Efficacy and Safety of Sunflower Oil for Mild to Moderate Plaque-type Psoriasis: A Double-blind, Randomized Controlled Trial

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ABSTRACT

Background: Psoriasis is a chronic, complex, inflammatory disease that needs safe and effective treatment options to decrease its disease burden.
Objectives: To determine the efficacy and safety of sunflower oil in mild to moderate plaque-type psoriasis at the outpatient department of a tertiary hospital.
Methods: This was an 8-week, single-center, randomized, double-blind controlled trial that compared the efficacy and safety of sunflower oil + placebo cream (Group SO), betamethasone valerate cream + placebo oil (Group BC), sunflower oil + betamethasone valerate cream (Group SO-BC) in mild to moderate plaque-type psoriasis. Psoriasis Area Severity Index (PASI) was used to measure the extent of psoriasis by assessing the erythema, induration, scaling, and body surface area involvement. The difference from baseline PASI was recorded. The Dermatology Life Quality Index (DLQI) questionnaire was used to measure the impact of psoriasis on the patient's quality of life.
Results: Fifty-one patients were randomized and blinded to three treatment arms; evaluated at baseline, week 4 and 8. The proportion of patients who achieved PASI ≥50 at week 4 was 29% in Group SO, 38% in Group BC, and 60% in Group SO-BC. By week 8, Groups SO and BC achieved 80% while Group SO-BC achieved 93%. There was significant decline of PASI at week 4 and week 8 compared to baseline. The mean percentage change of PASI was highest at Group SO-BC followed by Group BC and lastly Group SO at week 4 and week 8. The mean reduction in score for scaling was significantly higher in Group SO-BC. Mean reduction in induration and erythema was not statistically significant across the three groups. There was 40-50% improvement in DLQI scores in all groups. There were no adverse events.
Conclusion: This study showed that sunflower oil is effective and safe in mild to moderate plaque-type psoriasis.

Key words: sunflower oil, randomized controlled trial, psoriasis

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INTRODUCTION

Psoriasis, a chronic, complex, inflammatory disease affecting the skin and nails, is considered a global problem with prevalence ranging from

0.09%-11.4%. Approximately 2-5% of the world's population [1,2] with 1-2 million Filipinos are suffering from psoriasis.[3] It has a complex pathophysiology involving T cells, dendritic cells, cytokines, genetics, and keratinocyte differentiation.

Currently, there is no cure for psoriasis. The goals of treatment include control of lesions, symptoms and improvement in the quality of life.[1] Eighty percent of patients with psoriasis have mild-moderate disease [4] for which topical therapy is the modality of choice for less than 10% of the body surface area. The topical corticosteroid is most commonly used due to its potent anti-inflammatory properties. However, long-term use may result in undesirable side effects of telangiectasia, atrophy, purpura, folliculitis, and striae [5] causing physicians and patients to have steroid phobia leading to treatment non-adherence. [6,7] There is need for a long-term safe and effective treatment for patients with psoriasis to decrease its disease burden.

Sunflower oil has been shown to have moisturizing and anti-inflammatory properties.[8-11] Its high linoleic content causes reduction of TNF-alpha which plays a major part in the pathogenesis of psoriasis. It has also been shown to have no adverse skin reactions.[10,12]

The objective of this study was to determine the efficacy and safety of sunflower oil in mild to moderate plaque-type psoriasis in comparison to betamethasone valerate cream at the outpatient department of a tertiary hospital. It specifically aimed to compare the effect of sunflower oil + placebo cream (Group SO) versus betamethasone valerate cream + placebo oil (Group BC) versus sunflower oil + betamethasone valerate cream (Group SO-BC) at weeks 4 and 8 in terms of: 1) the proportion of patients achieving Psoriasis Area and Severity Index (PASI) ≥50; 2) mean PASI scores; 3) mean percentage improvement of PASI; 4) mean reduction in score of erythema, scaling, and induration; 5) mean reduction in Dermatology Life Quality Index (DLQI) score at 8th week of treatment compared to baseline and; 6) incidence of adverse events for each treatment group at the 4th and 8th week.

METHODOLOGY

Research Design

This study was an 8-week, single-center, randomized, double-blind controlled trial that compared the efficacy and safety of sunflower oil + placebo cream (Group SO), betamethasone valerate cream + placebo oil (Group BC), sunflower oil + betamethasone valerate cream (Group SO-BC) in patients with mild to moderate plaque-type psoriasis.

This study was approved by the hospital's Institutional Review Board and was conducted in accordance to the accepted ethical research practices of the International Conference on Harmonisation Good Clinical Practice regulations and guidelines. Informed consent was obtained from all participants prior to entering the study. This study was investigator-initiated and not industry funded or company sponsored and had no potential conflicts of interest.

Participants

Patients aged 18 years old and above with mild to moderate (≤10% of body surface area and PASI of ≤15) chronic plaque-type psoriasis who sought treatment at the outpatient department of a tertiary hospital between February 2019 and August 2019. Exclusion criteria included facial, scalp, palms, soles, nail, and intertriginous psoriasis, guttate, inverse, erythrodermic, pustular, and psoriatic arthritis, patients with known hypersensitivity to steroid or sunflower oil, pregnant and breastfeeding women, patients with psychiatric illnesses, and those who refused or were unable to provide consent.

Interventions

The aim of the study was to determine the efficacy and safety of sunflower oil in mild to moderate psoriasis. In this study, sunflower oil was compared to betamethasone valerate cream as a standard of treatment for mild to moderate plaque type psoriasis. In order to facilitate blinding, a placebo cream which has the same composition of the steroid cream minus its active ingredient was used with sunflower oil in Group SO. The second arm (Group BC), betamethasone valerate cream was given with placebo which was mineral oil. The third arm (Group SO-BC) was made to determine the additive effect of the combination of sunflower oil with betamethasone valerate cream.

