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A Clinical Study for Combined Effect of Shodhana and Ropana Karma by Panchwalkal Kwath and Madhukadi Tail in Dustha Vrana

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Abstract: ***Wound which heal very slowly or do not heal despite best efforts are known as dust vrana. Since the time surgery has evolved as a speciality, infection and hemorrhage have been recognized as two well known enemies of surgeon over a period. Nowadays many antibiotics have come into existence, However infection still dominates, and it is one of the major causes of mortality and morbidity in a patient. Acharya Sushruta a pioneer surgeon has mentioned various types of wound and Shasthi Upkrama for its management. Without debridement wound is not heal. So for adequate debridement and healing Panchvalkala kwath and Madhukadi Tail has been used for shodhana and Ropana of dustha vrana.***

Keywords: Dustha Vrana, Diabetic ulcer, Sodhana, Ropana, Panchwalkal kwath, Madhukadi tail

I. INTRODUCTION

In present scenario change in life style of human being has created several conflicts in this biological system as the advancement of busy professional and social life, improper diet habits, which cause digestion problem and deficiency of proper nutrition leads to hormone imbalance that is responsible for unhealthy life or lots of metabolic disorder.

There are Lots of local and general factors which affect the wound healing among, those diabetes mellitus is one such metabolic disorder that impaired or delay the normal process of the wound healing. Diabetic foot ulcer is a major complication of diabetes mellitus and possibly major component of diabetic foot in most developing countries. Diabetes has reached epidemic proportion worldwide, the International Diabetes Federation (IDF) estimates 425 million people living with DM worldwide in 2017[1] Sub-Saharan Africa is currently continuing the heaviest global burden of diabetes estimated 628 million by 2045[2]. Diabetic foot disease (DFD) is one of the diabetic complications associated with major morbidity, mortality and reduced quality of life and the most serious complication of diabetes mellitus[3].The incidence of DFD is still raising .According to international consensus on diabetic foot, a foot ulcer is defined as a full thickness wound below the ankle in diabetic patient, irrespectively of duration according to a systematic review in 2017 prevalence of foot ulcers among diabetic patients ranges from 3% to 13% globally the burden of DFU is increasing due to late diagnosis, poor awareness among patient and poor access to health care[4,5].DFU is preventable and frequency of lower limb amputation can be lowered by 49-87% by preventing the development of DFU. Evidence in the literature suggests that the early detection and treatment of diabetic foot complication could reduce the prevalence of ulceration by 44% to 85% [6, 7]. Age, gender, peripheral vascular disease; peripheral neuropathy and renal disease were common risk factors for death after ulceration [8]. Patient at risk of developing DFU can easily be identified by clinical examination of the feet during follow up early screening of high risk patient is important to prevent development of foot ulcer and its associated morbidity [9]

The knowledge of wound is known since antiquity. Wounds which heal very slowly or do not heal despite best efforts are known as dust vrana. Advancement in science technology and antibiotics has improved a lot in wound healing but understanding its pathology and management is still in the phase of evolution. Ayurveda the oldest and holistic system of medicine offers various tools for the management of dustha vrana. In Sushruta Samhita diabetic ulcer is correlated with "*Madhumehjanya vrana*" during its management sushruta explain that it is difficult to manage i.e. *Kastasadhya* according, to Acharya Sushruta *Meda* and *Rakta* along with *Dosh* and *Dushaya* lead to the formation *Prameh Pidika* which at advanced stage converted to non healing ulcer. In sushruta Samhita the diabetic patient's lower extremities get affected with foot complications, the reason for this given as

Ras carrying channels in patient suffering from *Madhumeha* become weak so *Dosha* fail to come back to the upper part of the body hence cause much problem in the lower half of the body and ultimately give rise to *Pidika/Vrana/Vidradhi/ulce.*[10]

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A. According to Acharya Charka

