Effectiveness of Color and Picture Labeling in Improving the Knowledge on Topical Medications among Patients with Psoriasis: A Randomized Controlled Trial

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Aim and Objective: The success of topical treatment in patients with psoriasis is still below par in Malaysia. The contributing factors include patients’ understanding and knowledge about prescribed topical medications. The aim of this study was to assess the effectiveness of color and picture labeling (C and P labeling) in improving the knowledge about topical medications among patients with psoriasis.

Materials and Methods: An unblinded randomized controlled trial was undertaken at the dermatology clinic of a tertiary care hospital. Consent from the patients fulfilling inclusion criteria were obtained, and they were included in this study. They were randomized into two groups, namely Gp-1 (C and P labeling) and Gp-2 (conventional labeling). Both groups were assessed at week 0, 6, and 12 (visit 1, 2, and 3) using knowledge assessment list and psoriasis severity assessment score. For visit 2 (week 6), reinforcement of their understanding of topical treatment was performed.

Results: A total of 101 patients were recruited. Only 91 of them completed the study. The mean ages were 44.52 (±16.61) and 45.49 (±15.84) years, with 70.3% males and approximately half Malay ethnics. The changes of knowledge and comparison of Topical Application Assessment Score between the groups showed an incremental raise of significance with every visit ($P = 0.006$ [week 1], $0.004$ [week 6], and $0.002$ [week 12]). Psoriasis Area and Severity Index 75 could not draw any conclusion as patients who achieved >75% improvement were inadequate.

Conclusion: C and P labeling was effective in improving the understanding and knowledge of patients with psoriasis. Both groups showed improvement in body surface area and Dermatology Life Quality Index for every visit; however, it was statistically insignificant.

Keywords: Color and picture labeling, knowledge, psoriasis, understanding

INTRODUCTION

Psoriasis is a chronic inflammatory disease that occurs worldwide, with plaque psoriasis being the most common type of psoriasis. It is a genetically determined, systemic immune-mediated disorder that affects not only the skin but also joints and nails. In Malaysia, approximately 85.3% of the 4445 patients registered in Malaysian Psoriasis Registry have this type of psoriasis.

Plaque psoriasis is characterized by well demarcated erythematous plaques with silvery scales.[³] Hence, it can cause a significant psychological distress, poor social interactions, and low self-esteem for the patients[¹⁴]

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From literature review, the first-line topical therapies that were widely used, especially for patients with plaque psoriasis, are emollients, topical corticosteroid, topical keratolytic, and tar-based preparation. Role of emollients in psoriasis is to reduce dryness and scaling, which can cause painful fissuring and may help in controlling itchiness. They also act as a basic therapy in supporting skin care due to its ability to restore normal hydration and epidermal barrier function but without a distinct clinical response in psoriasis severity. Topical corticosteroids are used as a first-line therapy in mild-to-moderate psoriasis. Their roles are anti-inflammatory, immunosuppressive, and antiproliferative. They are available in various strengths, ranging from very potent (class I) to mild or weak potent (class IV) according to the UK classification of potency of topical corticosteroid. The choice of topical corticosteroid potency depends on the site and severity of the lesions. For example, potent and very potent topical corticosteroid should be avoided for the lesions on the face, genital, and body folds. Thus, mild potency corticosteroid may be used for these areas. They are also available in many formulations including ointment, cream, gel, lotion, solution, and spray. Therefore, patients’ preference to any form of topical corticosteroid should be considered in treating patients with psoriasis. To reduce the scaly plaque in psoriasis lesions, topical keratolytic agents are used. Keratolytic such as salicylic acid and urea cause peeling of the epidermis; however, at low concentrations, they can act as moisturizers and humectant. Tar-based preparation such as coal tar and wood tar are used as anti-inflammatory agent. A systemic review carried out by Slutsky et al., using 5% liquor carbonis distillate (a coal tar preparation), showed improvement in total severity score based on scaling, erythema, induration, and pruritus at week 4 compared to placebo with 48.7% and 35.3% improvement, respectively. On the basis of the internal findings regarding psoriasis at dermatology clinic hospital Pulau Pinang, Malaysia, the success of topical treatment in our patients is still below par. There are many contributing factors to the poor outcome of topical treatment, which include poor knowledge and insight of the disease, lack of motivation, and lack of explanation by health-care providers on the benefit of treatments and their potential side effects.