The study coordinator was blinded to patient allocation and obtained informed consent from the patients. The washout periods of previous treatments

were 2 weeks for topical treatments and UVB phototherapy, one month for systemic treatment and three months for biologics.[13-16]

The participants were randomly assigned in a 1:1:1 ratio into the three treatment arms (Group SO, Group BC, and Group SO-BC) by a research assistant. Patients on Group SO applied a placebo cream 2x a day on the affected areas followed by the sunflower oil; Group BC applied betamethasone valerate cream 2x a day on the affected areas followed by the placebo oil, and Group SO-BC applied betamethasone valerate cream 2x a day on the affected areas followed by sunflower oil. In all treatment groups, the cream was applied first followed by the oil after 15 minutes.[17] The treatment was applied daily until resolution of lesions or up to 8 weeks, whichever came first. The research assistant showed the application of the treatment materials and a return demo was done by the participant. All trial products namely the 100% sunflower seed oil and betamethasone valerate cream utilized were approved by the Food and Drug Administration (FDA) of the Philippines.

Cleansing agents used were similar in all groups.

Baseline assessment was done on Day 0 which included the demographic data (age, sex, comorbidities, previous psoriasis treatment, and disease duration) (Appendix A), Physicians Area and Severity Index (PASI), and Dermatology Life Quality Index (DLQI). Baseline measures and PASI was done by the study investigator while the DLQI on Day 0 and week 8 was self-administered.

Treatment was discontinued anytime if (1) the patient requested to withdraw from the study; (2) there was development of severe adverse reaction; (3) there was exacerbation or worsening of the clinical condition to severe psoriasis or progression to pustular, erythrodermic or psoriatic arthritis.

Outcomes

The primary outcome of this study was the proportion of patients achieving PASI ≥50 at the 4th and 8th week compared to baseline in the three treatment arms. Studies showed that PASI 50 is a meaningful cut-off value and translates to good clinical improvement and DLQI score. Patients who achieved PASI 75 did not seek treatment until PASI was below 50 from baseline and effective therapies were differentiated from placebo at PASI 50. It was concluded that PASI 50 is considered a clinically significant endpoint in patients with psoriasis.[18-20]

The secondary outcomes were assessment of clinical response in each treatment group at weeks 4 and 8 based on mean PASI scores, mean percentage improvement of PASI, mean reduction in score of erythema, scaling, and induration, mean reduction in DLQI score at 8th week of treatment compared to baseline and incidence of adverse events for each treatment group at the 4th and 8th week.

The PASI and the DLQI are the most widely used tools in clinical trials of psoriasis.[18,21,22] PASI was determined by grading erythema, induration, scaling, and the body surface area involvement. It is a quantitative measure of the extent of psoriasis and a validated measure of treatment response.[21] The changes in the PASI score from baseline determines the efficacy of treatment given (Appendix B).[18] The DLQI is a simple and easy quantitative measure of the impact of skin disease to the person's quality of life which can be applied to patients with psoriasis (Appendices C-D).[23]

Incidence of adverse events such as pruritus, pain, and increase in erythema were recorded. A physician assessor assessed the outcome measures at the 4th and 8th week of follow-up. Patients were asked to follow-up every 2 weeks to sustain compliance with the medications.

Sample Size

PASS 2008 was used to calculate the minimum sample size of the study. A previous study showed that PASI 50 was achieved by 88% of psoriasis patients after treatment with betamethasone valerate.[24] It was assumed that 50% of Group SO and 100% of Group SO-BC patients will achieve PASI 50 at the end of the 8-week treatment. Sample size computation for Chi-square test was used specifying an effect size of 0.53, degree of freedom of 2, and alpha equal to 0.05. A sample of 46 patients with mild to moderate psoriasis achieved 90% power to detect a difference in the proportion of patients who achieved PASI 50 at the end of the treatment period. The sample size was then increased to 51 to account for 10% potential drop-out (Appendix E).

Sampling, Randomization, and Blinding

Prior to start of the study the statistician generated the allocation schedule. A list of patient numbers were randomly assigned in a 1:1:1 ratio into three treatment groups using www.randomization.com. Block randomization technique was employed with random block sizes of 17. The allocation schedule was given to the research assistant who then prepared sequentially numbered opaque containers for creams and amber colored bottles for oils according to the allocation schedule. The allocation schedule was concealed from other study investigators and patients until the end of the study.

Convenience sampling was employed in the selection of study participants. Each patient was screened by a primary investigator for eligibility during their visit to the outpatient department. Upon completion of the washout period, participants were assigned a number sequentially according to the time they entered the study. Eligible patients were referred to the study coordinator to obtain their written consent and baseline data. Treatment materials based on their study number and instructions to the patients were also given.

A blinded physician assessor assessed the outcome measures which were PASI, DLQI, and adverse events at the 4th and 8th week of follow-up.

Statistical Methods

Data were encoded in MS Excel by the researcher. Stata MP version 14 was used for data processing and analysis. Continuous variables were presented as mean/standard deviation (SD) and were analyzed using One-Way Analysis of Variance (ANOVA) or Kruskal-Wallis test. Post-hoc analyses using Tukey Honestly Significant Difference (HSD) and Dunn's test were performed for significant results. Categorical variables were presented as a frequency/percentage and were analyzed using the Chi-square test or Fisher's exact test.

The proportion of patients who achieved PASI 50 for each treatment group at week 4 and week 8 were compared using Fisher's exact test. In order to minimize alpha error, Bonferonni correction was applied such that alpha is set at 0.025. Within group differences in PASI score over time was analyzed using Repeated Measures ANOVA. The mean change in PASI improvement and DLQI scores by treatment group were analyzed using One-Way ANOVA, and significant results were further analyzed using Tukey HSD. Adverse events were compared by the treatment group using the Chi-square test or Fisher's exact test. P values ≤ 0.05 were considered statistically significant. Intention-to-treat analysis was followed and in order to assess the effect of dropouts or lost to follow-up participants a per-protocol analysis was also performed.

