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Efficacy of *Trivratyadi Taila* as an Adjuvant to the IFTAK Procedure in the Management of Complex Fistula-in-Ano (*Bhagandara*): A Randomized Comparative Clinical Trial

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Abstract: ***Background: Bhagandara (fistula-in-ano) is a chronic anorectal condition associated with significant morbidity. The IFTAK (Interception of Fistulous Tract with Application of Ksharasutra) procedure is a minimally invasive Ayurvedic surgical technique with established efficacy in complex fistulae.[6] However, postoperative sequelae including pain, purulent discharge, itching, and swelling remain clinical challenges. Trivratyadi Taila, a classical Ayurvedic medicated oil formulation described by Acharya Sushruta,[16] possesses Shodhana (wound-cleansing), Ropana (healing), and anti-inflammatory properties potentially relevant to postoperative wound management.***

Aim: To evaluate and compare the clinical efficacy of IFTAK alone versus IFTAK combined with local application of Trivratyadi Taila in the management of Bhagandara.

Methods: A randomized, open-label, comparative clinical trial was conducted on 40 patients with complex fistula-in-ano, divided equally into Group A (IFTAK alone, n=20) and Group B (IFTAK + Trivratyadi Taila, n=20). Subjective parameters like pain (Visual Analogue Scale), discharge, itching, and swelling, were assessed at baseline, 1st post-operative day, and weekly for one month. Intra-group analysis employed the Wilcoxon signed-rank test; inter-group comparison used the Mann-Whitney U test ($p < 0.05$).

Results: All 40 patients completed the trial. Group B demonstrated significantly superior outcomes at one month: pain relief 84% vs. 62.26% ($p < 0.0001$), discharge reduction 82.86% vs. 44.83% ($p < 0.0001$), itching improvement 83.87% vs. 43.48% ($p = 0.0004$), and swelling reduction 86.79% vs. 65% ($p < 0.0001$).

Conclusion: Adjuvant application of Trivratyadi Taila following IFTAK significantly enhances postoperative outcomes in complex fistula-in-ano. This integrative approach warrants inclusion in standardized postoperative protocols for Bhagandara management.

Keywords: Bhagandara; fistula-in-ano; IFTAK; Trivratyadi Taila; Ksharasutra; Ayurvedic surgery; wound healing; Shalya Tantra.

I. INTRODUCTION

Fistula-in-ano is among the oldest documented surgical conditions in medical history, with references traceable to ancient Mesopotamian and Egyptian traditions.[1,2] Clinically, it is defined as a chronic granulating tract establishing an abnormal communication between the anorectal canal and the perianal skin, typically manifesting with persistent purulent discharge, pain, and recurrent perianal sepsis.[5] Although not life-threatening, its chronicity and associated morbidity substantially impair patients' quality of life.

Globally, fistula-in-ano affects approximately 18–20 per 100,000 population, with an annual incidence of 1–2 per 10,000 in European cohorts.[17] A clear male predominance exists, with male-to-female ratios of 2:1 to 4:1, and peak incidence in the third to fifth decades.[1] In India, hospital-based data report that fistula-in-ano constitutes approximately 15–16% of all anorectal disorders seen in surgical outpatient departments.[18]

Complex fistulae, defined by sphincter involvement exceeding 30%, multiple external openings, associated abscesses, or horseshoe configuration, pose particular therapeutic challenges.[5] Standard surgical options including fistulotomy, seton placement, ligation of the intersphincteric fistula tract (LIFT), video-assisted anal fistula treatment (VAAFT), and fibrin glue injection each involve trade-offs between recurrence prevention and preservation of anal continence.[4] No universally accepted gold standard exists for complex disease.

In the Ayurvedic surgical tradition, *Ksharasutra* (medicated alkaline thread) therapy as codified by Acharya Sushruta achieves simultaneous chemical debridement and healing of the fistulous tract.[14] The IFTAK technique (Interception of Fistulous Tract with Application of *Ksharasutra*), innovated in 2007 by Padma Shri Prof. M. Sahu at Banaras Hindu University, is a minimally invasive refinement wherein *Ksharasutra* is applied exclusively to the proximal tract segment containing the infected crypt, while the distal segment heals spontaneously.[6] Published outcomes report success rates of 93–97% with minimal continence compromise.[7,8,9]

