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Protocol for an Open Labelled Randomised Comparative Clinical Study to Evaluate Efficacy of *Gudanagaradi Gutika* and *Phalatrikadi Kwatha* in Management of *Pandu Roga* (Iron Deficiency Anaemia)

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Abstract: Background: In Ayurveda, Pandu Roga is one of the major disease described in classical Ayurvedic texts, presents with symptoms similar to Iron Deficiency Anaemia (IDA) such as pallor, fatigue, anorexia. In India Anaemia affects estimated 50% of the population. Conventional iron supplements, although effective, are often accompanied by gastrointestinal and other adverse effects. Traditional formulations Gudanagaradi Gutika and Phalatrikadi Kwatha offer potential safer alternatives based on their hematopoietic and digestive stimulant properties. This study aims to compare these two Ayurvedic interventions for managing Pandu Roga .
Objective: To evaluate and compare the clinical efficacy and safety of Gudanagaradi Gutika and Phalatrikadi Kwatha in the management of Pandu Roga (Iron Deficiency Anaemia).
Methods: A single-centered, open-labelled, parallel comparative clinical trial will be conducted on 60 patients (aged 25–45 years) diagnosed with Pandu Roga. Participants will be randomized into two groups (n = 30 each).Group-A(Intervention),Gudanagaradi Gutika (500 mg twice daily) and Group-B (Comparator),Phalatrikadi Kwatha (50 ml twice daily).The treatment will continue for 28 days. Outcome assessments include subjective parameters (pallor, anorexia, etc.) and objective parameters (Hemoglobin levels, Serum Ferritin etc). Follow-up evaluations on days 7^{th}, 14^{th}, 21^{st}, 28^{th} during treatment and days 42^{nd} and 56^{th} post-treatment. Statistical significance is set at $p < 0.05$.
Expected Results: Both formulations will anticipated to improve clinical symptoms and hematological parameters; however, Gudanagaradi Gutika is hypothesized to yield a superior efficacy because of its hematopoietic and digestive stimulant components.
Conclusion: This study may validate evidence-based Ayurvedic alternative to conventional IDA therapies, supporting the integration of traditional formulations into mainstream management protocols.
Keywords: Pandu Roga, Iron Deficiency Anaemia, Gudanagaradi Gutika, Phalatrikadi Kwatha, Ayurveda, Clinical Trial.

I. INTRODUCTION

Ayurvedic classics like the *Charaka Samhita* and *Sushruta Samhita* describe its etiology and symptomatology in detail. According to *Acharya Charaka*, *Pandu Roga* is a *Rasapradoshaja Vyadhi* which is a *Pitta* dominant *Tridoshaja* disease. According to *Acharya Charaka*[1], and *Acharya Sushruta*[2] *Rasa Dhatu* which is formed by digested food particles contains the *Sara* of all seven *Dhatu* becoming *Rakta Dhatu* from the function of *Ranjak Pitta* and *Raktagni* on it. *Rakta* has been considered as one of the *Dhatu* a key factor for *Jeevana*, *Prinana*, *Dharana* and *Poshana Karma* of the body. In Ayurveda, due *to Nidana Sevan, Pitta dosha* gets vitiated and expelled by *Vayu*. It then reaches the *Hridya* and from there it mobilizes into entire body via *Dasha dhamani* and get localized between *Twaka* and *Mamsa* causing *Dhatu Shaithayata* and *Guruta*.