Majority of the patients with psoriasis attended at dermatology clinic hospital Pulau Pinang, Malaysia, had mild-to-moderate disease and only required topical treatment. There were instances where even patients with extensive psoriasis can be effectively treated with topical therapy alone. Thus, the treatment success may entirely dependent on patients’ ability to use the medications appropriately. However, owing to more than one type of topical medications usually prescribed, this may cause confusion for the patients. Previous study showed that pictorial methods improve patients understanding of their medication and adherence to drug regimen in other medical condition. Hence, this study was aimed to assess the effectiveness of color and picture labeling (C and P labeling) in improving the knowledge on topical medications among patients with psoriasis.

**Materials and Methods**

*Trial design:* This was an unblinded randomized control trial (RCT) with allocation ratio 1:1.

*Study setting:* This study was conducted in Dermatology clinic, Hospital Pulau Pinang, Pulau Pinang, Malaysia.

**Inclusion criteria:**
1. Patients aged 18 years or more
2. Diagnosed with mild-to-moderate psoriasis
3. Patients that require topical treatment only
4. Physically and mentally capable for self-care
5. Able to give consent

**Exclusion criteria:**
1. Mentally and physically handicap
2. Pregnant patients
3. Patients who require systemic agents or phototherapy
4. Color blind

*Interventions:* The information printed on the original medication label is used at all public hospitals in Malaysia. It includes the generic name of the medication, patients’ particular, volume, strength of steroid in ratio, expiry date, and frequency to use [Figure 1]. Most commonly prescribed topical medications were selected in the study are showed in Table 1.

For intervention, color and pictorial stickers were used to label the medication given to patients [Figure 2]. C and P labeling is a tool to help patient to identify their topical medications based on the treatment group (steroid, emollients, and keratolytic or tar preparation). It was also used to assist patient to accurately apply the medication on specific skin lesion based on the pictographic given. This intervention was developed based on experts opinion and literature review.

A color coding of C and P labeling:
- Red for topical steroid
- Yellow for keratolytic or tar preparation
- Green for emollients
These colors were chosen based on the colors of the traffic light because it is easy to remember as most of the patients were familiar with it.

- Red signifies “danger” thus has to be used with care
- Yellow for “caution”
- Green is “safe”

Pictogram of body parts were used to mark the specific area for application of the medication. The strengths of topical corticosteroid were labeled as “sangat kuat,” “kuat,” “sederhana kuat,” and “kurang kuat” (very strong, strong, moderately strong, and mildly strong, respectively) based on UK classification.

**Randomization:**

1. Opaque envelopes were used to counsel patient assignment (control group or intervention group).
2. The envelopes were sealed and put inside a box (in a block of 20).
3. Patients who were eligible and who consented were asked to take one envelope from the box.
4. The patients’ assignment was recorded and noted by the patients.
5. All participants were enrolled by the principle investigator.

**Ethical approval:** This study was registered with the National Medical Research Registry (NMRR-16-1226-31395) and approved by the Medical Research Ethics Committee in Malaysia.

**Sample size and sampling:** Sample size estimation was calculated using two formulae for population proportions.[13] Prior data indicated that the proportion of patient acceptability of the labels among women[11] of the control group was 0.47. If the proportion of the intervention group was 0.78, we will need to study 38 samples to be able to reject the null hypothesis with probability (power) 0.8. The type I error probability

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**Figure 1:** Regular labels dispensed at public hospitals in Malaysia