Despite the procedural efficacy of IFTAK, the postoperative phase presents challenges including persistent pain, wound discharge, perianal itching, and inflammatory swelling that extend convalescence and reduce patient satisfaction. *Trivratyadi Taila*, referenced in the *Sushruta Samhita (Chikitsa Sthana* 8/48–49) and specifically indicated for *Bhagandara*,[16] contains constituent herbs including *Trivrat (Operculina turpethum), Haridra (Curcuma longa), Triphala, Danti (Baliospermum montanum), Arka (Calotropis procera), and Vidanga (Embelia ribes)* that collectively confer antimicrobial, anti-inflammatory, and tissue-regenerative properties. Nevertheless, no rigorous comparative clinical evidence has previously evaluated its role as a postoperative adjuvant after IFTAK.[10,11,12]

The present randomized comparative trial was designed to evaluate whether the addition of *Trivratyadi Taila* to standard IFTAK postoperative care provides superior symptomatic and clinical outcomes compared to IFTAK alone in patients with complex fistula-in-ano.

II. MATERIALS AND METHODS

A. Study Design and Setting

This was a randomized, open-label, interventional comparative clinical trial conducted at the OPD and IPD of the Department of *Shalya Tantra*, Sanjeevani Ayurveda Hospital, Jodhpur, Rajasthan, India. The study received ethical clearance from the Institutional Ethics Committee (IEC letter no. DSRRAU/PGIA/IEC/22-23-630) and was registered with the Clinical Trials Registry of India (CTRI/2024/06/068947; Ref. REF/2024/06/086108).

B. Sample Size and Randomization

A total of 40 patients diagnosed with complex *Bhagandara* fulfilling predefined criteria were enrolled through simple random sampling and allocated equally into two groups of 20 patients each. Randomization employed sequentially numbered sealed envelopes to maintain allocation concealment.

C. Eligibility Criteria

Inclusion criteria encompassed patients aged ≥18 years with complex fistula-in-ano, specifically: fistulae involving >30% of the sphincter musculature; high inter-sphincteric, high trans-sphincteric, or supra-sphincteric tracts; multiple external openings; associated abscesses; high horseshoe fistulae; and recurrent fistulae.[5]

Exclusion criteria included: simple (low inter-sphincteric or low trans-sphincteric) fistulae; non-cryptoglandular aetiology; extra-sphincteric tracts; and concurrent conditions including inflammatory bowel disease, uncontrolled diabetes mellitus, uncontrolled hypertension, coronary artery disease, severe anaemia or hypoproteinaemia, carcinoma rectum, or HIV-positive status.

D. Interventions

Both groups underwent the IFTAK procedure under spinal or local anaesthesia as described by Sahu et al.[6] Following identification of the infected anal crypt and fistulous tract via digital rectal examination and methylene blue delineation, a 2–2.5 cm linear vertical incision was made at the anterior or posterior midline approximately 2 cm from the anal verge. The tract was intercepted, and a standard surgical linen thread (No. 20) was introduced into the proximal segment as a loose draining seton, subsequently converted to *Ksharasutra* changed weekly using the railroad technique.

Group A (Control): Received IFTAK with standard postoperative care comprising betadine dressings, intravenous antibiotics for 24 hours followed by oral antibiotics and analgesics for five days, warm sitz baths, *Triphala Guggulu* (500 mg thrice daily), and *Erandabhrishta Haritaki* (5 g at bedtime).

Group B (Trial): Received all elements of Group A care plus daily local application of *Trivratyadi Taila* into the fistulous tract via a rubber catheter (Fr. 6–9) and 10 mL syringe, commencing on the first postoperative day and continuing until complete wound healing.[16]

Trivratyadi Taila was prepared at Nagarjuna Rasayanashala using authenticated ingredients in equal proportions, processed according to classical *Taila-paka* method with *Murchhana* pre-treatment, as described in *Sarangadhara Samhita* (*Madhyama Khanda* 9/1–13).

E. Outcome Assessment

Subjective parameters were recorded at baseline (day 0), first postoperative day, and weekly for four weeks. Four parameters were assessed on validated ordinal scales: pain (VAS-derived, 0–4); discharge (gauze pad saturation, 0–4); itching (frequency per day, 0–4); and swelling (diameter-based, 0–3). Overall therapeutic effect was graded from complete remission (100%) to no change (<1%).

F. Statistical Analysis

Data were analysed using GraphPad InStat 3 and Microsoft Excel. Intra-group ordinal comparisons employed the Wilcoxon matched-pairs signed-rank test (two-tailed); inter-group differences in percentage improvement were assessed using the Mann-Whitney U test. $p < 0.05$ was considered statistically significant; $p < 0.01$ highly significant.