Pidika are most common complication of *Prameha* as negligence of treating *Prameha Pidika* developed. Acharya Charka has mentioned 10 type of *Pidika* while Acharya Sushruta and Vagbhata has mentioned 10 types of *Pidika* as complication of *Prameha*. [11, 12, 13]

Slightly injury to glucose laden tissue may cause chronic infection and ulcer formation. Ulceration in diabetes may be precipitated by ischemia due to diabetic arthrosclerosis. Glucose laden tissues are more prone to infection and a cause of ulceration. Diabetic polyneuropathy or peripheral neuritis commonly damages nerves in leg and feet and also affect any other part of body. [14]

To treat a wound one must carry out the process of tissue restoration in a way that it must be beneficial to the well being of patient. Without a complete understanding of *Vrana Shodhana* and *Ropana* as well as modern theories such purpose cannot be fulfilled. Every surgeon's main goal is to achieve better wound healing is addressed at various levels since beginning and still a lot of scope for research to figure out and develop a better wound healing solution today. In contrast to ayurveda few healing agent have been used in modern medicine either as internal or external most of the modern drugs serve only to remove slough/debris and prevent bacterial growth which result in wound healing. Several medications derived from plants have been shown to aid in the healing of various types of wounds. Some of these medications have been studied scientifically for their healing properties. The wound/ulcer of diabetic patient is also considered to be challenging to heal. Despite having the most advanced technology and contemporary medicine available as well as a highly trained medical staff on hand the majority of diabetic ulcers results in the amputation of the affected limb. This demonstrates the sage Sushruta's statement reliability.[15] Keeping all these things in view *Panchvalkala kwath*[16] and *Madhukadi Tail*[17] has been selected the present clinical study. The designed clinical study on *Dustha Vrana* and its management drugs for *Shodhana* and *Ropana* study was designed to analyze and evaluate the efficacy of drugs.

B. Aims and Objectives

1) To study dustha vrana as per doctrine of ayurveda.
2) To evaluate the efficacy of vrana shodhana property of Panchwalkal kwath in dustha vrana w.s.r. to diabetic ulcer
3) To evaluate the efficacy of vrana Ropana properties of Madhukadi Taila in dustha vrana w.s.r. to diabetic ulcer
4) To evaluate the efficacy of Betadine ointment in dustha vrana.

II. MATERIAL AND METHODS

A. Source of Data

Diagnosed patient of diabetic ulcer were selected randomly from the O.P.D and I.P.D of M.M.M.Gov.Ayurveda College Campus Hospital Udaipur and Moti Chohatta Ayurveda Hospital Hathipole Udaipur**.**

B. Informed Consent

Information about the drugs to be used, the procedure to be carried out and the probable benefit and risk were explained to the patient in details in non-technical declaration and trilingual. There after their written consent was taken prior to starting the procedure.

C. Selection Criteria

1) Inclusion Criteria

a) Adult male and female
b) Age between 16-80 years
c) Diabetes of type 1 and type 2
d) Wagner grade 1 or 2
e) Patient having clinical features of diabetic ulcer is included.

2) Exclusion Criteria

a) Patient having past history of tuberculosis were excluded.
b) Diagnosed case of critical limb ischemia.
c) Wagner grade. 2 ulcers exposed to tendon and bones.
d) Osteomyelities or gangrenous ulcer
e) Patient suffering from Malignancy, Tubercular ulcer.
f) Uncontrolled diabetes mellitus.

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g) Heart disease like myocardial infarction (MI), Coronary artery disease (CAD), Ischemic heart disease (IHD).
h) Immunosuppressive medications users
i) Patient below 16 years and above 80 year.
j) HIV and STD

3) *Diagnosis Criteria:* Patients were diagnosed on the basis of sign and symptoms of Dushta vrana (diabetic ulcer) as per ayurveda and modern literature.
4) *General investigation*
a) *Routine Examination (Blood Examination)*

- Hb%
- CBC
- B.T.
- C.T.
- E.S.R.
- FBS, PPBS (Before treatment and after treatment).
- Urine examination -Routine and microscopic.

