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IMPLEMENTATION OF ITRACONAZOLE TO REDUCE REOCCURRENCE OF TINEA CORPORIS IN A CORRECTIONAL FACILITY

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Implementation of Itraconazole to Reduce Reoccurrence of Tinea Corporis in a

Correctional Facility

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Abstract

Tinea corporis is a superficial fungal infection that involves a circular pruritic rash on different parts of the body. Many individuals recognize this type of fungal infection as "ringworm." Tinea corporis thrives in areas of the body that experience humidity and friction and can be spread from person to person. Vulnerable populations such as those in detention centers are more susceptible due to the environment and close quarters. During 10 days of reflective practice, more than half of the patients cared for developed reoccurring tinea corporis after treatment with fluconazole. After conducting a literature review, a variety of medications were identified for the treatment of tinea corporis, including fluconazole, terbinafine, and itraconazole. The medication regimens analyzed, revealed that itraconazole was the best for reducing the reoccurrence of tinea corporis. According to the literature, 100 mg of itraconazole should be given once daily for two weeks, which was not reflective of local practice. As a quality improvement project, the use of 100 mg of itraconazole by mouth for two weeks was implemented, and follow-up was performed at four weeks by assessing the elimination of tinea corporis according to the absence of itching, erythema, hypopigmentation, and breakdown of the skin. Individual skin sites were documented upon assessment of infection, and if consent was given, photographs were obtained and compared. The modification of treatment was successful. After treatment, the patient sites appeared clear with no circular pruritic rash. The project was found to reduce the cost of medication required for retreatment as well as the reoccurrence of tinea corporis among patients in the facility.

Keywords: tinea corporis, fungal infections, jail, skin, antifungal, medication, detainees, prison, Dermatophytes

Implementation of Itraconazole to Reduce Reoccurrence of Tinea Corporis in a Correctional Facility

Tinea corporis is a fungal infection that can occur throughout the body. Also known as ringworm, the diagnosis of tinea corporis is based on skin assessment, which includes evaluation of the site, size, and symptoms, such as pruritis. Tinea corporis is treated with either topical or oral medication regimens depending on the severity. If it reoccurs, current evidence-based practice suggests using oral medications. Tinea corporis and tinea cruris are usually treated with a topical antifungal agent unless the infection is unresponsive, involves an extensive area, is chronic, or is difficult to access. In these cases, oral antifungals are frequently used (Sanmano et al., 2003).

A quality improvement project was conducted for the treatment of tinea corporis. Before the project, fluconazole was used at 150 mg by mouth for three days. After 10 days of reflective practice and review, tinea corporis was found to reoccur with this regimen, which was not supported in the literature. In an effort to eliminate reoccurrence, the treatment was modified by implementing a new prescription regimen that has supporting evidence for reducing reoccurrence of tinea corporis infections.

A search of the literature revealed that the use of itraconazole at 100 mg by mouth once a day for 14 days is recommended to prevent reoccurrence of tinea corporis. Itraconazole is an orally active triazole-antifungal agent that has been demonstrated to be safe and effective in the treatment of dermatophyte infections. Dermatophyte infections have been reported to respond well to short courses of itraconazole because of the drug's high affinity for the skin. Pharmacokinetic studies have demonstrated persistence of the drug in the stratum corneum for 2 to 4 weeks after discontinuation of treatment (Pariser et al., 1994). The goal of the quality improvement project was to convert evidence-based literature into clinical practice by implementing a new prescription regimen that has supporting evidence in reducing reoccurrence of tinea corporis infections. The resulting implementation would be cost effective in the long term and reduce reoccurrence. It could also provide a cleaner environment for patients living in close quarters.

Clinical Practice Problem

Reoccurrence of tinea corporis was identified as one of the main three predicaments during 10 days of comprehensive reflective practice. After providing care for symptomatic patients with tinea corporis, more than half of the patients required secondary treatment for reoccurrence of tinea corporis after using 150 mg of fluconazole for three days by mouth. The increased incidence of reoccurrence of tinea corporis raised concern due to returning visits for secondary treatment for reoccurrence symptomatic tinea corporis and high use of medication, medication cost, and prolonged treatment. Thus, a quality improvement project was performed for this population.

The study population was comprised of incarcerated symptomatic patients between the ages of 19 and 57 years with tinea corporis, and the intervention was the implementation of itraconazole at 100 mg *per os* (P.O.) daily for 2 weeks. The intervention was compared with fluconazole by mouth at 150 mg for 3 days or topical miconazole on the affected area for 7 days. The studied outcome was the elimination of tinea corporis infections and their reoccurrence. The study was carried out over 4 weeks.

