longer a distinction between tube and ovary.[16]

According to the data collected, common sonographic findings pertaining to genital tract tuberculosis were adnexal masses (probably tuberculous salpingitis) and moth-eaten endometrium. For abdominopelvic Koch's infection, other common sonographic findings include palisading bowel loops, thickening of the peritoneum, bowel serosa and uterine serosa, pelvic adhesions, and pseudocyst formation. For this study, only the adnexal masses and endometrium were used in

evaluating the response to treatment since the other findings (such as serosal thickening and pseudocyst formation) may be considered chronic findings or sequelae that do not indicate disease activity.

There is note of marked delay in the resolution of the above-mentioned sonographic findings as exhibited by the relatively small proportion of patients with complete resolution in the sonographic response category. One patient took an additional year after completion of 12 months of treatment before complete resolution of sonographic findings. This finding is consistent with previous studies showing that even after anti-tuberculosis treatment, finding associated with advanced disease—major adhesions, frozen pelvis, and blocked tubes—persisted and may result to poor prognosis for fertility.[4,9] A study by Bahadur et al. noted that on repeat hysteroscopy after treatment, only low-grade adhesions had significant improvement, but major adhesions persisted.[17]

A retrospective study done locally reviewed the clinicodemographic profile and outcome of genitourinary tuberculosis cases treated. Their results showed that it took an average of six months before sonographic improvement was noted.[18]

The results of this study showed that extending the treatment to nine months does not result to a significant increase in the proportion of patients who respond to treatment. This may imply that a 6-month treatment regimen has the same effect as the extended (9 to 12 months) treatment regimen in terms of microbiologic, histologic, radiologic, and sonographic responses.

However, published literature also indicates that for TB patients with different clinical presentations and risk factors, a different treatment duration may be needed.[7] A study done by Qin, Barry and Pascopella recommended that a longer treatment duration should still be considered in patients with positive sputum culture at two months and with cavities in chest radiograph.[11]

CONCLUSION

Our results showed that the proportion of patients who responded to treatment are similar at the 6th month of treatment and at the end of treatment (9th to 12th month), and that there is no significant difference in the incidence of adverse drug events between the two treatment intervals. However, in cases of premenopausal women with persistent amenorrhea, the treatment may be extended until 12 months or until with resumption of menstruation. Further studies are also needed to determine the rate of resolution of sonographic findings post-treatment, as well as the rate of recurrence post-treatment.

Limitations and Recommendations

If further studies are to be undertaken, the following are recommended: (1) choosing a prospective study design, (2) improvement of documentation, (3) having complete or uniform baseline diagnostics for better interpretation of results, (4) larger population size, and (5) further studies on post-treatment relapse rates and rate of resolution of sonographic findings.

Response to treatment in some of the cases were not evaluated due to lack of or incomplete baseline diagnostics. Ensuring that baseline diagnostics are uniform and complete could improve assessment of response to treatment. Better documentation, in terms of legibility of handwriting or completeness of important details such as sizes of the adnexal masses, will also allow better evaluation and increase the proportion of patients with treatment response.

One of the division's reasons for extending the treatment is the high rate of relapse, based on clinical experience. However, since most of the patients were discharged from the clinic after completion of post-treatment work-up, this study was unable to address the issue of relapse. It would be worthwhile if further studies would tackle this. Lastly, studies on post-treatment resolution of abnormal sonographic findings are also needed to ensure that the persistence of adnexal masses does not mean inadequate treatment.

Statement of Authorship

Both authors certified fulfillment of ICMJE authorship criteria.

Author Disclosure

Both authors declared no conflicts of interest.

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