Original Article

Evaluation of the Effect of Methotrexate on Psoriasis Based on Specialized Pharmaceutical Education

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ABSTRACT

Background: Methotrexate (MTX) is still the gold standard therapy for moderate to severe psoriasis. There is a marked interpersonal variation in the therapeutic response and toxicity profile of MTX which brings difficulty for clinical application. **Objectives:** To establish the specialized pharmaceutical education (SPE) mode for psoriasis administrated with MTX and assess the therapeutic effect between cases received SPE and usual health care in the real-world. **Materials and Methods:** In this retrospective cohort study, patients of usual health care received prescription as proof of properly taking medicine and being required return to the hospital every 4 weeks. Patients of SPE intervention were referred to the pharmaceutical clinic every 4 weeks. Body surface area(BSA), psoriasis area severity index (PASI) of 0, 4, 8, 12 week, PASI 75 of 12 week and times of self-adjusting dosage were observational noted and analyzed. **Results:** Records of 12 cases of usual care and 16 cases of SPE received MTX for psoriasis were reviewed. The decline range of BSA of SPE was higher than that of usual care at 4 week, and the difference was statistically significant ($p=0.043$).The decline range of PASI of SPE was higher than that of usual care at 8 week and 12 week with statistically significant difference separately ($p=0.048$; $p=0.029$).Times of self-adjusting dosage was zero of SPE and was statistically significant different compared to that of usual care ($p=0.026$). **Conclusion:** Statistical significant faster improvement on efficacy with no significant difference of safety in the SPE than usual care came to the conclusion. The SPE conducted by the pharmacists appears suitable for the real world implementation.

Key words: Methotrexate, Psoriasis vulgaris, Pharmaceutical education, Effect evaluation, Real world implementation.

INTRODUCTION

Psoriasis, a chronic multifactorial inflammatory disease that develops in genetically predisposed individuals, affects approximately 0.12% of the Chinese population according to the epidemiological survey in 1984 and 0.50% of 4 cities of Southwest China according to the latest data of prevalence in 2017.[1,2] This disease has a negative impact on patients` quality of life for the stigmatization, skin discomfort and pain.

MTX, a classic antipsoriatic drug, as one of the manifold treatment options is still the gold standard therapy either applied into single-drug therapy or in combination with other systemic drugs for patients with moderate to severe plaque psoriasis. But the adverse reactions from long-term low-dose MTX treatment may be present in 30% to 80%, and acute toxicity at low doses may be life-threatening in cases rarely.[3] Besides, there is a marked interpersonal variation in the therapeutic response and toxicity profile of MTX. All these bring difficulties of clinical application.[4]

Patient education is an integral part of comprehensive chronic disease management definition by the WHO. Offering patients acquire or maintain the competencies they need to manage as well as possible their lives with a chronic disease such as psoriasis so

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they can self-manage their condition therefore remains a key principle of psoriasis care guidelines.[5]

Hence, an adequate patient education for the individual psoriasis patient administrated with MTX appears to be crucial. In this study, we considered it of interest to evaluate the effect of methotrexate on psoriasis based on SPE in the real-world with a view to assess the therapeutic effect between cases received SPE service and usual health care.

METERIALS AND METHODS

Study Design

This was a retrospective study conducted at the Beijing Tsinghua Changgung hospital in Beijing, China. Data abstraction was done from the hospital medical records of eligible patients who accessed care between the periods of January 2016 to December 2020. Records of patients received SPE service applied by the pharmacists were differentiate from usual care through pharmacy service note in the Hospital Information System (HIS).

SPE Service

SPE service was offered in the pharmaceutical clinic and usual care discharge process was offered in the physician clinic. Patients with usual health care were received prescription as proof of properly taking medicine home and were required to re-visit physician clinic every 4 weeks. Patients with SPE service were referred by the fixed dermatologist to the pharmaceutical clinic for receiving specialized education service in addition to the usual health care before the next physician clinical visit. There is non-intervention of pharmacists in medical decisions but suggestion for consideration of physician in the whole process.

Data cleaning and evaluating indicator

In/ex-clusion criteria of records was set to ensure that the data was correctly collected and evaluated. Records with patients of psoriasis vulgaris were over 18 years old and with BSA ≥ 3%, applying MTX as prescription were enrolled into study, while records of patients with chronic disease, consult visits less than twice or incomplete information record of physician in 12 weeks after the first administration of MTX were excluded.

