

Original Research Article

A prospective observational study on efficacy of black acetic acid combination peel in patients of facial nodulocystic acne

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ABSTRACT

Background: Nodulocystic acne is a severe form of acne which can result in significant damage to the skin with great impact on quality of life. Oral isotretinoin is considered to be the best treatment for such cases. Although it has a high rate of success and its efficacy is well established in the treatment of nodulocystic acne, it may occasionally fail to meet expected degree of disease control. Known side-effects and long duration to achieve cumulative dose might lead to poor compliance and known contraindications sometimes as well limit its usage.

Methods: A prospective observational studies on 20 patients who presented themselves with facial nodulocystic acne on regular OPD basis and were poorly compliant to treatment with isotretinoin owing to its side-effects, the drug failed to meet patients' expectations or due to any contraindication to isotretinoin usage were included. A peel containing black acetic acid, jasmonic acid, salicylic acid, potassium iodide ("black peel", Theraderm) was used topically as an alternative treatment, for a course of 3 treatment sittings 2 weeks apart.

Results: Significant reduction of nodulocystic lesions was noted after 3 sittings of "black peel" 2 weeks apart. Among 20 patients 55% showed excellent response; 45% showed good response while none of the patients were non responsive. Post treatment ISGA score of 0.45 as opposed to pre-treatment score of 3.70 ($p < 0.0001$) was observed.

Conclusions: Black peel can be used as promising and hopeful alternative treatment for difficult to treat nodulocystic acne.

Keywords: Acne vulgaris, Acne conglobata, Isotretinoin, Black peel

INTRODUCTION

Acne vulgaris is one of the commonest skin disorders which may present at any age but mainly affects adolescents. Acne by definition is multifactorial chronic inflammatory disease of pilosebaceous units.¹ Various clinical presentations include seborrhoea, comedones, erythematous papules and pustules, less frequently nodules, deep pustules or pseudocysts, and ultimate scarring in few of them. Acne has four main pathogenetic mechanism-increased sebum productions, follicular

hyperkeratinisation, *Propionibacterium acne* (*P. acne*) colonization, and the products of inflammation.²⁻⁵

Nodulocystic acne is a severe form of acne treated mainly by oral isotretinoin. Even though it is a very effective drug, it has been implicated in numerous reports that describe a wide range of systemic side effects. Moreover, it could result in worsening of acne lesions, up to an extremely serious form of acne known as acne fulminans, characterized by systemic symptoms, including fever, weight loss, myalgia, and arthralgia.⁶ Here we did prospective case studies of patients of nodulocystic acne

not responding to oral isotretinoin treated with a newer combination of organic peel containing black acetic acid, jasmonic acid, salicylic acid, potassium iodide and biosulfur ("black peel", Theraderm) as an alternative treatment, and we reached a significant remission of acne lesions assessed after 3 treatment sittings 2 weeks apart. "Black peel" can be used as promising and hopeful alternative treatment for nodulocystic acne when isotretinoin fails to meet the expected level of results.

METHODS

The present prospective observational study was conducted between December 2018 to August 2019 in the Department of Skin, Venereology and Leprology, BRD Medical College, Gorakhpur. A written informed consent was taken from all the patients and ethical clearance was obtained from appropriate authorities of the college. Twenty patients with facial nodulocystic acne who were poorly compliant to treatment with isotretinoin, failed to achieve expected disease control or due to any known contraindication to isotretinoin usage in the age group of 15 to 50 years, were included in the study. The drug was discontinued for at least 3 months before starting the sessions of peeling. Diagnosis was made on the basis of typical clinical features. The skin of each patient was thoroughly prepared with a cleanser and a toner followed

by comedone extraction; if needed and application of black peel with the help of a tooth-pick. The peel was left 7-10 minutes and then washed with normal saline. Finally a thick coating of sunscreen was applied over the whole face. After each session antibiotics and anti-inflammatory agents were prescribed for 5 days to prevent secondary infection, erythema and pain (due to comedone extraction). A face cleanser and a sunscreen was also prescribed for regular application. Maximum of 3 treatment sessions of black acetic acid containing peel ("black peel"), every 2 week were undertaken. Final assessment was made 2 weeks after last treatment on the basis of investigators static global assessment (ISGA) scale (Table 1) having 6 levels from Grade 5 (severest) to Grade 0 (clear) and self-satisfaction assessment scale by patients in 5 levels from excellent (4) to aggravation (0), excellent (4), good (3), fair (2), no change (1), aggravation (0). Patient was checked for adverse effects if any on each session. Patient was graded to have excellent treatment outcome if there was complete clearance of acne. Rare non-inflammatory papules with almost clearance of acne was graded to be having good response while patients with no improvement from the treatment or aggravation of the disease were considered to be graded as of poor respondents.

Table 1: Investigators static global assessment scale.