**Figure 2:** Color and picture labels
| Parameters                  | Control group (n = 52) mean (SD) | Intervention group (n = 49) mean (SD) | P value |
|-----------------------------|----------------------------------|---------------------------------------|---------|
| Age                         | 44.52 (+16.61)                   | 45.49 (+15.84)                       | 0.765*  |
| BMI                         | 26.13 (+5.88)                    | 26.58 (+5.15)                        | 0.686*  |
| Gender                      |                                  |                                       |         |
| Male                        | 28 (53.8%)                       | 36 (73.5%)                           | 0.041b  |
| Female                      | 24 (46.2%)                       | 13 (26.5%)                           |         |
| Ethnicity                   |                                  |                                       |         |
| Malay                       | 26 (50%)                         | 22 (44.9%)                           | 0.241b  |
| Chinese                     | 8 (15.4%)                        | 14 (28.6%)                           |         |
| Indian                      | 16 (30.8%)                       | 13 (26.5%)                           |         |
| Others                      | 2 (3.8%)                         | 0 (0%)                                |         |
| Alcohol consumption         |                                  |                                       |         |
| Yes                         | 13 (25.0%)                       | 11 (22.4%)                           | 0.763b  |
| No                          | 39 (75.0%)                       | 38 (77.6%)                           |         |
| Smoking                     |                                  |                                       |         |
| Smoker                      | 9 (17.3%)                        | 13 (26.5%)                           | 0.430b  |
| Ex-smoker                   | 6 (11.5%)                        | 7 (14.3%)                            |         |
| Nonsmoker                   | 37 (71.2%)                       | 29 (59.2%)                           |         |
| Comorbidity                 |                                  |                                       |         |
| No. of comorbidities        | 27 (51.9%)                       | 32 (65.3%)                           | 0.291b  |
| Three or less               | 19 (36.5%)                       | 11 (22.4%)                           |         |
| More than three             | 6 (11.5%)                        | 6 (12.2%)                            |         |
| Marital status              |                                  |                                       |         |
| Single                      | 17 (32.7%)                       | 12 (24.5%)                           | 0.538b  |
| Married                     | 30 (57.7%)                       | 34 (69.4%)                           |         |
| Widow/widower               | 4 (7.7%)                         | 3 (6.1%)                             |         |
| Divorced                    | 1 (1.9%)                         | 0 (0%)                               |         |
| Education level             |                                  |                                       |         |
| Primary                     | 2 (3.8%)                         | 4 (8.2%)                             | 0.649b  |
| 7 (13.5%)                   | 8 (16.3%)                        |                                       |         |
| PMR                         | 7 (13.5%)                        | 8 (16.3%)                            |         |
| SPM/STPM                    | 22 (42.3%)                       | 22 (44.9%)                           |         |
| Diploma/degree/Master’s     | 21 (40.4%)                       | 15 (30.6%)                           |         |
| Occupation                  |                                  |                                       |         |
| Government                  | 8 (15.4%)                        | 5 (10.2%)                            | 0.200b  |
| Employee                    | 14 (26.9%)                       | 18 (36.7%)                           |         |
| Private                     | 12 (23.1%)                       | 10 (20.4%)                           |         |
| Self-employed               | 1 (1.9%)                         | 5 (10.2%)                            |         |
| Unemployed                  | 5 (9.6%)                         | 2 (4.1%)                             |         |
| Housewife                   | 12 (23.1%)                       | 7 (14.3%)                            |         |
| Others                      | 0 (0%)                           | 2 (4.1%)                             |         |
| Language preference         |                                  |                                       |         |
| Malay                       | 21 (40.4%)                       | 18 (36.7%)                           | 0.723b  |
| Tamil                       | 1 (1.9%)                         | 0 (0%)                               |         |
| English                     | 2 (3.8%)                         | 1 (2.0%)                             |         |
| Malay, Mandarin             | 0 (0%)                           | 2 (4.1%)                             |         |
| Malay, Tamil                 | 4 (7.7%)                         | 8 (16.3%)                            |         |
| Malay, English               | 6 (11.5%)                        | 7 (14.3%)                            |         |
| Malay, Others               | 1 (1.9%)                         | 1 (2.0%)                             |         |
| Malay, Mandarin, English    | 4 (7.7%)                         | 4 (8.2%)                             |         |
| Malay, Mandarin, Others     | 1 (1.9%)                         | 1 (2.0%)                             |         |
| Malay, Tamil, English       | 10 (19.2%)                       | 5 (10.2%)                            |         |
| Malay, English, Others      | 1 (1.9%)                         | 2 (4.1%)                             |         |
| Malay, Mandarin, English,   | 1 (1.9%)                         | 0 (0%)                               |         |

BMI = body mass index, SD = standard deviation, PMR = Penilaian Menengah Rendah, SPM = Sijil Pelajaran Malaysia, STPM = Sijil Tinggi Pelajaran Malaysia

*P value of <0.05 was considered significant

*Paired t test, *Pearson chi-square test
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The design of this study included three measurements for 12-week study. Patients who were eligible were recruited to the study during their normal appointment in the dermatology clinic (week 0). After obtaining signed consent, they were randomized into the following two groups, using simple randomization of a block of 20 and using sealed opaque identical envelopes: C and P labeling group and standard labeling group. Both groups were assessed at week 0, week 6, and week 12 using knowledge assessment list (Topical Application Assessment Score [TAAS]) and psoriasis severity assessment (Psoriasis Area and Severity Index [PASI], body surface area [BSA], and Dermatology Life Quality Index [DLQI]) score. TAAS is a 13-item questionnaire adapted from Tang et al.[12] and edited by the consensus of a group of dermatologists and pharmacists in Hospital Pulau Pinang, Malaysia, and subsequently it was validated.