Treatment aims to reduce inflammation and decrease irregular skin cell proliferation. Severity of psoriasis is measured most commonly using the body surface area (BSA), psoriasis area severity index (PASI).[6,7] Clinical respond is considered if there is a PASI score reduction >75% compared with baseline PASI(PASI 75) at inspection time after the beginning of treatment.[8]

Drug administration

The MTX used in this research is 2.5 mg/tablet. 10 mg of MTX was orally taken for 1-4week, and 2.5 mg was orally added every week for 5-12 week according to the condition. The highest treatment and maintained dose could be given 25mg/week. When the PASI score decreased to 75%, the current dose was maintained or decreased gradually with a reduction of 2.5 mg every 2-4 week as the improvement of skin lesions. At the end of the follow-up period of 12 week, the MTX was maintained or gradually reduced with or without other treatment methods.

Statistical Analysis

SPSS 21.0 software was used for statistical analysis. The continuous data (BSA, PASI, *et al.*) of non-normal distribution was represented by median (25 quartile, 75 quartile), and the rank sum test of two independent samples was used for group comparison. The data of different time points in the group were compared with the rank sum test of multiple related samples. The continuous variable of normal distribution are presented as $\bar{x}\pm s$ with independent *t*-test. The constant variables (sex, family genetic histories al.) are presented as number or frequency and Pearson's chi-squared test was used for constant variables. Values of $p<0.05$ were considered statistically significant.

RESULTS

Enrollment

Between Jan 1, 2016 and Dec 31, 2020, a total of 65 cases were applying MTX for psoriasis vulgaris while 13 cases were withdraw for comorbid with other chronic disease. 36 cases received usual care and 16 cases received SPE service. Among the patients with usual care, 12 cases were finally brought into analysis for 8 cases lost to follow-up, 4 cases` BSA substandard (>3%) of the inclusion criteria and 12 cases with incomplete information record. Overall, 16 cases with the SPE service were all included in the final analysis (Figure 1).

Baseline characteristics

Table 1 established the baseline of demographics and clinical characteristics of cases with the usual health care and the SPE service. Overall, there was no statistically significant difference between the SPE group and the usual care group at age, sex, family genetic history, BSA, PASI and normal routine biochemical examination.

Therapeutic efficacy and safety

Table 2 showed the results of BSA compared with the SPE group and the usual care group. There was no significant difference of BSA between the two groups at baseline. The decline range of BSA in the SPE group was higher than that in usual care group at 4 weeks, and the difference was statistically significant (z=-2.024, p=0.043) while no significant difference was found between the two groups at 8 weeks nor 12 weeks (p>0.05). Within the usual care group, the difference of BSA between different time points was statistically significant (χ^2=9.138, p=0.028) and further pairwise comparison found that the difference between 0 week and 12 weeks was statistically significant. Within the SPE group, the difference of BSA between different time points was statistically significant (χ^2 = 28.187, p= 0.000) and there was significant difference between 4, 8, 12 weeks compared with 0 week with the decreased trend of BSA.

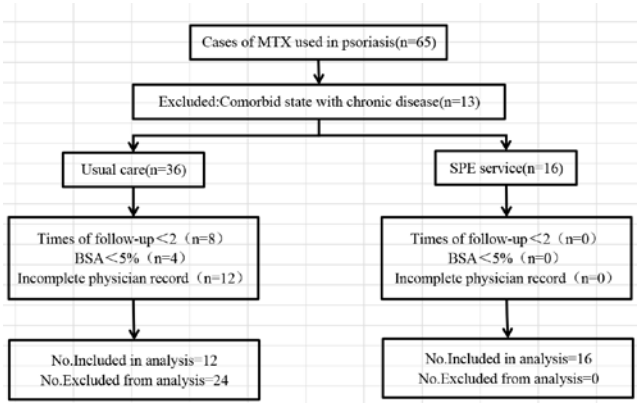

Figure 1: Flow chart of analysis.

Table 3 showed the result of PASI compared with the SPE group and the usual care group. There was no significant difference in PASI between the two groups at baseline. The decline range of PASI of the SPE group was higher than that of the usual care group at 8 weeks and 12 weeks with statistically significant difference separately(z=-1.975,p=0.048 of 8 weeks and z=-2.183, p=0.029 of 12 weeks) while no significant difference was found between the two groups at 4 weeks (p>0.05). Within the usual care group, the difference of PASI between different time points was statistically significant (χ^2=40.316,p=0.028) and further pairwise comparison found that the difference between 0 week and 8 weeks, 12 weeks was statistically significant. Within the SPE group, the difference of PASI between different time points was statistically significant (χ^2 =61.981, p= 0.000) and there was significant difference between 4, 8, 12 weeks compared with 0 week with the decreased trend of PASI. Meanwhile, we collected several pictures of patients with their informed consent to illustrate the

Table 1: Clinical and demographic characteristics.