RESULTS

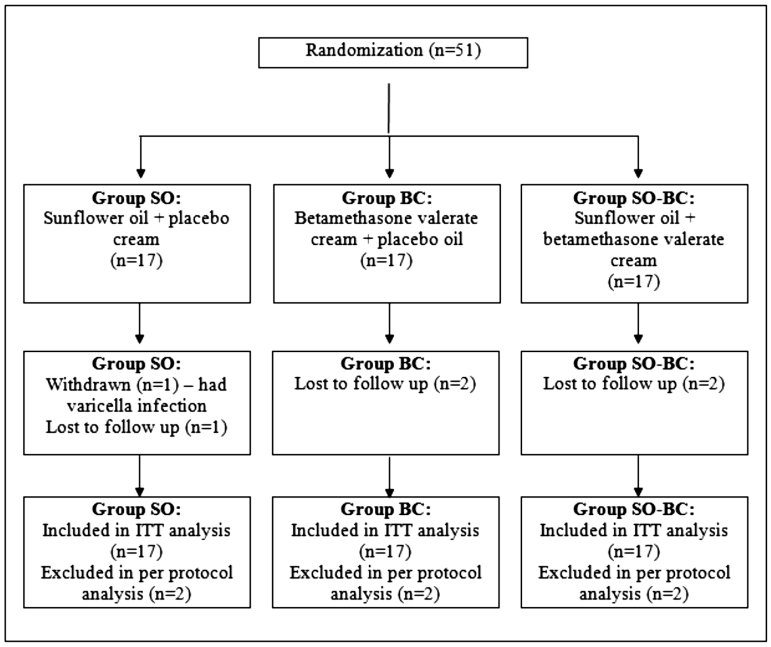
Study Population

A total of 51 patients were enrolled into the study, 17 patients in each of the treatment arms. Of the 51 patients, 45 were included in the per protocol analysis since 6 patients were lost to follow up or withdrew from the study. A flow diagram of patients' treatment and reasons for discontinuation are shown in Figure 1.

Baseline demographics and characteristics of patients per treatment arm are shown in Table 1. The median age is 40 years old (IQR: 29-62 years old). There was no significant difference between baseline demographics and characteristics of patients in the three treatment groups in terms of age, comorbidities, BMI, duration of psoriasis, previous treatments for psoriasis, mean PASI and mean DLQI at baseline. The proportion of male patients was significantly higher in Group SO-BC (82%) compared to Group BC (41%) but not to Group SO (59%). A majority of patients in the study were overweight or obese and had used topical steroids in the past.

Psoriasis Area and Severity Index (PASI) ≥50

Figure 2 shows the proportion of patients who achieved PASI ≥50 by treatment group at week 4 and week 8. At week 4, PASI 50 was achieved by 29% patients in Group SO, 38% in Group BC, and 60% in Group SO-BC. There was further increase in a proportion of patients who achieved PASI 50 in week 8. Eighty percent of patients in both Groups SO and BC, and 93% of patients in Group SO-BC achieved PASI 50 at week 8. The proportion of patients who achieved PASI 50 did not significantly differ across treatment arms in both week 4 (p-value = 0.204) and week 8 (p-value = 0.668).



ITT, intention to treat.
Figure 1. Schematic diagram of patient disposition for Groups SO, BC, and SO-BC.

Table 1. Demographics and baseline characteristics of patients with mild to moderate plaque-type psoriasis by treatment arm seen at a tertiary hospital (n=51)

Characteristics	Group SO: Sunflower oil + placebo cream (n=17) n(%)	Group BC: Betamethasone valerate cream + placebo oil (n=17) n(%)	Group SO-BC: Sunflower oil + betamethasone valerate cream (n=17) n(%)	P value
Age (in years), median	29 [IQR: 21 – 60]	51 [IQR:38 – 63]	38 [IQR: 31 – 58]	0.2139
Sex				
Male	10 (59)	7 (41)	14 (82)	0.048*
Female	7 (42)	10 (59)	3 (18)	
Comorbidities				
Hypertension	3 (18)	7 (41)	4 (24)	0.384
Diabetes mellitus	0	1 (6)	4 (24)	0.111
Dyslipidemia	2 (12)	2 (12)	0	0.528
BMI				
Normal	4 (24)	0	2 (12)	0.145
Overweight/Obese	13 (76)	17 (100)	15 (88)	
Psoriasis duration (in months), median	72 [IQR: 24-120]	108 [IQR: 36-180]	36 [IQR: 28-120]	0.5854
Previous treatment for psoriasis				
Topical	17 (100)	17 (100)	14 (82)	0.098
Phototherapy	2 (12)	1 (6)	1 (6)	1.000
Systemic	2 (12)	4 (24)	6 (35)	0.330
PASI, mean	2.18 ± 0.92	2.76 ± 0.95	3.09 ± 1.56	0.0879
DLQI, mean	6.24 ± 2.56	5.82 ± 1.59	6.59 ± 5.37	0.8221

IQR, interquartile range; PASI, Physicians Area and Severity Index; DLQI, Dermatology Life Quality Index