At baseline (week 0), both study population were given counseling by pharmacist on proper use of topical treatment and emphasis on recognition of the type of topical treatment, site of application, frequency of application, and potency of topical steroid. The marks were documented in TAAS [Table 2 and 3]. Their baseline PASI, BSA, and DLQI scores were documented in the standard form available in our clinic. All PASI scores were evaluated by two physicians (one study physician and one independent physician). Chart 1 presents the flow of sample size calculation and sampling procedure.

**Statistical analysis**: The IBM Statistical Package for Social Sciences software, version 23.0, was used to manage and analyze the data. Paired t test was used to compare between two mean values. Pearson chi-square test and Fisher’s exact test were used to compare between categorical data of the two groups. A P value of <0.05 was consider to be significant.

**RESULTS AND DISCUSSION**

A total of 101 patients were recruited in the study. Only 91 of them (46 patients in intervention, C and P group) completed the study. A total of nine patients were lost to follow-up as they were uncontactable, and one patient was withdrawn from the study as he was started on oral medical therapy. Demographic characteristics of all the patients are summarized in Table 1. Overall, the mean age of control and intervention group was comparable (44.52 vs. 45.49 years) with majority being male patients (70.3%). Their body mass index (BMI) mean (26 kg/m²) falls under the lower limit of overweight group. Approximately half of them were Malays, which represent the ethnic distribution in this country. Majority of the patients completed upper secondary level of education and almost all of them can (95.6%) understand the Malay language.

TAAS was developed initially as a checklist to ensure no important points or information were missed out.
during counseling. TAAS was modified based on a study conducted by Tang et al.\textsuperscript{[12]} For measuring psoriasis severity, tools that were used are BSA, DLQI, and PASI.\textsuperscript{[1]} Comparison of TAAS between the groups is shown in Table 4. BSA involvement and DLQI score are presented in Table 5 and Table 6 respectively. Figure 3 showed a significant higher score for the intervention group, and this finding was sustained throughout the study ($P < 0.05$). Paired $t$ test was used to compare between the two groups and it showed an incremental raise of TAAS for every visit ($P = 0.006$ [week 0], 0.004 [week 6], and 0.002 [week 12]). During visit 2, it was found that both groups have a reduction in TAAS.

![Figure 3: Mean TAAS for both group ($P$-Value of <0.05)](image)

| TAAS questions | Visit 1 (week 0) (correct answers) | Visit 2 (week 6) (correct answers) | Visit 3 (week 12) (correct answers) |
|----------------|-----------------------------------|------------------------------------|-----------------------------------|
| (1) Able to recognize type of application | | | |
| (1a) Emollient | 38 | 28 | 34 |
| (1b) Keratolytic or tar preparation | 23 | 19 | 23 |
| (1c) Steroid | 33 | 19 | 30 |
| (2) Site of application | | | |
| Body part | | | |
| Keratolytic or tar preparation | | | |
| (2ia) Emollient | 42 | 39 | 43 |
| (2ib) Keratolytic/ tar preparation | 44 | 40 | 40 |
| (2ic) Steroid | 42 | 34 | 36 |
| (2iia) Emollient | 40 | 37 | 41 |
| (2iib) Keratolytic/ tar preparation | 29 | 19 | 21 |
| (2iic) Steroid | 37 | 35 | 32 |
| (3) Frequency of application | | | |
| (3a) Emollient | 42 | 36 | 42 |
| (3b) Keratolytic/ tar preparation | 37 | 39 | 35 |
| (3c) Steroid | 43 | 31 | 37 |
| (4) Strength of steroid | | | |
| Very strong or strong or moderate or weak | 34 | 31 | 32 |
| Total | 484 (82.7%) | 407 (69.6%) | 446 (76.2%) |

Table 4: Comparison of Topical Application Assessment Score (color and picture versus conventional)

| TAAS score each visit | Conventional (mean) | C and P (mean) | $P$ value ($t$ test) |
|-----------------------|---------------------|----------------|---------------------|
| Visit 1 (week 0)     | 10.69               | 11.67          | 0.006               |
| TAAS                  | (+1.998)            | (+1.248)       |                     |
| Visit 2 (week 6)     | 9.02                | 10.53          | 0.004               |
| TAAS                  | (+2.624)            | (+2.158)       |                     |
| Visit 3 (week 12)    | 9.91                | 11.22          | 0.002               |
| TAAS                  | (+2.304)            | (+1.489)       |                     |
| No. of subjects       | 45                  | 46             |                     |

*$P < 0.05$ is consider significant to reject the null hypothesis
However, both groups also showed an improvement in the score after reinforcement during visit 2. With regard to PASI score assessment, no conclusion can be made as the number of patients able to achieve more...
than 75% improvement (PASI 75) was not adequate [Table 7].