Literature Review

Various databases were searched, including PubMed, Cochrane, Indiana Journal of Dermatology, EBSCO, MEDLINE, and UpToDate. A search of the literature was organized and revealed a variety of medication regimens that minimize the reoccurrence of tinea corporis. Medication regimens include fluconazole, terbinafine, and itraconazole. Specifically, the benefits of itraconazole have been compared to other regimens, and it has been proven to be most beneficial. Although side effects have been identified, these adverse effects are likely to be seen in patients on long-term treatment with fluconazole for the treatment of other diseases. Providers should be vigilant in monitoring for these adverse effects and consider dose adjustments or therapeutic alternatives where appropriate (Davis et al., 2019).

Itraconazole is ideal for the treatment of cutaneous mycosis and has produced a consistently high cure rate. Current treatment regimens, especially pulse therapy, produce fewer side-effects and greater patient compliance (Sanmano et al., 2003). Itraconazole is superior to fluconazole, griseofulvin, and terbinafine, and fluconazole is superior to griseofulvin. The results were calculated in comparison to griseofulvin based on cure rates. Thus, itraconazole was the most effective treatment out of the four treatments tested in the study, followed by fluconazole (daily), terbinafine, and griseofulvin in the context of an altered dermatophytosis epidemic in India (Singh et al., 2020).

Project Design

There are several quality improvement processes for organizations that cover a wide range of activities. As organizations have unique structures, histories, and challenges that influence the change process, they need to consider these intra- and inter-organizational factors when making decisions regarding what kind of quality improvement process will work best (Powell et al., 2008). In the workplace environment examined, quality improvement is aided by management and a health services administrator. During the course of a month, the health services administrator reviews quality measures, evaluates measures for continuous improvement, and emphasizes leadership involvement in quality improvement projects. To obtain approval to conduct the quality improvement project, supporting evidence was presented with a literature review along with the findings of 10 days of reflective practice.

For the quality improvement project, the supervisor and nursing staff were provided with an overview of the 10-day reflective practice problem, and the problem in practice was identified. An overview was provided in regard to the quality improvement project, current practice, and literature review with implementation of the itraconazole treatment regimen for reoccurring tinea corporis. The health services administrator was hesitant in the beginning and wanted more education and literature. Once provided, it was further reviewed, another quality improvement proposal was presented, and it was approved.

After approval, a letter of support was obtained from the health service administrator and the management of the facility. Once this was obtained, the project proposal could be completed and presented to the institutional review board at the University of Texas at El Paso. Approval was obtained, but it was determined that the project was not based on research. Approval from an institutional review board or research ethics committee is intended to protect the rights of human subjects. Assurance that ethical standards are met is essential for educational research and quality improvement projects involving human subjects (Oermann et al., 2021). A notification email was received from the University of Texas that the Institutional Review Board determined that the project was not research, and a work letter permitting the quality improvement project to go forth at the worksite was obtained. The worksite is a privately-owned for-profit facility. The clinical site has one physician who works remotely and two nurse practitioners in house. Among the current practicing staff, fluconazole is used by the nurse practitioner. The project was discussed in person with staff and the nurse practitioner to communicate updates and progress. Literature reviews were provided, and medication regimens were discussed with the other nurse practitioner. She was very supportive and willing to participate. Once the project was completed, evidence was presented based on patient outcomes from follow-up at four weeks by assessing for elimination of tinea corporis, which was evidenced by an absence of itching, erythema, hypopigmentation, and breakdown of the skin.

Support was obtained from all staff and one provider. The project was well received because adoption of the proposed implementation would help a population that is vulnerable to infections such as tinea corporis, as well as significantly reduce its incidence, and prevent reoccurrence. Furthermore, it would reduce the cost of medication required for retreatment.

Transitional Framework

A transitional framework was implemented for the quality improvement project based on Lewin's change model. His theoretical framework model is straightforward for the process of change. "Unfreezing change" allows flexibility that is necessary as a learner gains knowledge and equips the team or individual for the upcoming changes as the problem is identified (Burnes, 2020). During the "moving" stage, change arises from research for the intended purpose, and the forces for change are greater than the individuals that resist change (Burnes, 2020). The final stage, the "freezing" process, reinforces the change by stabilizing the change that was implemented to find equilibrium and decrease the risk of regression (Burnes, 2020). The first step in this process in the project application was education and improving understanding among providers and staff of the apparent practice issue and evidence-based practice. The second step was then alteration, innovation, and explanation of outcomes of change while remaining open so as to reduce refutation on the new implementation. The framework was carried out by disseminating evidence supporting the replacement of the medication regimen of 150 mg of fluconazole by mouth for three days with 100 mg of itraconazole by mouth for two weeks, as well as training the providers on the regimen's use, contraindications, and benefits.