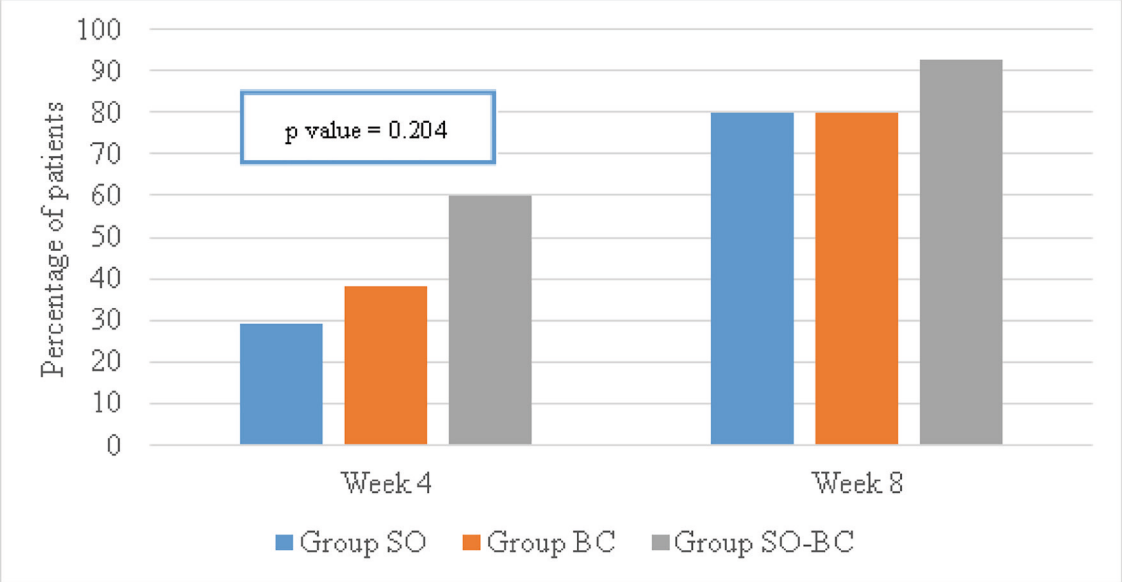


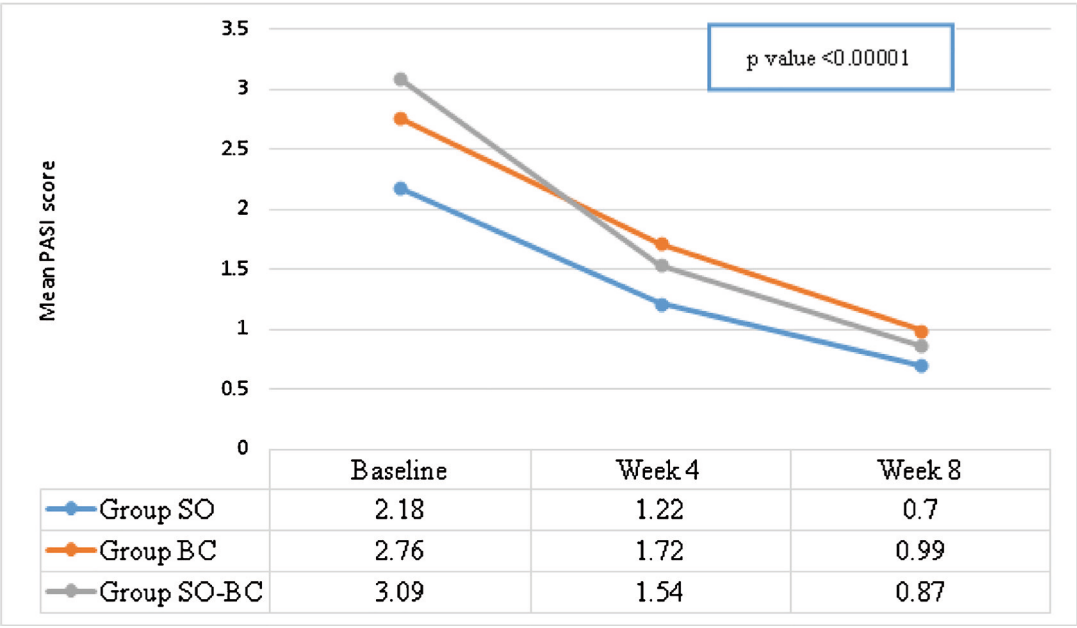
Figure 2. Percentage of patients who achieved PASI 50 at week 4 and week 8 by treatment arm (n=51)

Mean PASI Score

Figure 3 shows the decreasing trend in mean PASI score at week 4 and week 8 compared to baseline in all treatment groups. Repeated measures ANOVA showed significant decrease in mean PASI score at week 4 and week 8 compared to baseline PASI in all three groups (p-value <0.00001). Post-hoc analysis using Tukey HSD showed that in all three groups mean baseline PASI was significantly higher compared to mean PASI score at week 4 and week 8; and mean PASI score at week 4 was still significantly higher compared to week 8.

Mean Percentage Improvement of PASI From Baseline

Figure 4 shows mean percent improvement of PASI from baseline in all treatment groups. At week 4, the mean percent change of PASI was highest at Group SO-BC (56.12% ± 27.72) followed by Group BC (45.50% ± 24.55) and lastly Group SO (36.48% ± 21.17). There was a further increase in mean percentage improvement of PASI at week 8 in Group SO-BC (76.25% ± 18.59), Group BC (69.79% ± 25.83), and Group SO (65.03% ± 27.24). There was no significant difference in mean percentage



	Baseline	Week 4	Week 8
Group SO	2.18	1.22	0.7
Group BC	2.76	1.72	0.99
Group SO-BC	3.09	1.54	0.87

Figure 3. Mean PASI score at baseline, week 4, and week 8 by treatment arm (n=51)