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Vitiated *Kapha, Vata, Asruk, Twaka* and *Mamsa* cause *Twakavaivarnata* such as *Pandu, Haridra, Harita,* etc. [3] Faulty dietary habits and lifestyle produces *Ama* which further causes *Agnimandya* and ultimately *Amayukta Ahararasa* produced. It hampers *Rasa Dhatu Utapatti* and manifests *Pandu Roga*. *Pandu Roga*, presents with symptoms similar to Iron Deficiency Anaemia (IDA) such as pallor, fatigue, and anorexia. Anaemia is functionally defined as an insufficient red blood cell (RBC) mass to adequately deliver oxygen to peripheral tissues. It may be due to increased RBC clearance, decreased RBC production, or both and caused by intrinsic or extrinsic causes[4] . Iron deficiency is very common condition prevalent in society. The prevalence of Anaemia among six groups as per the National Family Health Survey 5 (2019-21), is 25.0 percent in men (15-49 years) and 57.0 percent in women (15-49 years). 31.1 percent in adolescent boys (15-19 years), 59.1 percent in adolescent girls,52.2 percent in pregnant women (15-49 years) and 67.1 percent in children (6-59 months) [5]. Many drugs are available in modern sciences for combating Anaemia but they are costly and produce gastric irritants and have side effects like nausea, constipation, diarrhea etc. which further deteriorates the health of the patients. Herbal contents of *Gudanagaradi Gutika Yoga* have *Ushna, Deepan, and Pachan,* properties that are useful to produce *Strotovishodhana* and *Aampachana*. *Mandoor Bhasma* due to its hematopoietic nature helps in increasing hemoglobin level in Iron Deficiency Anaemia[6]. *Phaltrikadi Kwatha* is a preparation having the drug with predominance of *Tikta Rasa*, which has *Pittashamana* effect and will help to alleviate the *Pitta dosha* in body. *Tikta Rasa* also having *Amapachana* effect so it will help in proper formation of *Rasa Dhatu* and thus the subsequent *Raktadhatu* formation. Although numerous formulations have been trialed, comparative research is lacking on the efficacy of *Gudanagaradi Gutika* versus *Phalatrikadi Kwatha.*This study aims to fill that research lacuna and provide evidence for integrating Ayurvedic innovations into clinical practice.

II. MATERIALS AND METHODS

A. Study Design

This study is single-centered, open-labelled, parallel comparative clinical trial. Study will randomized using a computer generated allocation series. Patient will split into two groups, one for *Gudanagaradi Gutika* and other for *Phalatrikadi Kwatha.*

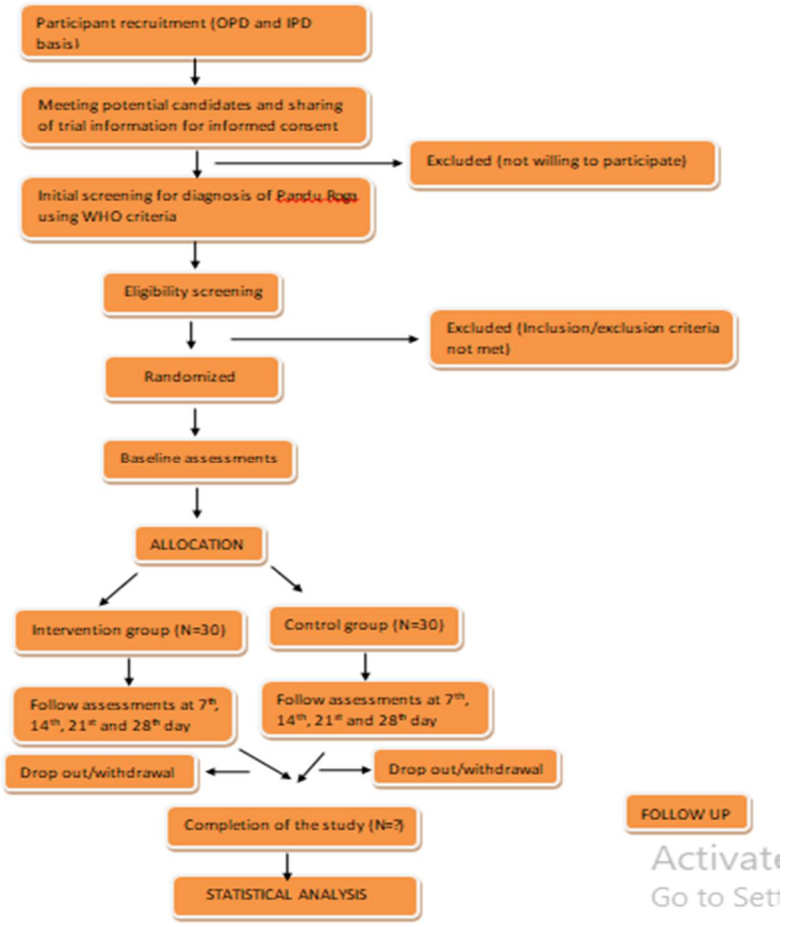


Fig.1: Study Flow Chart.