Grade	Description
Grade 0	Normal, clear skin with no evidence of acne vulgaris.
Grade 1	Skin almost clear, rare non-inflammatory lesions present with rare non-inflamed papules (papules must be resolving and may be hyperpigmented, though not pink red) requiring no other treatment in the investigators
Grade 2	Some non-inflammatory lesions are present, with few inflammatory lesions (papules/pustules only, no nodulocystic)
Grade 3	Non-inflammatory lesions predominate with multiple inflammatory lesions evident: several to many comedones and papules/pustules and there may or may not be one small nodulocystic lesions.
Grade 4	Inflammatory lesions are more apparent: many comedones and papules/pustules, there may or may not be a few nodulocystic
Grade 5	Highly inflammatory lesions predominate: variable number of comedones, many papules/pustules and nodulocystic lesions.

RESULTS

Following results were noted 2 weeks after 3 sessions of black acetic acid combination peel (Figures 1-3) on the basis of ISGA and self-satisfaction assessment scale by patients.

Table 2: Demographic distribution of patients.

Total no. of patients	%
Male (10)	50
Female (10)	50

Out of twenty patients (20) included in my study having 10 males and 10 females (Table 2) excellent response with complete clearance of acne (ISGA 0) was observed

in 55% patients (11 out of 20) while a good response with almost clear skin and rare non-inflammatory papules (ISGA 1) were observed in 45% patients (9 out of 20).



Figure 1: Response observed after 3 sessions of "black peel" in an ISGA grade 4 patient.

Almost complete clearance of acne after 3 sessions of black peel (good response). ISGA score improved from 5 to 1.



Figure 2: Response observed after 3 sessions of black peel in an ISGA grade 4 patients.

Complete clearance of acne after 3 sessions of black peel (excellent response). ISGA score improved from 4 to 0.



Figure 3: Response observed after 3 sessions of black peel in an ISGA grade 4 patients.

Complete clearance of acne after 3 sessions of black peel (excellent response). ISGA score improved from 4 to 0.

No patient (0 out of 20) in my study was observed to have a poor response with non-responsiveness or aggravation on treatment (Figure 4).

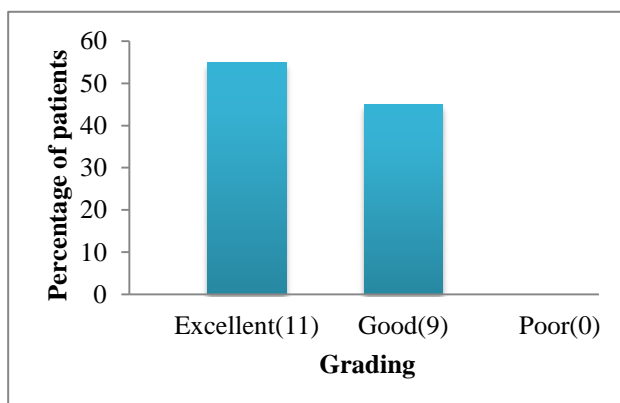


Figure 4: Response of treatment after 3 sessions of "black peel" with respect to ISGA scoring.

55% of patients (11 out of 20) assessed the treatment to be excellent, 40% of patients (8 out of 20) assessed it to be good while 5% of patients assessed it to be fair (1 out

of 20). None of the patients (0 out of 20) assessed the treatment as being non-responsive or aggravating (Figure 5).

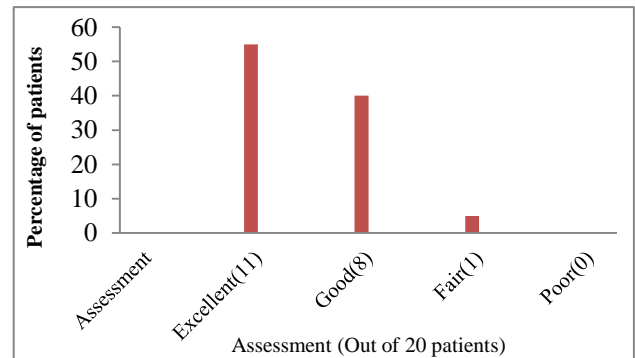


Figure 5: Self-assessment of patient satisfaction.

No major adverse effects were reported with no or minimal scarring, post inflammatory hyperpigmentation or erythema. Pre-treatment of average ISGA scale score of 3.70 improved to post-treatment average of 0.45 ($p < 0.0001$). Individually ISGA score in males improved from 3.8 pre-treatment to 0.2 post-treatment and in females from 3.5 pre-treatment to 0.7 post-treatment with response in males found slightly better than or equal to females in my study (Table 3).

Table 3: Average improvement in ISGA scores pre and post treatment.