b) *Bacteriological Assay:* Wound swab culture and sensitivity (if needed)
c) *Radiological examination (if needed)*

- X-ray Foot (Dorso-ventral and lateral)
- Chest x-ray posterior anterior view
- MRI ,CT SACN

5) *Study Type:* Intervention
6) *Allocation:* Randomized
7) *Primary Purpose:* Treatment

8) *Treatment Procedure*
a) *In Group A: Panchwalkal Kwath* in form of Decoction is Soaked with Gauze and Applied daily for shodhana .*Madhukadi Oil* in form of Oil Soaked with Gauze and Applied on Wound Area for Ropana and a sterile pad was applied over the ulcer and bandaging was done for 28 days
b) *In Group B:* Betadin Ointment Is applied daily on the ulcer and a sterile pad was applied over the ulcer and bandaging was done for 28 days.

9) Time frame -6 week
10) Trial period -4 weeks
11) Follow up – 2 weeks after the completion of treatment

III. CRITERIA FOR ASSESSMENT

A particular scoring pattern was adopted for the symptomatic relief of subjective parameters as follows during consideration period which mentioned in following table.

1) *Pain (VAS Score)*

Score	Explanation
0	No pain
1	Mild pain (1-3)
2	Moderate pain(4-7)
3	Severe pain (8-10)

Table no.1 pain

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2) Exudate Quantity

Score	Quantity
0	None
1	Dressing marked
2	Dressing wet
3	Dressing soaked

Table no.2 Exudate Quantity

3) Wound area Measurement

Score	Wound measurement (cm^2)
0	<1 cm^2
1	1-4 cm^2
2	5-8 cm^2
3	9-12 cm^2
4	13-16cm^2
5	17-20 cm^2

Table no.3 showing Wound area Measurement

4) Skin Color Surrounding Wound

Grade	Skin Color
0	Pink or normal
1	Bright red or blench
2	White or Grey pallor or hypo pigmented
3	Dark red or purple
4	Black or hyper pigmented

Table no.4 SKIN COLOR SURROUNDING WOUND

5) Odor

Score	Assessment
0	No odour (no order is evident at close proximity to the patient when the dressing is removed)
1	Slight (odour is evident at close proximility to the patient when the dressing is removed
2	Moderate (odour is evident at close proximity to patient when the dressing is intact)
3	Strong (odour is evident upon entering the room (6-10feet from the patient)with dressing is removed
4	Very strong (odour is evident upon entering the room (6-10 feet from the patient) with the dressing intact)

Table no.5 showing Odor

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6) Wound Bed Appearance

Grade	Appearance
0	Granulation (Red)
1	Sloughy (Yellow/Green)
2	Necrotic/ Black
3	Hyper granulation

Table no.6 showing wound bed appearance

IV. RESULTS

Effect of treatment; the effect of treatment was observed in 30 patients who completed the study. Software Graph pad InStat 3(Trial) was used to calculate all the results. To calculate intra-group result nonparametric data Wilcoxon matched pairs signed rank test was used. While intergroup comparisons were calculate by Mann-Whitney test.

A. Within The Group Analysis

1) (Group A Variable Analysis (Wilcoxon matched pairs signed rank test)

Table.No.7. Effect of *Panchwalkal kwath* and *Madhukadi tail* on all variables of Group A

Variable	Mean		Diff. in mean	% Relief	S.D.	S.E	P value	Re.
	B.T	A.T						
Pain	1.73	0.60	1.13	65.31	0.8338	0.2153	0.0002	ES
Exudate	1.93	0.73	1.20	62.17	0.4140	0.1069	<0.0001	ES
Circumference of wound	2.33	0.93	1.40	60.08	0.5071	0.1309	<0.0001	ES
Odour	1.93	0.67	1.27	65.80	0.4577	0.1182	<0.0001	ES
Peri wound skin color	2.00	0.80	1.20	60.00	0.5606	0.1447	<0.0001	ES
Wound bed appearance	1.53	0.40	1.13	73.85	0.3519	0.09085	<0.0001	ES