The third and final step in this framework was "refreezing," which is integrating and stabilizing a new equilibrium into the system so that it becomes habit and resists further change (Wojciechowski et al., 2016). During the project, the use of itraconazole was implemented and had a favorable outcome. The collaborating physician and practitioner participated in the implementation. However, the nurse practitioner colleague left the facility, and a new provider was not open to adaptation of the implementation. As a result, "unfreezing" was needed to help in the adaptation of the implementation of itraconazole. The medication regimen continues to be used on suitable patient populations, and the importance of evidence-based practice to improve patient outcomes is continually being stress. Having great success requires teamwork and joint effort from all participating staff to improve the quality of care.

Quality Improvement Model

The quality improvement model selected for this project was the Plan, Do, Study, and Act (PDSA) model. The first step of the PDSA cycle is citing a plan or hypothesis for improvement (Taylor et al., 2014). The second step involves executing or carrying out the plan. The third step is analysis or data interpretation. In the last step, a decision is made to either make changes, adopt the new practice, or abandon the hypothesis (Taylor et al., 2014). During the "Plan" phase, patients who met criteria for the project were targeted and identified through assessment. The "Do" phase involved application of implementation of the medication regimen. The "Study" phase included monitoring and analyzing the progress of the patient, the process and change of site improvement, and symptoms. Finally, the "Act" phase involved implementing the use of itraconazole, adapting to change, and repeating the cycle based on patient outcomes.

The effectiveness of the medication regimen was measured by review after two weeks and at a follow-up at four weeks by assessing for elimination of tinea corporis. The assessment was based on the absence of itching, erythema, hypopigmentation, and breakdown of the skin. Individual skin sites were documented upon assessment of infection, and if consent was given, photographs were obtained and compared at four weeks. Data from the 10-day reflective practice were compared to data obtained during the project time frame on the incidence of tinea corporis. Patient records were reviewed, and the results of treatment and effectiveness of the medication regimen were analyzed.

Population

The population was incarcerated, symptomatic, male or female patients aged 19-57 years with tinea corporis who were previously treated with fluconazole at 150 mg by mouth for 3 days or topical miconazole on affected area for 7 days. Given the environment of the practice, all of the patients were incarcerated in either the general population or isolation depending on the extent of the criminal charges.

Inclusion

Patients were included if they had previously been diagnosed with tinea corporis with previous treatment of fluconazole at 150 mg for three days or miconazole topical twice daily on

affected area for seven days. Patients also had to have recent lab results and liver enzymes within normal limits, no history of heart disease, no decreased kidney function, and no current pregnancy.

Exclusion

Patients were excluded if they did not fit the proper criteria for administration of itraconazole (those with liver function test levels out of normal limits, AST >40 units per liter, or ALT >56 units per liter). Patients were also excluded if they had a history of liver dysfunction, decreased kidney function, history of heart disease, or pregnancy. The risk of developing antifungal-associated hepatotoxicity is multifactorial and is influenced by pre-existing liver disease, chemical properties of the drug, patient demographics, comorbidities, drug-drug interactions, environmental, and genetic factors. Antifungal-related liver injury typically manifests as elevations in serum aminotransferase levels (Frank et al., 2016).

Methods

Data from the 10-day reflective practice were compared to information obtained after changing the treatment regimen. During the 10-day reflective practice, eight patients who had previously been treated with fluconazole experienced reoccurrence of tinea corporis. Eight patients were treated, and all had the previous treatment regimen, normal liver function tests, and no contraindications for Itraconazole use. Inspection of the site and its location, size, and symptoms of pruritis were documented. If consent was given, a photograph of the site was obtained immediately and again at the two-week follow-up. All patients were given identical instructions for local hygienic care and advised to clean with soap when bathing, avoid the use of any other topical agents, and always keep the infected areas dry and clean. Patients returned to the clinic every week following treatment, and treatment efficacy was evaluated 2 weeks after treatment initiation (Sanmano et al., 2003). The nursing staff was informed about the specifics for correct assessment of site documentation and consent forms. Self-reporting of pruritis was used for patient assessment. A study conducted by Sanmano et al. (2003) included patients diagnosed with tinea corporis from January 1997 to December1999. The evaluation process used in the present study was modeled after that used by Sanmano et al., who evaluated patients two weeks after treatment based on signs, symptoms, and scrapings. Due to limited resources, scrapings were not obtained in the present study, but signs and symptoms were evaluated in terms of severity of redness, erythema, and scaling.