		Cohort		Comparison between groups
		The SPE group	The Usual care group	
		12	16	*P*-value
Age	Min	25	31	0.912
	Max	73	77	
	`x±s	45.69±15.06	44.25±12.86	
Sex	Male	9	7	0.533
	Female	7	5	
Family genetic history	Yes	8	4	0.378
	No	8	8	
BSA	%	30.00(12.50,47.50)	20.00(10.00,30.00)	0.302
PASI		11.35(9.45,16.95)	11.25(9.38,19.50)	0.981
Leukocyte	`x±s	7.04±2.43	8.07±3.62	0.394
Platelet	`x±s	251.88±54.16	249.10±57.79	0.902
Red blood cell	`x±s	4.62±0.47	4.81±0.54	0.351
Hemoglobin	`x±s	140.37±13.24	150.40±15.27	0.089
AST*	`x±s	20.26±6.60	22.62±7.85	0.417
ALT*	`x±s	20.62±8.84	27.76±21.65	0.249

*: AST, Aspartate aminotransferase; ALT, Alanine aminotransferase.

Table 2: BSA comparison of two groups at different time points.					
Cohort	**Cases**	**0 week**	**4 week**	**8 week**	**12 week**
The SPE group	16	30.00(12.50,47.50)	12.50(7.75,18.75)#	12.50(10.00,20.00)#	9.00(3.00,13.75)#
The Usual care group	12	20.00(10.00,30.00)	20.00(10.00,30.00)	15.00(5.00,27.50)	10.00(5.00,18.75)#
z		-1.032	-2.024	-0.190	-0.895
p		0.302	0.043*	0.850	0.371

**p*<0.05: Compared with the control group at each time point.
#*p*<0.05: Compared with the o week within group.

Table 3: Comparison of PASI at different time points.					
Cohort	**Cases**	**0 week**	**4 week**	**8 week**	**12 week**
The SPE group	16	11.35(9.45,16.95)	7.30(5.78,14.80)#	5.45(2.48,9.50)#	2.9(1.53,4.75)#
The Usual care group	12	11.25(9.38,19.50)	10.95(8.75,18.04)	8.20(5.85,15.825)#	4.45(3.00,8.30)#
z		-0.023	-1.184	-1.975	-2.183
p		0.981	0.236	0.048*	0.029*

**p*<0.05: Compared with the control group at each time point.
#*p*<0.05: Compared with the o week within group.

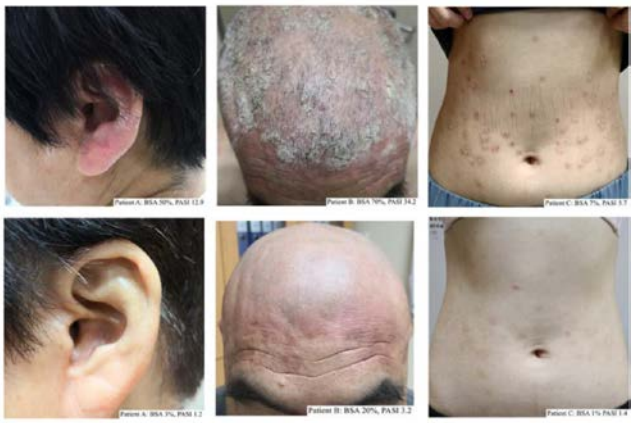

Figure 2: Examples illustrated the effectiveness before and after the SPE service.

effectiveness of MTX on psoriasis vulgaris based on SPE (Figure 2).

The Psoriasis Area and Severity Index (PASI) was often used to assess the clinical severity of psoriasis and 75% reductions in PASI was used to define significant, clinically relevant improvement.[9] Table 4 indicated the trend of PASI 75 between the SPE group and the usual care group at different time points and the occurrence of complication and times of without taking MTX of two groups in the whole 12 weeks. The decline range of PASI 75 in the SPE group was higher than that of the usual care group at 12weeks, and the difference was statistically significant(p=0.022) while no significant difference was found between the two groups at 4 weeks nor 8 weeks(p>0.05). With the SPE service, times of self-adjusting dosage was zero and was statistically significant different compared to that of usual care group (p=0.026) while no significant different was found of the occurrence of complication (p=0.902).