	Pre-treatment average ISGA	Post-treatment average ISGA
Males	3.8	0.2
Females	3.5	0.7
Overall average	3.7	0.45

DISCUSSION

Acne is the most common chronic skin disorder among adolescents affecting about 85% of teenagers.¹ It has both financial and psychosocial impact; the latter increases significantly with the severity of the disease.² Treating severe forms of acne including nodulocystic acne is challenging and always requires systemic treatment.³ Different therapeutic options are available including oral antibiotics, hormonal antiandrogens for female patients, oral isotretinoin, and other combination treatments.⁴

Systemic isotretinoin is an extremely useful drug for the treatment of not only severe refractory acne but also moderate acne that fails to respond to conventional therapy or that produces physical scarring or significant psychological distress.^{5,7} It is considered the only drug which changes the course of the disease permanently in severe forms as well as the only drug that targets all four pathogenesis of acne.^{1,3} It reduces sebaceous gland size, sebum secretion, comedone formation, and follicular colonization of *P. acnes*.⁷ However, the reported serious

systemic side effects from isotretinoin usage such as liver damage, depression, behavioural change, suicidal tendency and teratogenicity have created an obstacle to its use as it has been recommended by many clinicians to restrict such treatment for those with severe recalcitrant acne.^{1,7}

Black peel is a new chemical composition based on black acetic acid mixed with jasmonic acid, salicylic acid, potassium iodide and biosulfur.

Black acetic acid so called fermented vinegar has been made traditionally in Japan and Korea. It is characterized by higher levels of amino acids and organic acids.^{8,9} There have been reported many good effects of black acetic acid such as anti-tumor, anti-oxidant, anti-hypertensive.¹⁰⁻¹³ In addition black acetic acid used topically as a skin dressing shows the strongest bactericidal activity against all strains tested. Empirically many people in South Korea have used Black acetic acid for their healthy skins not only drink but also topical wash.¹⁴ Potassium iodide (KI) was empirically used for deep fungal infection and severe vacuities-induced wound. *In-vivo* and *in-vitro* study showed fast wound recovery effects of KI.¹⁵ It can be used as a topical treatment for some skin conditions as it works against infection and as an anti-bacterial and anti-fungal agent. In the topical use for inflammatory lesions and cysts, it works them to go away in a week or two; it appears that the iodide dissolves the fatty, oily material contained in the cysts, allowing our body to slowly reabsorb and dispose of it. In many researches, it has been used successfully for inflammatory dermatosis, most notably erythema nodosum, sub-acute nodular migratory panniculitis, nodular vasculitis, erythema multiforme, and Sweet's syndrome.¹⁶

Jasmonic acid and salicylic acid are plant secreting acid that are released to defend themselves when they are attacked or damaged. Jasmonic acid activates the expression of protease inhibitors which can stop the attack of the harmful insects. Both jasmonic acid and salicylic acid play an important role in the pathogen defence response and also have the anti-inflammatory effect as well as the exfoliating property which can induce a beneficial response of the living layers of skin by correcting a number of signs associated with skin impairment. In a study by Palmieri et al methyl jasmonate was applied topically twice daily on 8 patients having preneoplastic and malignant lesions. 32% (3 out of 8) patient exhibited positive response three months post-treatment.¹⁷

Biosulfur is useful in acne as it helps to kill bacteria on the skin, which results in an improvement in acne, pimples, seborrhoea and psoriasis conditions. It acts as a keratolytic and also has germicidal action.¹⁸

Many clinicians like Elghblawi have used various peeling agents in facial acne, scarring and hyperpigmentation like

black acetic acid with excellent response with single session of treatment but there have been not many well-controlled studies comparing them with other conventional agents.¹⁹

Preliminary study using "black peel" for acne patients was conducted on 13 patients in Department of Dermatology, Sungkyunkwan University School of Medicine, Kangbuk Samsung Hospital, Seoul, Korea showed that it is different from previously used chemical peel in aspect of its composition, safety and efficacy. 3 sessions of black peel for a total of 6 weeks were performed; excellent response to treatment with complete clearance of acne (ISGA 0) was observed in 69% (9 out of 13) patients; good response with almost clear skin having rare non-inflammatory papules (ISGA 1) was observed in 23% (3 out of 13) while poor response (ISGA 2) was observed in 7% (1 out of 13) patients. 38% (5 out of 13) patients assessed the treatment to be excellent, 31% of each (4 out of 13) assessed them good and fair while none of them (0%) assessed treatment to be poor. Pre-treatment of average ISGA scale score of 3.08 improved to post-treatment average of 0.38 ($p < 0.0001$).²⁰ Our study also showed similar results with the difference that none of our patient showed poor response. Post treatment ISGA score of 0.45 as opposed to pre-treatment score of 3.70 ($p < 0.0001$) (Table 2) was observed in our study with excellent response in 55% patient and good response in 45% patients (Figure 1).

Another study comparing peeling effect of black peel and Coomb's solution on acne showed comparable result of both but severe desquamation and post-inflammatory changes were noted in coomb's area which were absent in "black peel" area. In our study also minimal to nil side-effects like erythema, post inflammatory changes were observed.

CONCLUSION

Black acetic acid, KI, salicylic acid and jasmonic acid in "black peel" is ideally effective on various skin problems such as comedones and pigmentations. "Black peel" can be used as promising and hopeful alternative treatment for nodulocystic acne when isotretinoin fails to meet patient's expectations, in poorly compliant patients or where its usage is contraindicated. No significant adverse effects were noted with peeling treatment providing a safe and effective way for restoring patient's image and confidence.

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