Generally, doctors do not have enough time to explain the nature of a disease and the appropriate way to use the medications due to busy clinic and heavy workload. Several studies documented that patients’ knowledge about the disease is important to ensure patients’ adherence to treatment and thus better outcome. Usually adherence to treatment is poorer in chronic diseases such as psoriasis due to various factors including difficulty in applying the topical medication, social factors, and treatment-related factors such as satisfaction with the treatment and complexity of the treatment protocols.

The use of easy-to-understand labels may help patients to understand the medications more easily, and hence may reduce the counseling time spent by pharmacists during dispensing. Furthermore, in a multiethnic population such as us, language and comprehensibility is one of the restricting factors for health-care providers to deliver the information. Therefore, labeling aids such as color and picture are helpful to assist the tasks of health-care personnel and patient comprehension.

A few studies were carried out on intervention in assisting and improving medication dispensing. Pictographic interventions have been shown to improve the comprehension or recall of medications’ instructions. A few studies aiming to maximize patients’ knowledge and adherence to medications by modifying the labeling were reported. For our study intervention, we used a combination of pictorial and color adhesive stickers to modify the labeling of our topical medication. Till date only one study was conducted in Malaysia using cartoons and multi-language stickers as intervention. It documented a significant reduction of disease severity in patients with atopic eczema (65% reduction) and the knowledge of their medication.

Approximately 7% and 16.5% of the patients in our cohort had only completed primary and lower secondary school education, respectively. All of the patients were given multiple types of topical medications. This might cause confusion, thus leading to misidentification of medications meant for the specific site and type of skin lesions. According to Chan and Hassali, patients with primary education level (61.9%) had a preference for the pictogram-incorporated label. Their results for investigation of subjects’ preferences also showed patients with the age 50 years and older prefer the same types of labeling. An RCT of three arms (control, local label, and nonlocal label groups) among low-literate patients, which documented the use of pictorial labeling system in tandem with oral and written instructions, can improve understanding of drug indication and adherence to medication.

The TAAS is proportional to the understanding and knowledge of the patients. At baseline, the higher scoring in the intervention group showed that C and P labeling improved patients’ understanding more than conventional labeling. During visit 2 (week 6), there was a reduction of TAAS in both groups; however, it was greater in the conventional group. The TAAS assessment was carried out without reinforcement, thus this reflects the actual practice and recall ability of the patients. Again, the intervention group had a better sustainability of knowledge.

We also identified that many of the participants in both groups were unable to answer the site of application for keratolytic or tar preparation and steroid correctly. This may be due to the complexity of the treatment where these two medications need to be applied on specific types of lesions as compared to emollients, which can be applied anywhere on the body. This is our duty as health workers to reinforce on patients’ education about the disease and its proper treatment. We included potency of steroid as one of the compulsory education and counseling to the patients as previous study reported that only 33%–40% of patients were informed about this medication by health personnel. Previous study showed that only 33%–40% of patients were informed about this medication by health personnel. This is a very important issue because prolonged use of topical corticosteroid may cause adverse effects locally and systemically when used inappropriately. In our daily practice, we do encounter few patients with local side effect, especially in the elderly patients. In the present study, it was found that over 50% patients in both groups were able to indentify topical corticosteroids after counseling. But to retain this counseling knowledge, it is important to reinforce. In terms of response to treatment, both groups showed improvement in outcome; however, it was statistically not significant. This may be due to the small sample size, mild disease to begin with, and short study duration.

On the basis of the aforementioned results, it was found that the use of modified labeling, particularly color and pictorial labels, is effective in improving and sustaining the understanding and knowledge of topical medication. However, we recommend further study using bigger sample size, longer study duration, greater variations of education level and income,
and multicentre study sites, including rural areas, to produce a more significant clinical outcome between the two groups.

Being an RCT, this study provides in-depth cause-effect relationship between an intervention and outcome. Comparatively smaller sample and unblended design are only weaknesses of this study.

**CONCLUSION**

Our evaluation of C and P labeling was found to be effective in improving the understanding and knowledge of patients with psoriasis regarding the various types of topical medications. Both groups showed improvement in BSA and DLQI for every visit; however, it was statistically not significant.

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**Conflicts of interest**

There are no conflicts of interest.

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