DISCUSSION

This was the first retrospective cohort study of investigating the impact on clinical efficacy and safety under the pharmacist intervention of patient education applying MTX for psoriasis vulgaris in Chinese. In this study, MTX was confirmed as the systemic treatment in moderate to severe psoriasis for BSA, PASI and PASI 75, as the indicators of efficacy, were all declining within groups. The present study revealed that patients with SPE service applied by pharmacists had better efficacy of MTX with an improving of BSA, PASI and PASI 75 while no significant difference of complications due to MTX poisoning was found compared to patients received usual care.

Patients with SPE service received personal education including clinical education and self-management education. The first SPE service was carried out by pharmacist using teach back to verify understanding of "red flag" signs, symptoms and suitable expectation during MTX administration as clinical education, necessity of filling new personal medication record, importance of achievement of medication-related action plan and actively clinical follow-up as self-management education. Only the first SPE service was conducted after visiting dermatologist for

Table 4: Comparison of PASI 75, occurrence of complication and times of forgetting doses.

Cohort	Cases	PASI 75			Occurrence of complication	Times of self-adjusting dosage
		4 week n(%)	8 week n(%)	12 week n(%)	12 weeks median (25th, 75th)	12 weeks median (25th, 75th)
The SPE group	16	1(6.25%)	3(18.75%)	11(68.75%)*	0.00(0.00,0.75)	0.00(0.00,0.00)#
The Usual care group	12	1(8.33%)	3(25.00%)	3(25.00%)	0.00(0.00,0.75)	0.50(0.00,1.75)
p		0.317	0.160	0.022	0.902	0.026

*$p<0.05$: PASI 75 was compared with 0 week.
#$p<0.05$: Complication and Compliance were compared with the usual care group within the whole 12 weeks.

there is referral relationship between physician and pharmacist. After their baseline education, patients were required to pharmaceutical clinic before visiting dermatologist every 4 weeks. Patients` BSA, PASI were assessed every 4week by physician under the notification of pharmacists after the SPE service but before the clinical visit. PASI 75 of the two groups was calculated according to professional formula. In our study, within the SPE group, BSA and PASI of the 4weeks, 8weeks and 12 weeks were statistically significant better as to that of the baselines separately, while within the usual care group, BSA of the only 12 weeks and PASI of the 8 weeks and 12 weeks were statistically significant better as to that of the baselines. The decline range of PASI 75 in the SPE group was higher than that in usual care group at 12 weeks. We could see that there was a faster symptom control with the SPE service compared to that with the usual care.

Treatment goals of psoriasis revolved around symptom control rather than cure and so long-term therapy is often required but psoriasis patients are not as compliant or adherent to therapy regimens as required.[10-13] It had been reported that the correct number of medication applications declined over time (only 77 % after 2 weeks and only 50 % after 8 weeks),[14-16] and for patients with psoriasis, the reported primary adherence (redemption of initial prescription) was even lower reaching only 65 % while secondary adherence (correct use of medication) was even lower with 39–73 % of the patients not using the medication as prescribed.[12,16-21] A survey revealed that 67% of patients expect an improvement within 2 weeks of treatment,[22] and the recorded treatment abandonment rate is between 3%-6%.[23,24] In our study, we found out that within the usual care group, BSA of the only 12 weeks and PASI of the 8weeks and 12 weeks as to that of the baselines were statistically significant better which means according to the expectation of improvement within 2 weeks mentioned above, no matter BSA of 12 weeks or PASI of 8 weeks of patient in the usual care group, those would be considered too long to be effective which may reducing the confidence, active engagement and compliance of therapeutic schedule. Patient received SPE service showed better medication compliance than that of usual care (p=0.026). Though nausea and fatigue were noted occurring in both two groups, patients received SPE service were educated by our pharmacist and assessed tolerable with continuous administration. Patients received usual care trended to reduce the dose of MTX or withdraw MTX by themselves according to the record of HIS. That`s may explain why there are 8 cases lost follow-up and not included into final analysis initially. The difference between groups indicated the impact under the pharmacist intervention of patient education.