(BT-Before treatment, AT-After treatment, Diff.-Differences, S.D.-Standard Deviation, E.S.Standard Error ,Re.-Remark ,E.S.-Extremely Significance, N.S.-Not Significance)

2) Group B Variable Analysis **(**Wilcoxon matched pairs signed rank test)

Table No.8. GROUP B Effect of therapy by Betadine ointment

Variable	Mean		Diff.in mean	% Relief	S.D	S.E	P value	Re
	B.T	A.T						
Pain	1.46	0.53	0.93	63.69	0.7988	0.2063	0.0010	ES
Exudate	1.80	0.73	1.07	59.44	0.2582	0.06667	<0.0001	ES
Circumference of wound	2.40	1.13	1.27	52.91	0.4577	0.1182	<0.0001	ES
Odour	2.13	0.93	1.20	56.33	0.4140	0.1069	<0.0001	ES
Peri wound skin color	2.06	0.93	1.13	54.85	0.3519	0.09085	<0.0001	ES
Wound bed appearance	1.53	0.46	1.07	69.93	0.2582	0.06667	<0.0001	ES

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Table no.9. Comparative effect of Panchwalkal kwath + Madhukadi tail and Betadine ointment on wound healing (Mann-Whitney Test)

Variable	Mean		Diff.	%	P value	Re.
	Group A	Group B				
Pain	1.13	0.93	0.20	17.69%	0.2889	NS
Exudate	1.20	1.07	0.13	10.83%	0.1537	NS
Wound circumference	1.40	1.27	0.13	9.28%	0.4903	NS
Odour	1.27	1.20	0.07	5.51%	0.3460	NS
Peri wound skin	1.20	1.13	0.07	5.83%	0.4860	NS
Wound bed appearance	1.13	1.07	0.06	5.30%	0.2883	NS

Table no.10. Comparative effect of Panchwalkal kwath + Madhukadi tail and Betadine ointment on wound healing (Mann-Whitney Test)

Variable	Mean		Diff.	%	P value	Re.
	Group A	Group B				
Pain	1.13	0.93	0.20	17.69%	0.2889	NS
Exudate	1.20	1.07	0.13	10.83%	0.1537	NS
Wound circumference	1.40	1.27	0.13	9.28%	0.4903	NS
Odour	1.27	1.20	0.07	5.51%	0.3460	NS
Peri wound skin	1.20	1.13	0.07	5.83%	0.4860	NS
Wound bed appearance	1.13	1.07	0.06	5.30%	0.2883	NS

Table no. 11. Overall Effect of Therapies

Result	Panchwalkal kwath + Madhukadi Taila		Betadine ointment	
	No. of patient	%	No. of patient	%
Cured	02	13.33	00	00
Markedly improved	02	13.33	01	6.66
Moderately improved	07	46.66	11	73.33
Mild improved	04	26.67	03	20
Unchanged	00	00	00	00

It was asses that 13.33% were cured in group A (Panchwalkal kwath and Madhukadi tail) while 0% was cured in group B (Betadine). Marked improvement cases were observed 13.33% in treated group A Whereas 6.66% was observed in group B. 46.66% of patients get moderate improvement in group A and 73.33% in group B. 26.67 % of patient get mild improved in group A and 20 % of patient get mild improved in group B.