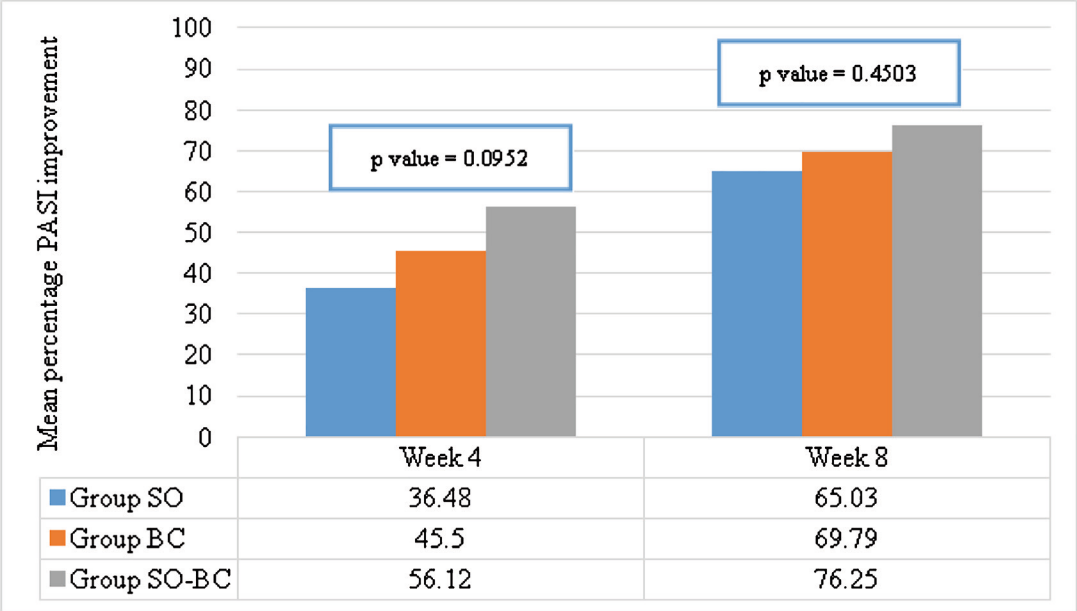


Figure 4. Mean percentage improvement of PASI from baseline at week 4 and week 8 in all treatment arms (n=51)

improvement from baseline PASI between treatment groups at both weeks 4 and 8.

Mean Reduction in Score of the Components of PASI: Erythema, Scaling, Induration

Table 2 shows the mean reduction in score of erythema, scaling, and induration from baseline and at week 4 and week 8. Mean reduction in erythema was higher in Group SO-BC (0.49, 0.70) followed by Group BC (0.41, 0.67) and lastly Group SO (0.32, 0.48) at weeks 4 and 8, respectively. However, the mean reduction in erythema was not statistically significant across the three groups in both week 4 and week 8.

In terms of scaling, mean reduction in score of scaling significantly differed across the treatment groups. Further analysis revealed that mean reduction in score was significantly higher in Group SO-BC compared to Groups SO and BC both at week 4 and week 8.

Mean reduction in induration was not statistically significant across the three groups in both week 4 and week 8. However, there was a higher mean reduction for induration in Group SO-BC followed by Group BC and lastly Group SO in week 4 and week 8.

Table 2. Mean reduction in score of erythema, scaling, and induration from baseline and at week 4 and week 8 in all treatment arms (n=51)

	Group SO: Sunflower oil + placebo cream Mean ± SD	Group BC: Betamethasone valerate cream + placebo oil Mean ± SD	Group SO-BC: Sunflower oil + betamethasone valerate cream Mean ± SD	P value *significant if p<0.05
Erythema				
Week 4	0.32 ± 0.30	0.41 ± 0.43	0.49 ± 0.40	0.4285
Week 8	0.48 ± 0.28	0.67 ± 0.50	0.70 ± 0.41	0.2827
Scaling				
Week 4	0.27 ± 0.21	0.25 ± 0.21	0.53 ± 0.28	0.0026*
Week 8	0.41 ± 0.32	0.41 ± 0.27	0.79 ± 0.41	0.0036*
Induration				
Week 4	0.37 ± 0.31	0.39 ± 0.21	0.49 ± 0.24	0.4150
Week 8	0.49 ± 0.38	0.63 ± 0.29	0.69 ± 0.41	0.3205

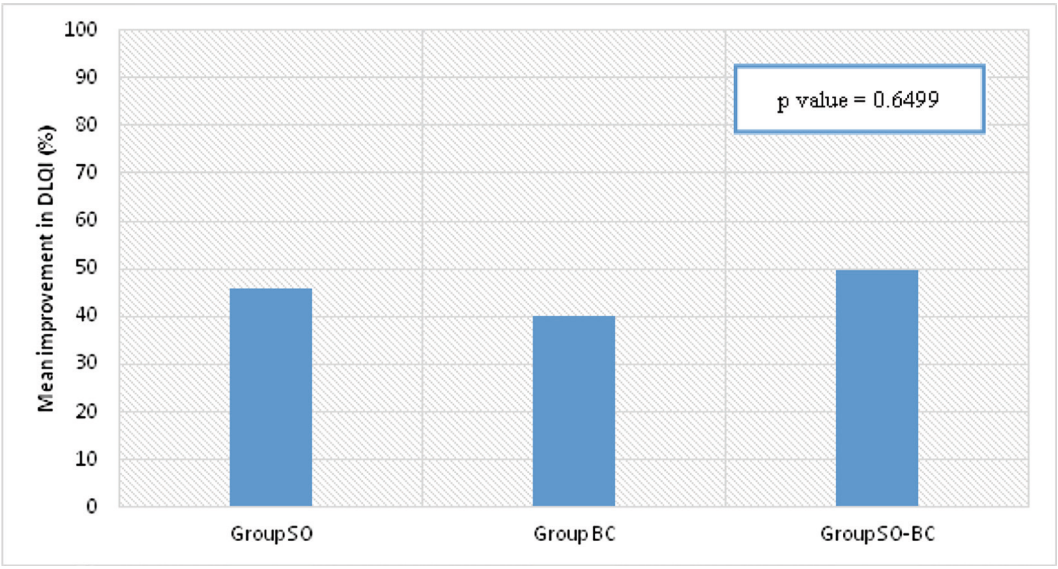


Figure 4. Mean improvement of DLQI at week 8 by treatment arm (n=51)

Dermatology Life Quality Index (DLQI)

Figure 5 shows the improvement in DLQI at week 8 in the three treatment groups. Group SO-BC (49.73%) had the highest mean improvement followed by Group SO (45.78%) and lastly Group BC (40.18%). However, the mean improvement of DLQI among the three groups was not statistically significant (p-value = 0.6499).

Safety

Adverse skin reactions were not seen in all study groups for the entire treatment duration.