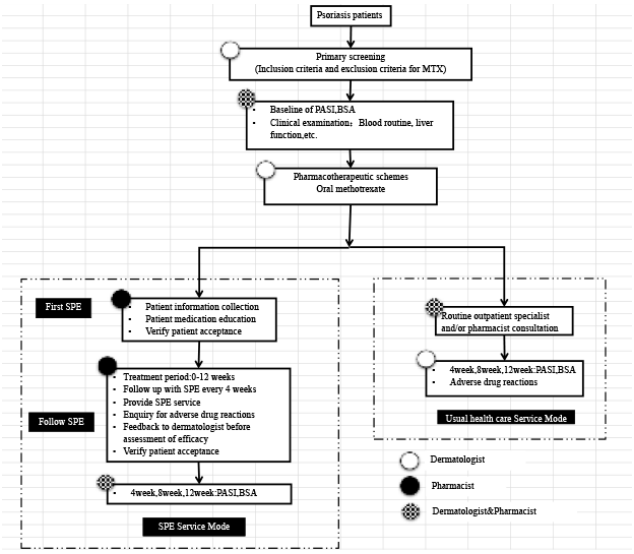

Figure 3: SPE service mode compared with usual health care mode for psoriasis administrated with MTX.

Despite the increasing emphasis on the need for structured disease-specific patient education program in severe chronic illness, only a few studies focused on the importance of the physician-patient relationship to improve the patients` perceived control of the disease.[25,26] In the real world, dermatologists always focused on the treatment goals and generally first evaluated at the 12th weeks at the end of the induction therapy. If the goal was not achieved, several strategies could be adopted such as raising the dose of the drug, reducing the time gap between administrations, or combining the drug with another drug.[27] The dermatologist of our hospital treated average 70 patients per day for example which implied that rare patients of psoriasis could receive the SPE service. In our study, we confirmed the efficacy of MTX for psoriasis and the positive impact of the SPE service conducted by pharmacists and established the ESP service mode for psoriasis administrated with MTX with better outcome compare to usual care mode (Figure 3).

CONCLUSION

In our study, statistical significant faster improvement on efficacy with no significant difference of safety of the SPE group than the usual care group comes to the conclusion. With the SPE service, patients receive specific personal education, and new experiences of comprehensibility, manageability, and meaning through education and counselling by, and interactions with, pharmacists besides. The SPE service appears suitable for the real world implementation. It is reasonable to think that the SPE service mode conducted by the pharmacists with emphasis on active adaptation in the interplay between patient education and medication therapy could have been stronger and possibly sustained.

ACKNOWLEDGEMENT

We declare that this work was done by the authors named in this article and all liabilities pertaining to claims relating to the content of this article will be borne by the authors. All authors agree to be accountable for all aspects of work ensuring integrity and accuracy.

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CONFLICT OF INTEREST

The authors declare no Conflict of interest.

ABBREVIATIONS

MTX: Methotrexate; **SPE:** Specialized pharmaceutical education; **BSA:** Body surface area; **PASI:** Psoriasis area severity index; **PASI 75:** PASI score reduction >75% compared with baseline PASI; **HIS:** Hospital Information System.

Limitations

Our study analyzed the impact of the SPE service for patients with psoriasis vulgaris rather than other type of psoriasis. Meanwhile, cases involved final analyzing excluded patient with other chronic disease were limited and the score of BSA, PASI with physicians may be bias. All these constraints limited the applicability of the finding. Future studies will benefit from better outcome measures.

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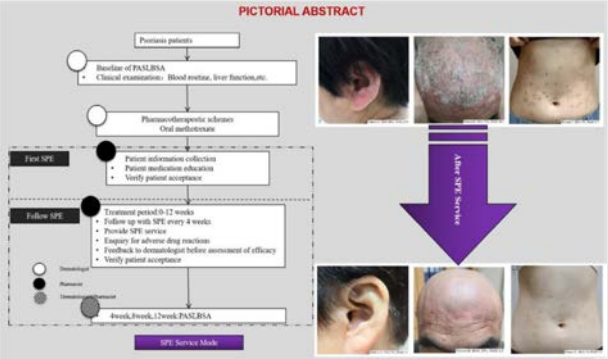
PICTORIAL ABSTRACT



SUMMARY

This study evaluate the effect of methotrexate (MTX) on psoriasis based on specialized pharmaceutical education (SPE) in the real-world with a view to assess the therapeutic effect between cases received SPE service and usual health care. The present study revealed that patients with SPE service applied by pharmacists had better efficacy of MTX with an improving of BSA, PASI and PASI 75 while no significant difference of complications due to MTX poisoning was found compared to patients received usual care.

About Authors

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