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B. Participants

Patients will be recruited for the study from OPD and IPD of Institute for Ayurved Studies and Research, Faculty of Ayurved, Kurukshetra, Haryana.

- Sample Size and Randomization: 60 patients (30 per group), using a computer generated randomization schedule.

C. Eligibility

1) Inclusion Criteria

- Patient willing to sign the consent form.
- All patients of age group (25-45years) irrespective of any sex, community and locality will be included.
- Patients fulfilling the diagnostic criteria for Pandu Roga.
- Iron Deficiency Anaemia (IDA) of mild & moderate types (Hb% within the range of 8- 11gm/dl) will be included.

2) Exclusion Criteria

- Patient not willing for clinical trials.
- Patient below age 25 and above age 45 years.
- Anemia other than IDA will be excluded.
- Patients of acute blood loss will be excluded.
- Anemia due to Leukemia & other malignant disorders will be excluded
- Hb% below range of 8gm/dl.
- Patients with history of other systemic diseases such as Diabetes mellitus, CAD, CKD, AKD and endocrinal disorder.
- Pregnant and lactating women

3) Withdrawal Criteria

- Blood hemoglobin level becomes less than 5 gm/dl during the course of treatment.
- Any other acute illness.
- Patients not willing to continue.
- Any severe untoward effect.

D. Ethical Considerations and Trial Registration

The Institutional Ethical Committee granted Ethical approval before the commencement of the study (SKAU/Acad/2024/10802). The clinical Trial was registered with the clinical Trial Registry of India under registration number (CTRI/2024/07/071147).

E. Study Plan

Written informed consent will be taken from all participants about the study purpose and interventions in their preferred language. The patients will be asked about their medical history and physical examination will be conducted. Clinical finding will be assessed before during and after treatment by using assessment scale.

Blood sample will be collected for lab investigations. Eligible patients who met all the inclusion criteria and did not meet any of the exclusion criteria will be enrolled into the study.

Patients will be split into two group. Group-A will receive *Gudanagaradi Gutika* 500 mg BD and Group-B will receive *Phalatrikadi Kwatha* 50 ml BD for 28 days. After screening and enrollment of patients into the study at Day-0 (visit-1) weekly in treatment visits will be planned at Day-7 (visit-2), Day-14 (visit-3), Day-21(visit-4), Day-28 (visit-5) and post treatment follow up on Day-42 (visit-6),Day-56 (visit-7).

In every visit vital signs, physical examination will be assessed. Patients will be free to withdraw their consent from the study at any time without stating any reason.

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F. Interventions

1) Group A (Intervention): *Gudanagaradi Gutika*

Table no: 1- contents of *Gudanagaradi Gutika*[7]

Dravya	Botanical Name	Part used	*Rasa*	*Guna*	*Virya*	*Vipaka*	Quantity
Puran Guda	Jaggery	Guda	*Madhura*	*Laghu, Snigdha*	*Sheeta*	*Madhura*	1part
Tila	Sesamum indicum	Seed	*Madhura*	*Guru, Snigdha*	*Ushna*	*Madhura*	1part
Sauntha	Zingiber officinale	Rhizome	*Katu*	*Laghu, Snigdha*	*Ushna*	*Madhura*	1part
Mandoor Bhasma	Ferric oxide	*Bhasma*	*Kashaya*	*Sheeta*	*Sheeta*	*Katu*	1part
Pippali	Piper Longum	Fruit	*Katu*	*Laghu, Snigdha, Tikshana*	*Anushna*	*Madhura*	2part

2) Group B (Comparator): *Phalatrikadi Kwatha*

Table no: 2 - contents of *Phalatrikadi Kwatha* [8]