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V. DISCUSSION

A. Effect of therapies on Dustha Vrana

1) *Effect on Vrana Gandha:* Statically analysis the inter group study show that reduced odour of ulcer was not significant (P value 0.3460) with less 5.51% relieved in Group B from Group A.
2) *Effect on peri- wound Skin:* According to statically analysis, the peri wound skin color get normal color was not significant (P value 0.4860) with 5.83% less relieved in group B from group A.
3) *3 & 4 Effect on exudates (Exudates level and Types):* As a result, according to statically analysis, the inter group study found that Exudate quantity (Discharge from wound) reduced in ulcer was not significant (P value 0.1537) with 10.83% less reduced in Group B from Group A.
4) *Effect on Pain:* According to statically analysis, the intergroup study found that pain relieved in the wound was not significant (P value is 0.2889)17.69% less relief in Group B from Group A.
5) *Effect on Akriti (Shape and Size of Wound):* According to statically analysis the wound bed get granulation tissue was not significant (P value 0.2883) with 5.30% less in Group B from group A.
6) *Overall Effect of Treatment:* The improvements in the symptoms of *Dustha Vrana* are in Group A 63.96% followed by group B 58.50%.

VI. CONCLUSION

Following conclusion drawn on the basis of this study.

1) Maximum patients was from age group 41 to 60 years (66.66%)
2) Maximum no. of patient was male 80.00%
3) Maximum no. of patient were Hindu 70 %
4) Maximum no. of patient were married 93.33%
5) Maximum no. of patient was uneducated 36.66% and labor 40% and 50%, belongs to lower socio economic status.
6) Maximum number of patient 36.66% no addiction.
7) Maximum number of patient was followed mixed diet 60%
8) Maximum number of patient had *Mand Agni* 56.66%
9) Maximum number of patient has *Visham Nindra* 40%
10) Maximum No. of patient were suffering from diabetic ulcer 1-6 month 86.66%
11) Maximum no. of patient have chronic onset 96.665%
12) Maximum no. of patient have single wound 96.66%
13) Maximum no of patient having *Peetabhav* discharge 56.66% and 90% having thick consistency. Mild discharge 86.0%
14) Maximum no. of patient having pain at the site of ulcer during walking and dressing and at the stage of healing 73.33%.
15) All patient observed that having odour from ulcer site.
16) Maximum no. of location of ulcer on lower limb 86.65%

A. Overall Result of Therapy

It was asses that 13.33% were completely cured in Group A (*Panchwalkal kwath* and *Madhukadi Tail*) while 0% was completely cured in Betadine. Marked improvement cases were observed 13.33% in treated group A (*Panchwalkal kwath* and *Madhukadi tail).* Whereas 6.66% was observed in Group B (Betadine ointment).46.66% of patient get moderate improvement in Group A (*Panchwalkal kwath* and *Madhukadi tail)* and 73.33% in Group B Betadine ointment.26.67 % of patient get mild improved in Group A (*Panchwalkal kwath and Madhukadi* tail) while 20 % of patient get mild improved in Group B (Betadine ointment).

1) Based on clinical observations, the study concluded that the *Panchwalkal kwath* is a better healing medicine in the therapy of diabetic wounds because its antibacterial action limits the growth of bacteria Panchwalkal kwath, a clinical trial drug, has wound debridement (*Vrana Lekhana*), wound cleansing (*Vrana-Shodhana*), *and Madhukadi Taila* quick wound healing (*Vrana-Ropana*) properties.
2) The drug's antioxidant and free radical scavenging activity cleans the wound while also promoting neovascularization and restoring nerve tone to restore feeling.
3) It was also determined that the wounds healed within the regular time period and with satisfactory results, with minimum scarring and no complications.

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4) The *Panchwalkal kwath* and *Madhukadi Taila Vaikritapaham* (good cosmetic impact) property results in re-pigmentation and reduced scar tissue formation that resembles surrounding tissue.

5) In comparison to Betadine ointment, *Panchwalkal kwath* and *Madhukadi tail* relieves the signs and symptoms of diabetic wounds such as *Gandha* (odour), *Varna* (color of periwound skin), *Srava* (exudates), *Vedana* (pain), and *Akriti* (shape and size of wound).

6) According to the current Ayurvedic management of *Vrana* in the form of *Panchwalkal kwath and Madhukadi tail*, the trial medicine is low cost effective due to the need for fewer pharmaceuticals and better recovery.

7) In the current study, there were no adverse drug reactions (ADRs) or side effects. Indicates that the drug in the form of kwath and Madhukadi Taila as an external or topical application is safe.