III. RESULTS

A. Demographic and Clinical Profile

All 40 enrolled patients completed the trial (Table 1). The cohort comprised patients aged 18–70 years, with the majority (35%) in the 18–30-year bracket, consistent with the known age distribution of fistula-in-ano.[1] A strong male preponderance was observed (92.5%), aligning with reported international sex ratios.[1,17] Constipation was documented in 67.5% of patients, a finding consistent with the Ayurvedic understanding of *Apana Vata* derangement as a contributing pathogenic factor and with modern recognition of increased straining as a risk factor for anal crypt infection.[19] *Pittakaphaja Prakriti* predominated (42.5%), followed by *Vatapittaja* (37.5%) and *Kaphavataja* (20%).

Table 1: Summary of Baseline Demographic and Clinical Characteristics (n=40)

Characteristic	Group A (n=20)	Group B (n=20)	Total (%)
Male	18	19	37 (92.5%)
Female	2	1	3 (7.5%)
Age 18-30 years (peak group)	8	6	14 (35%)
Constipation history	13	14	27 (67.5%)
Mixed diet	14	13	27 (67.5%)
Pittakaphaja Prakriti	7	10	17 (42.5%)
Opium addiction	8	8	16 (40%)

B. Intra-Group Analysis

Within Group A (IFTAK alone), statistically significant improvements were observed across all parameters. Pain scores improved by 62.26% (mean BT 3.4 ± 0.79 vs. AT 1.75 ± 0.79; $p < 0.0001$), discharge by 44.83% (BT 3.7 vs. AT 2.4; $p = 0.0002$), itching by 43.48% (BT 1.5 vs. AT 1.0; $p = 0.0192$), and swelling by 65% (BT 2.7 vs. AT 1.4; $p = 0.0002$). No significant first postoperative day changes were detected for any parameter.

Within Group B (IFTAK + *Trivratyadi Taila*), all parameters demonstrated highly significant improvement. Pain reduction reached 84% (BT 3.75 vs. AT 0.6; $p < 0.0001$), discharge reduction 82.86% (BT 3.5 vs. AT 0.6; $p < 0.0001$), itching improvement 83.87% (BT 1.55 vs. AT 0.25; $p = 0.0004$), and swelling reduction 86.79% (BT 2.65 vs. AT 0.35; $p < 0.0001$). Clinically meaningful Group B improvement was detectable from week one for pain, discharge, and itching.

C. Inter-Group Comparative Analysis

Inter-group comparison revealed no statistically significant difference at week one for pain ($p = 0.1217$) or itching ($p = 0.196$), indicating comparable early responses. From week two onwards, Group B demonstrated consistently and significantly superior outcomes for all parameters (Table 2). By study completion, inter-group differences were highly significant for all four outcome measures.

Table 2: Comparative Percentage Improvement at End of Trial (1 Month) with Inter-Group Statistics

Parameter	Group A Relief (%)	Group B Relief (%)	p-value	Significance
Pain	62.26	84.00	< 0.0001	HS
Discharge	44.83	82.86	< 0.0001	HS
Itching	43.48	83.87	0.0004	HS
Swelling	65.00	86.79	< 0.0001	HS

HS = Highly Significant ($p < 0.01$). BT = Before Treatment; AT = After Treatment at 1 month.

IV. DISCUSSION

A. Demographic Findings

The demographic profile of this cohort is consistent with established epidemiological data for fistula-in-ano. Male preponderance (92.5%) aligns with reported international sex ratios of 2:1 to 4:1,[1] attributed to greater depth of intersphincteric glands in males and higher occupational exposure to perianal trauma. Predominance of younger adults (35% aged 18–30 years) corroborates observations from Sainio's Finnish population-based study[1] and Indian tertiary-care reports,[18] reflecting the condition's predilection for active working-age individuals. The high prevalence of constipation (67.5%) mirrors the modern recognition of straining-induced anal crypt pressure as a risk factor for perianal sepsis[19] and is consistent with the Ayurvedic concept of *Apana Vata Dushti* as a key pathogenic driver in *Guda Rogas*.