Dravya	Botanical Name	Part used	Rasa	Guna	Virya	Vipaka	Quantity
Haritaki	Terminalia chebula	Phala	Panchrasa (lavan varjit)	Ruksha, Laghu	Ushna	Madhura	1 part
Vibhitaki	Terminalia bellirica	Phala	Kashaya	Ruksha, Laghu	Ushna	Madhura	1 part
Amalaki	Emblica officinalis	Phala	Panchrasa (lavan varjit)	Guru, Ruksha, Sheet	Sheet	Madhura	1 part
Guduchi	Tinospora cordifolia	Mula, Kand	Tikta, Kashaya	Guru, Snigdha	Ushna	Madhura	1 part
Vasa	Adhatoda zeylanica	Mula, patra, puspa	Tikta, Kashaya	Ruksha, Laghu	Sheet	Katu	1 part
Tikta (katuki)	Picrorhiza kurroa	Mula	Tikta	Ruksha, Laghu	Sheet	Katu	1 part
Bhunimba (kiratikta)	Swertia chirata	Panchanga	Tikta	Ruksha, Laghu	Ushna	Katu	1 part
Nimba	Azadirachta indica	Bark	Tikta, Kashaya	Laghu	Sheet	Katu	part

G. Assessment criteria

1) Subjective Criteria

The following clinical findings will be assessed before, during and after treatment. According to WHO Assessment Scale of Clinical Features on the basis of classical ayurvedic text:

Scoring pattern for Subjective criteria

Vaivarnyata (Pallor or paleness)

No Pallor	0
Pallor restricting itself to only conjunctiva and/or Mucous membrane	1
Obvious Skin colour	2
Palmer creases too are affected	3

Aruchi/ Annadvesha (Anorexia)

Normal appetite	0
Unwilling to take food, but eats	1
Unwilling to take food, intake of food Decreases	2
No interest to take food	3

Daurbalyata (Weakness)

No weakness	0
Weakness in heavy work	1
Weakness in routine work	2
Weakness even on rest	3

Shrama (Fatigueness)

No fatigueness or fatigueness only after excessive work	0
Fatigueness on doing less than accustomed work	1
Fatigueness on doing routine work	2
Fatigueness even on rest or no activity	3

Shwasa (Dyspnoea)

No dyspnoea or dyspnoea more than accustomed work	0
Dyspnoea on accustomed work	1
Dyspnoea while doing less than accustomed work	2
Dyspnoea on rest	3

Hridayaspanda (Palpitation)

No palpitation	0
Palpitation on excessive exercise	1
Palpitation on slight exercise	2
Palpitation on rest	3

Shotha (oedema)

No oedema	0
Swelling in one particular region like in the face (around eyeball), or pedal oedema etc.	1
Oedema in the two or more different sites	2
Generalized oedema	3

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Bhrama (Giddiness)

No Giddiness	0
Occasionally present	1
Present most of the time	2
Always present	3

Atinidra (Excessive sleep)

Normal sleep	0
Total duration of sleep is exceeded by 1-2 hr. than his normal sleep	1
Total duration of sleep is exceeded by 3-4 hr. than his normal sleep	2
Total duration of sleep is exceeded by 5-6 hr. than his normal sleep	3

Gatrashula (Body ache)

No body ache	0
Body ache present on excessive exertion	1
Body ache present on mild exertion	2
Body ache present even on rest	3

2) Objective Criteria

Increase in Hb (gm/dl) value

0%	Grade 0
1-24 %	Grade 1
25 -49%	Grade 2
50-74%	Grade 3
75-99%	Grade 4
100%	Grade 5

Increase in Serum Ferritin (ng/mL) value

0%	Grade 0
1-24 %	Grade 1
25 -49%	Grade 2
50-74%	Grade 3
75-99%	Grade 4
100%	Grade 5

3) Laboratory Investigations

S no	Parameters	Before Treatment	During Treatment				Post Treatment Follow up	
		0^{th} day	7^{th} day	14^{th} day	21^{st} day	28^{th} day	42^{nd} day	56^{th} day
1.	Hb (gm/dl)	✓		✓		✓	✓	✓
2.	TLC	✓						
3.	DLC	✓						

4.	ESR	✓				✓		
5.	Serum Ferritin	✓				✓		
6.	PBF	✓				✓		
7.	BT	✓						
8.	CT	✓						
9.	PT	✓						
10.	Platelet count	✓						
11.	SGOT	✓						
12	SGPT	✓						
13.	Blood urea	✓		✓		✓		
14.	Serum Creatinine	✓		✓		✓		
15.	Urine Routine/Microscopic)	✓						
16.	Stool for occult blood	✓						

III. OUTCOME MEASURES

1) Subjective: Clinical symptom scoring (pallor, anorexia, weakness, dyspnea, etc.) using standard Ayurvedic scales.
2) Objective: Laboratory tests including Hemoglobin, serum ferritin.