Sensitivity Analysis

Figure 5 shows the proportion of patients who achieved PASI ≥50 by treatment group at week 4 and week 8 using per protocol analysis. At week 4, PASI 50 was achieved by 27% patients in Group SO, 40% in Group BC, and 60% in Group SO-BC. There was a further increase in proportion of patients who achieved PASI 50 in week 8. Eighty percent of patients in both Groups SO and BC, and 93% of patients in Group SO-BC achieved PASI 50 at week 8. The proportion of patients who achieved PASI 50 did not significantly differ across treatment arms in both week 4 (p-value = 0.216) and week 8 (p-value = 0.668).

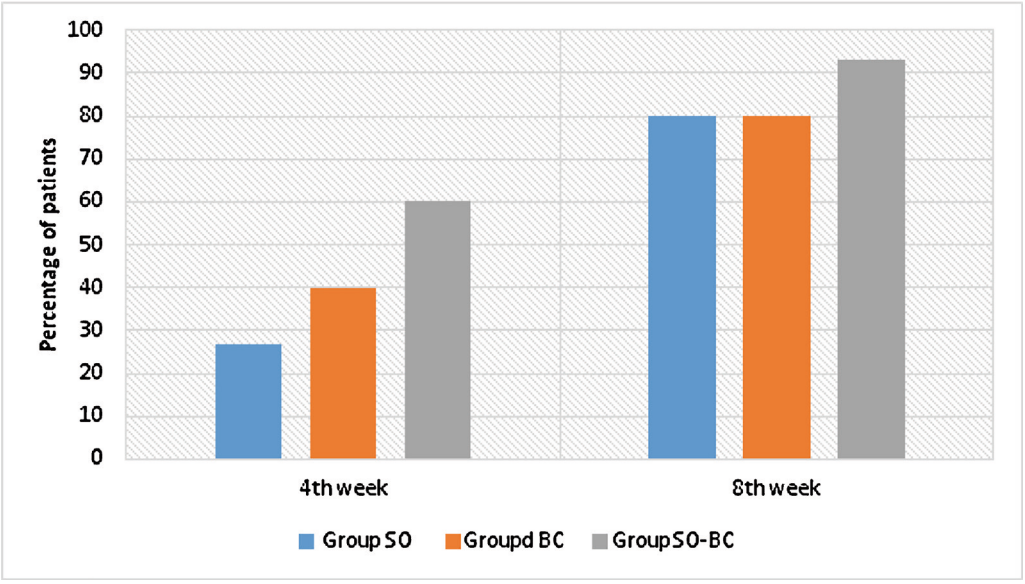


Figure 5. Percentage of patients who achieved PASI 50 at week 4 and week 8 by treatment arm using per protocol analysis (n=45)

DISCUSSION

Efficacy of Sunflower Oil

This study shows that sunflower oil can be used as a monotherapy for psoriasis, achieving equal PASI 50 in 80% of patients similar to the standard steroid cream. This can be attributed to its anti-inflammatory property. Sunflower oil has a high content of linoleic acid which is a potent activator of peroxisome proliferator activated receptor-alpha (PPAR-alpha). [12] In an experiment made by Rivier et al, they demonstrated that there was a decrease in PPAR-alpha in the lesional skin of patients with psoriasis. [25] A topical PPAR-alpha agonist was shown to decrease tumor necrosis factor alpha (TNF-alpha) and interleukin-1 alpha in the skin.[26] TNF-alpha plays a central role in the pathogenesis of psoriasis. It is a pro-inflammatory cytokine produced by activated T cells and dendritic cells and it works synergistically with other cytokines to promote inflammation. Thus, a PPAR-alpha agonist like sunflower oil can reduce TNF-alpha leading to the improvement of psoriasis.

Another mechanism of sunflower oil in psoriasis is its moisturizing effect. Psoriasis skin exhibits increased transepidermal water loss (TEWL) along with its associated decreased barrier function, which was found to be correlated to the severity of psoriasis. [27] Moisturizers are considered adjuncts in the treatment of psoriasis. It enhances the penetration of other topical medications by increasing the hydration of the stratum corneum.[28] Studies on sunflower oil showed that it preserved the stratum corneum integrity, improved skin hydration by 18%, and reduced dryness and scaling by 54%.[12,29] Sunflower oil is composed of 55-70% linoleic acid, an essential polyunsaturated omega-6 fatty acid with 2 cis double bonds.[30] A linoleic acid transporter is present on keratinocytes that enables the absorption of sunflower oil which contributes to the formation of a functional epidermal barrier.[31] This essential fatty acid together with the activation of PPAR-alpha receptor helps maintain the skin barrier and decrease transepidermal water loss.[29]

The efficacy of sunflower oil was further seen in the decrease of the mean PASI score. This study shows that there was continuous improvement in the sunflower oil group from baseline till the end of treatment.

Furthermore, the mean percentage improvement in PASI at week 8 showed 65% in Group SO and 70% in Group BC. This is similar in literature in which a mid-potent corticosteroid cream achieved a mean percentage improvement in PASI by 60-69.36% in 8 weeks.[32,33] The results were also higher compared to moisturizers that were used as controls on different trials which showed improvement of only 15-47%.[34] Due to its effectiveness as a monotherapy, sunflower oil can be a good treatment option, especially to those patients with steroid phobia. To those who have adverse effects of prolonged steroid use, drug holidays can be recommended by using sunflower oil.

Despite both Groups BC and SO-BC being given a similar steroid cream, Group SO-BC had a higher percentage improvement in PASI from week 4 and was able to sustain it effectively till the end of treatment when compared to Group BC. The mineral oil in Group BC only exhibits moisturizing properties and does not significantly decrease PASI from baseline to 12 weeks of treatment.[35-37] This highlights the advantage of the additive effect of sunflower oil to the standard topical steroids treatment in mild to moderate psoriasis.