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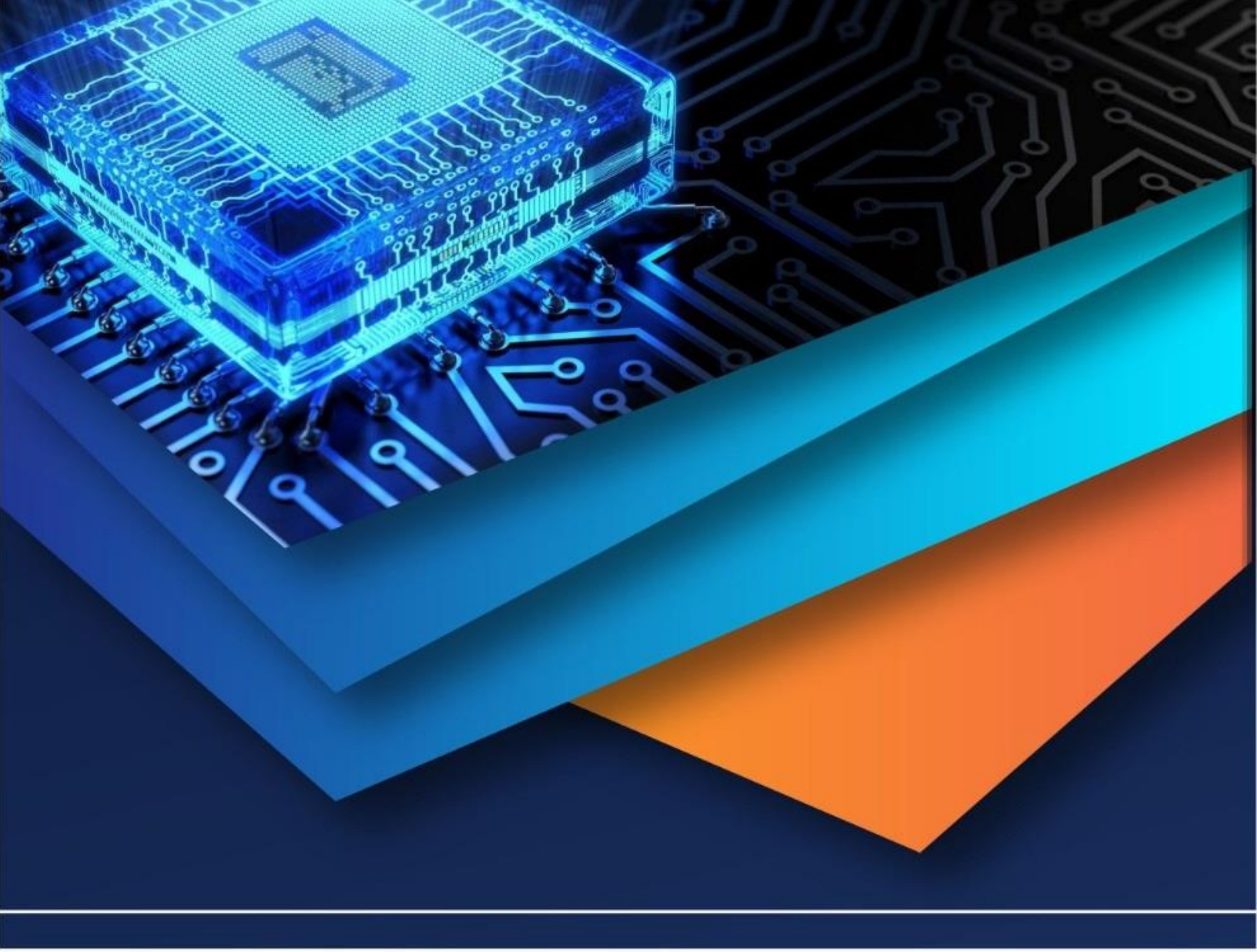

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