IV. ANALYSIS

Data will be summarized as mean ± SD. Intergroup comparisons will utilize independent t-tests (or nonparametric equivalents), and within-group changes will be analyzed by paired t-tests. Statistical significance will be set at $p < 0.05$ using standard statistical software.

V. DISCUSSION

Pandu Roga is the disease mentioned in Ayurveda characterized by the altered skin colour like yellowish, white discolouration of the skin. The causes of Iron Deficiency Anaemia are insufficient dietery intake and improper absorption of iron which causes symptoms such as feeling of weakness, tiredness, shortness of breath, palpitations, koilonychias, glossitis, dysphagia and altered sensation of taste[9] [10]. This protocol addresses a critical gap in Ayurvedic research by comparing a novel formulation, *Gudanagaradi Gutika*, with the traditional *Phalatrikadi Kwatha* in the management of *Pandu Roga*. In *Gudanagaradi Gutika*, Jaggery is known to purify the blood and enhance its quality. Its regular use is believed to improve *Rakta Dhatu* (blood tissue), promoting better circulation, skin health, and overall vitality. *Guda* is rich in iron and other minerals, making it beneficial for preventing and managing Anemia (*Pandu Roga*). It helps in improving hemoglobin levels and combating Iron Deficiency. *Krishna Tila* is considered beneficial for improving blood quality and preventing excessive bleeding. It helps in conditions like anaemia and also has a hemostatic effect, controlling abnormal bleeding. Ginger had protective effect against liver damage induced by adriamycin and this is due to its antioxidant activities. *Mandoor Bhasma* is renowned for its ability to improve hemoglobin levels and increase red blood cell (RBC) production. It directly helps in managing Anemia by addressing Iron Deficiency, thereby improving energy levels and reducing symptoms like fatigue, paleness, and weakness. *Pippali* is considered a *Rasayana* (rejuvenative) in Ayurveda, promoting longevity and vitality. It nourishes the tissues, supports immune function, and revitalizes the body by strengthening the *Dhatus* (tissues) and enhancing overall health. In *Phalatrikadi Kwatha*, formulation is having the drugs with predominance of
Tikta Rasa,which has *Pittashamana* effect and will help to alleviate the *Pitta Dosha* in body.

Tikta Rasa also having *Amapacana* effect so it will help in proper formation of *Rasa Dhatu* and thus the subsequent *Raktadhatu* formation. *Guduchi* does the *Shamana* of *Raktagata Pitta* it also
does *Raktaprasadana* (enhance the quality) and ultimately nourishes the subsequent *Dhatus*.
Krimi is one of the reason for the manifestation of *Pandu*, *Nimba* might help in such cases, which acts on *Raktaja* and *Kaphaja Krimi* due to its *Prabhava* and also having *Pittakaphahara* property.
In *Pandu* as there is *Srotodhoosti* caused due to excessive or aggravated *Doshas*, due to *Shodana* and *Bhedana* property of *Katuki* that is why it may act as *Shrotoshodana* ultimately *Samprapti Vighatana*. By integrating classical Ayurvedic principles with modern clinical evaluation techniques, this study strives to validate the potential benefits, safety, and cost effectiveness of *Gudanagaradi Gutika* as an alternative treatment for *Pandu Roga*. The open label design is balanced by rigorous, objective outcome assessments which are expected to yield reproducible and clinically relevant data that could inform future large scale trials.

VI. CONCLUSION

This study protocol details an open labelled, parallel comparative clinical trial aimed at evaluating the efficacy and safety of *Gudanagaradi Gutika* versus *Phalatrikadi Kwatha* in patients with *Pandu Roga* (IDA). Successful results could pave the way for evidence based integration of Ayurvedic treatment modalities into modern healthcare practice.