In terms of erythema, Groups BC and SO-BC had a higher mean reduction in score when compared to Group SO alone. Sunflower oil has no vasoconstrictive effect. Steroid creams however induce vasoconstriction of the blood vessels in the upper dermis which can result in early decrease of lesion erythema.[38] Group SO-BC showed a statistically significant reduction of score in scaling and had the highest decrease in induration compared to the other groups. The inherent properties of sunflower oil is to decrease TNF-alpha and improve skin barrier function along with its moisturizing property that can enhance the absorption of the vasoconstrictive, anti-inflammatory, and anti-mitotic effects of steroids. All these lead to decrease in scores of all the components of PASI.[29,38] The additive effect of both medications may decrease the amount and duration as well as the risks of adverse reactions to topical steroids.

The per protocol analysis showed similar results with the intention to treat analysis and thus similar findings can be concluded.

Improvement in Quality of Life

There was a 40-50% improvement in the DLQI scores in the three groups. The mean improvement of

DLQI scores among the groups was not statistically significant. This shows that whether you use sunflower oil, a standard steroid cream, or a combination of both will all give improvement in the quality of life.

Safety of Sunflower Oil

Adverse skin reactions were not seen in all study groups for the entire treatment duration.

Studies on sunflower oil recommended its use in all skin types. It does not cause irritation or erythema on the skin of normal individuals, neonates, and patients with atopic dermatitis.[10-12]

Limitations and Generalisability

Post-hoc power analysis showed only 16% and 34% statistical power to detect a significant difference in between groups for the primary outcome of interest in week 4 and week 8, respectively. The non-significant difference in between groups could have been due to a high beta error or there is really no significant difference between the groups. The study included adult patients with mild to moderate psoriasis, thus the results may be different in pediatric patients.

CONCLUSION

This study showed that sunflower oil is effective and safe in mild to moderate chronic plaque-type psoriasis. The proportion of patients who achieved PASI ≥50 at week 8 was similar in Groups SO and BC while Group SO-BC achieved a higher proportion. The mean percentage change of PASI was the highest in Group SO-BC followed by Group BC and Group SO; however, the differences between groups did not reach statistical significance. Baseline PASI was significantly higher and showed a decreasing trend in both week 4 and week 8 in all treatment groups. There was a 40-50% relative improvement in the DLQI scores in the three groups. There was no incidence of adverse events for each treatment group for the entire treatment duration.

RECOMMENDATION

The mean PASI score showed a decreasing trend in week 4 and week 8 in Groups SO and SO-BC. This study recommends a longer duration to see the maximum treatment effect of sunflower oil. A research study with a larger population to detect significant difference between groups is also warranted. We also recommend exploring the role of sunflower oil as a steroid-sparing agent.

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APPENDICES

APPENDIX A. Data Collection Sheet

STUDY NUMBER: _____

A. DEMOGRAPHIC AND CLINICAL INFORMATION

Age	_____ years old
Sex	o Male o Female
BMI	
Duration of disease	_____ months _____ years
Previous medications:	o Topicals: _____ o Phototherapy o Systemic treatment: _____ o Biologics
Underlying disease *Check all that applies*	o Hypertension o Diabetes mellitus o Dyslipidemia Others:_____

B. DERMATOLOGIC ASSESSMENT

	Baseline	**Wk4**	**Wk8**
PASI			
DLQI			

C. ADVERSE EVENT

Week 4 *Check all that applies*	o Erythema **("pamumula")** o Stinging sensation/pain **("pagkahapdi")** o Pruritus **("pangangati")** o Others: _____
Week 8 *Check all that applies*	o Erythema **("pamumula")** o Stinging sensation/pain **("pagkahapdi")** o Pruritus **("pangangati")** o Others: _____

APPENDIX B: Psoriasis Area and Severity Index (PASI)

Study Number: _____ Date of visit: _____ Week: _____

Plaque characteristic	Lesion Score	Head	Upper limbs	Trunk	Lower limbs
Erythema	0 = None				
	1 = Slight				
Induration/thickness	2 = Moderate				
	3 = Severe				
Scaling	4 = Very severe				
Add together each of the 3 scores for each body region to give 4 separate sums (A)					
	Lesion Score Sum (A) Multiply by Area Score				
Area Score (B) *Degree of involvement as a percentage for each body region affected (score each region with score between 0-6)* 0 = 0% 1 = <10 2 = 10 – <30% 3 = 30 – <50% 4 = 50 – <70% 5 = 70 – <90% 6 = 90 – <100%					
Subtotals (C) *Multiply Lesion Score Sum (A) by Area Score (B), for each body region, to give four individual subtotals (C)*					
Multiply each of the Subtotals (C) by amount of body surface area represented by that region.		×0.1	×0.2	×0.3	×0.4
Total (D)					
PASI: (A+B+C+D)					

APPENDIX C: DERMATOLOGY LIFE QUALITY INDEX (DLQI)

Study Number: _____ Date of visit: _____ Week: _____

The aim of this questionnaire is to measure how much your skin problem has affected your life OVER THE LAST WEEK. Please tick one box for each question.

1. Over the last week, how **itchy, sore, painful or stinging** has your skin been?	Very much A lot A little Not at all	☐ ☐ ☐ ☐
2. Over the last week, how **embarrassed** or **self-conscious** have you been because of your skin?	Very much A lot A little Not at all	☐ ☐ ☐ ☐
3. Over the last week, how much has your skin interfered with you going **shopping** or looking after your **home** or **garden?**	Very much A lot A little Not at all Not relevant	☐ ☐ ☐ ☐ ☐
4. Over the last week, how much has your skin influenced the **clothes** you wear?	Very much A lot A little Not at all Not relevant	☐ ☐ ☐ ☐ ☐
5. Over the last week, how much has your skin affected any **social** or **leisure** activities?	Very much A lot A little Not at all Not relevant	☐ ☐ ☐ ☐ ☐
6. Over the last week, how much has your skin made it difficult for you to do any **sport?**	Very much A lot A little Not at all Not relevant	☐ ☐ ☐ ☐ ☐
7. Over the last week, has your skin prevented you from **working or studying**?	Yes No Not relevant	☐ ☐ ☐
If "No", over the last week how much has your skin been a problem at **work or studying**?	A lot A little Not at all	☐ ☐ ☐
8. Over the last week, how much has your skin created problems with your **partner** or any of your **close friends** or **relatives?**	Very much A lot A little Not at all Not relevant	☐ ☐ ☐ ☐ ☐
9. Over the last week, how much has your skin caused any **sexual difficulties?**	Very much A lot A little Not at all Not relevant	☐ ☐ ☐ ☐ ☐
10. Over the last week, how much of a problem has the **treatmen**t for your skin been, for example by making your home messy, or by taking up time?	Very much A lot A little Not at all Not relevant	☐ ☐ ☐ ☐ ☐

Please check if you have answered EVERY question. Thank you.