Patients were instructed to visit the clinic, and at each visit, the clinical morphology of the infected skin was assessed, and clinical photography and fungal examinations were performed. Clinical assessment of lesions was evaluated according to signs (severity of redness, erythema, and scaling) and symptoms (pruritus, burning, and stinging). With consideration of the patient population, this method of documentation for re-evaluation was used. The nursing staff was able to assist with documentation of the completion of patients' two-week follow-up visits in the clinic. However, two of the eight patients could not be assessed upon the two-week follow-up because they were released from incarceration, and there was no way of following up with them as one was sent to another state, while the other was sent to another county.

Medication Costs

In the United States, the average cost of a single 150-mg dose of fluconazole is approximately \$12.00 (Vensel, 2002). According to GoodRX (2022), the price of itraconazole is \$8.41 per dose. Itraconazole has shown higher mycological and clinical cure rates. Patients who were prescribed terbinafine have indicated that there is growing resistance to the drug and increased chances of failure of treatment of dermatophyte infections, and failure of therapy also adds to the financial burden on patients (Bhati et al., 2019). According to Martin (1999), approximately 70% of fluconazole-resistant isolates (MIC ≥ 25 mg/L) remain susceptible to itraconazole in vitro, although data are limited, and itraconazole can be effective in treating patients who are non-responsive to fluconazole treatment.

In anticipation of the quality improvement project, the cost and availability of itraconazole were discussed with the health service administrator. The cost of 14 pills of itraconazole was \$117 dollars. Another element to consider for the project was the cost effectiveness. On average, patients had previously received three 150-mg doses of fluconazole on three separate occasions, which totaled to \$144 dollars per patient with reoccurrence. All 8 patients were treated with fluconazole for an average of four times prior to use of itraconazole, which means the total cost of fluconazole was \$144 for each patient. Thus, for all 8 patients, the cost of fluconazole was \$1152, and they were still having reoccurrence. With the use of itraconazole, the cost for all 8 patients would be \$942, which demonstrates the cost effectiveness of itraconazole.

Challenges

The effectiveness of the continuation of the same treatment regimen for an extended duration in the partially cured group was not assessed due to patients leaving of the detention facility without a way of contacting them for follow-up.

Findings and Outcomes

The findings of the quality improvement project were similar to the anticipated outcomes. No patient had signs of reoccurrence of tinea corporis, and all symptoms subsided at two weeks without returning at the four-week follow-up assessment. By using itraconazole, overall patient outcomes were improved. However, 1 of the 2 practicing nurse practitioners did not embrace this medication regimen in their practice. The patients showed a decrease in reoccurrence of tinea corporis within the two-week window of the medication adherence. This outcome should decrease the overall cost for the facility by reducing the repeated administration of medication for reoccurrence and repeated visits.

Figure 1

(Left) Tinea corporis after fluconazole treatment with reoccurrence. (Right) Tinea corporis after itraconazole treatment at 2-week follow-up.



Conclusion

In conclusion, the use of itraconazole is superior to fluconazole at 150 mg by mouth for 3 days. According to previous studies, itraconazole is superior to fluconazole, griseofulvin and

terbinafine, and fluconazole was superior to griseofulvin (Singh et al., 2020). Furthermore, itraconazole is more cost-effective than fluconazole. This may encourage other providers to question the medication regimens used in their current practice for tinea corporis and modify them to improve patient care for vulnerable populations.

Implications for Practice

Current evidence-based practice indicates that the use of 100 mg of itraconazole by mouth daily for 14 days is superior to 150 mg of fluconazole by mouth for reducing the reoccurrence of tinea corporis. However, challenges were faced in the implementation of the new treatment regimen. For instance, the patients were either placed in a general prisoner population or in isolation. The placement of the patient could impact medication adherence, cleanliness, and limited sharing of items. For this specific quality improvement project, overall patient-care outcomes were assessed among incarcerated individuals from both isolated and general populations. Another consideration is having access to patients after release from facilities and follow-up care thereafter. The data obtained during this project could have considerable significance for practice indications. Overall, the project provided evidence that itraconazole is effective for reducing recurrence of tinea corporis and is more cost-effective than fluconazole.

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