A. Funding Sources

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B. Conflict of Interest

The authors declare no conflict of interest.

C. Declaration of generative AI in scientific writing

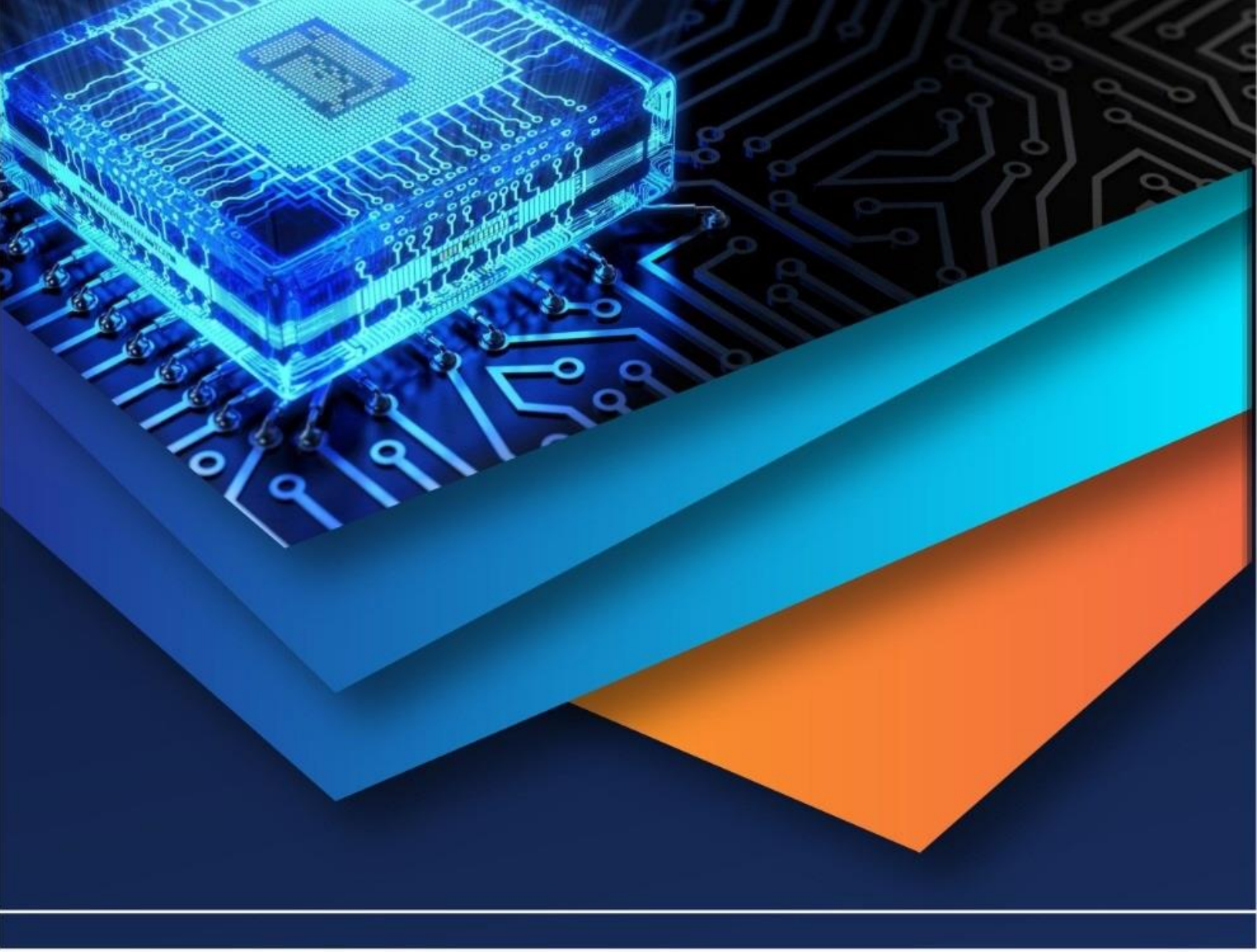
The authors have not used any AI tools for writing this manuscript.

D. Acknowledgments

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