SCORING

Very much	Scored 3
A lot	Scored 2
A little	Scored 1
Not at all	Scored 0
Not relevant	Scored 0
Question 7, "prevented work or studying"	Scored 3

The DLQI is calculated by adding the score of each question resulting in a maximum of 30 and a minimum of 0. The higher the score, the more quality of life is impaired.

0-1	no effect at all on patient's life
2-5	small effect on patient's life
6-10	moderate effect on patient's life
11-20	Very large effect on patient's life
21-30	Extremely large effect on patient's life

APPENDIX D. Taluntunin ng kalidad ng buhay na hinggil sa dermatolohiya (DLQI)

Study Number: _____ Araw ng Pagbisita: _____ Linggo: _____

Ang layunin ng palatanungang ito ay upang masukat kung gaano naapektuhan ng iyong problema sa balat ang iyong buhay SA NAKARAANG LINGGO. Mangyaring lagyan ng tsek ang isang kahon para sa bawat tanong.

1. Sa nakaraang linggo, gaano **kakati, kakirot, kasakit** o **kahapdi** ang iyong balat?	Labis-labis Labis Bahagya Walang wala	☐ ☐ ☐ ☐
2. Sa nakaraang linggo, gaano ka **napahiya** o **may labis na kamalayan sa tingin ng ibang tao** dahil sa iyong balat?	Labis-labis Labis Bahagya Walang wala	☐ ☐ ☐ ☐
3. Sa nakaraang linggo, gaano nakasagabal ang iyong balat sa iyong **pamimili** o pag-aasikaso sa iyong **bahay** o **bakuran**?	Labis-labis Labis Bahagya Walang wala Hindi angkop	☐ ☐ ☐ ☐ ☐
4. Sa nakaraang linggo, gaano nakaimpluwensya ang iyong balat sa **mga damit** na iyong sinusuot?	Labis-labis Labis Bahagya Walang wala Hindi angkop	☐ ☐ ☐ ☐ ☐
5. Sa nakaraang linggo, gaano nakaapekto ang iyong balat sa anumang mga gawaing **pakikisalamuha sa tao** o **panlibangan**?	Labis-labis Labis Bahagya Walang wala Hindi angkop	☐ ☐ ☐ ☐ ☐
6. Sa nakaraang linggo, gaano nagpahirap ang iyong balat na makalaro ka sa anumang **isport**?	Labis-labis Labis Bahagya Walang wala Hindi angkop	☐ ☐ ☐ ☐ ☐
7. Sa nakaraang linggo, nahadlangan ka ba ng iyong balat na **makapagtrabaho** o **makapag-aral**? Kung "Hindi", sa nakaraang linggo, gaano naging problema ang iyong balat sa **trabaho** o **pag-aaral**?	Oo Hindi Labis Bahagya Walang wala	☐ ☐ ☐ ☐ ☐
8. Sa nakaraang linggo, gaano nakalikha ng mga problema ang iyong balat sa iyong **kapareha** o sa sinuman sa iyong mga **malalapit na kaibigan** o **kamag-anak**?	Labis-labis Labis Bahagya Walang wala Hindi angkop	☐ ☐ ☐ ☐ ☐
9. Sa nakaraang linggo, gaano naging sanhi ang iyong balat sa anumang **mga kahirapan sa pakikipagtalik**?	Labis-labis Labis Bahagya Walang wala Hindi angkop	☐ ☐ ☐ ☐ ☐
10. Sa nakaraang linggo, gaano naging problema ang **paggamot** sa iyong balat, halimbawa, gawing makalat ang iyong tahanan o sa pag-aksaya ng oras?	Labis-labis Labis Bahagya Walang wala Hindi angkop	☐ ☐ ☐ ☐ ☐

PAGMAMARKA

Labis-labis	Scored 3
Labis	Scored 2
Bahagya	Scored 1
Walang wala	Scored 0
Hindi angkop	Scored 0
Ika-7 na tanong, nahadlangan ka ba ng iyong balat na **makapagtrabaho** o **makapag-aral**?	Scored 3

The DLQI is calculated by summing the score of each question resulting in a maximum of 30 and a minimum of 0. The higher the score, the more quality of life is impaired.

0-1	no effect at all on patient's life
2-5	small effect on patient's life
6-10	moderate effect on patient's life
11-20	Very large effect on patient's life
21-30	Extremely large effect on patient's life

APPENDIX E. – CHI-SQUARE TEST POWER ANALYSIS (sample size)

Chi-Square Test Power Analysis

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Numeric Results for Chi-Square Test

Power	N	W	Chi-Square	DF	Alpha	Beta
0.90624	46	0.5300	12.9214	2	0.05000	0.09376

Report Definitions

Power is the probability of rejecting a false null hypothesis. It should be close to one.
N is the size of the sample drawn from the population. To conserve resources, it should be small.
W is the effect size - a measure of the magnitude of the Chi-square that is to be detected.
DF is the degree of freedom of the Chi-square distribution.
Alpha is the probability of rejecting a true null hypothesis.
Beta is the probability of accepting a false null hypothesis.

Summary Statements

A sample size of 46 achieves 91% power to detect an effect size (W) of 0.5300 using 2 degrees of freedom Chi-square test with a significance level (alpha) of 0.05000.

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