B. Efficacy of IFTAK Procedure Alone (Group A)

Group A demonstrated significant improvement across all four parameters at one month, affirming the established efficacy of the IFTAK procedure in complex fistula management. The observed pain relief of 62.26% and swelling reduction of 65% are consistent with the outcomes documented by Sherkhane et al.,[7] who prospectively evaluated IFTAK in complex fistulae and reported high rates of tract healing with minimal sphincteric compromise. Similarly, the progressive but comparatively limited discharge reduction (44.83%) aligns with findings by Deshpande and Sharma,[14] who noted that conventional *Ksharasutra* therapy achieves adequate drainage but that microbial colonisation of the tract can persist without supplementary local antiseptic management. These observations from Group A confirm that IFTAK alone is a robust surgical intervention but leave scope for postoperative optimisation.

C. Superior Efficacy of Trivratyadi Taila as Adjuvant (Group B)

The addition of *Trivratyadi Taila* produced markedly superior outcomes, with improvements exceeding 80% for pain, discharge, and itching at one month. These findings parallel previous Ayurvedic oil studies in anorectal wound management. Goud et al.[10] demonstrated that *Vishyandana Taila* and *Kashisadi Taila* improved postoperative parameters in *Bhagandara* patients managed by *Ksharasutra*, underscoring the value of topical medicated oils in this context. Bhargava[11] reported accelerated unit cutting time when *Jatyadi Taila* was combined with standard *Ksharasutra* therapy, corroborating the principle that classical lipid vehicles enhance wound healing. Kulkarni et al.[12] documented improved outcomes with *Saindhavadya Taila* after IFTAK, further supporting the hypothesis that classical Ayurvedic oil formulations provide measurable postoperative benefit. Parhi et al.[13] additionally reported enhanced symptomatic outcomes when *Aragwadhadi Varti* was used alongside IFTAK, reinforcing the role of adjuvant phytochemical applications in this procedure. The inter-group differences became significant from week two onwards, consistent with the pharmacokinetic requirement for active phytoconstituents to achieve adequate tissue concentration through repeated application.

D. Probable Mechanisms of Action

The superior performance of Group B can be rationalised through convergent Ayurvedic and modern pharmacological mechanisms:

Antimicrobial Activity: Curcumin from *Haridra (Curcuma longa)* inhibits common perianal pathogens including *Staphylococcus aureus* and *Escherichia coli* through disruption of bacterial membrane integrity and biofilm inhibition. Embelin from *Vidanga (Embelia ribes)* and gallic acid from *Triphala* components exert broad-spectrum antimicrobial and antioxidant effects. This activity aligns with the classical *Krimighna* (anti-microbial) and *Shodhana* (wound-cleansing) properties of the formulation.[16]

Anti-inflammatory and Analgesic Activity: Curcumin modulates NF-κB signalling and inhibits COX-2 and lipoxygenase enzymes, attenuating prostaglandin-mediated inflammation. Flavonoids from *Arka (Calotropis procera)* and *Kaner (Nerium indicum)* contribute additional membrane-stabilising and analgesic actions. The sesame oil base contains sesamin and sesamolin with anti-inflammatory properties and facilitates deep percutaneous penetration of active constituents into perianal tissues, enhancing local bioavailability. These actions correspond to the *Vedanasthapana* (analgesic) and *Shothahara* (anti-inflammatory) pharmacodynamic categories.

Wound Healing and Tissue Regeneration: Curcumin promotes fibroblast proliferation, collagen synthesis, and angiogenesis. Emblicanin A and B from *Amalaki (Emblica officinalis)* enhance collagen maturation through ascorbic acid-mediated proline hydroxylation. Honey (*Madhu*) creates an osmotically unfavourable wound environment, maintains optimal moisture, promotes granulation tissue, and releases sub-inhibitory hydrogen peroxide concentrations with sustained antimicrobial effect. *Madhucchishta* (beeswax) provides a biocompatible protective barrier retarding desiccation and mechanical friction. These mechanisms collectively constitute the *Ropana* (tissue-regenerative) action.[16]

From a doshic perspective, the *Snigdha* (unctuous) and *Ushna* (warm) properties of *Taila* pacify aggravated *Vata*, the primary driver of pain and tissue degeneration, while the *Tikta* (bitter) and *Katu* (pungent) *Rasa* of constituent herbs counteract *Pitta*-mediated inflammation and *Kapha*-driven suppuration, comprehensively addressing the *Tridoshaja* pathogenesis of *Bhagandara*.

E. Strengths and Limitations

Strengths include a prospective randomized design with 100% follow-up completion, validated ordinal outcome measures, appropriate non-parametric statistical methods, IEC approval, and CTRI registration. Inclusion exclusively of complex fistulae enhances clinical relevance. Limitations include the small sample size (n=40), single-centre design, absence of objective wound-area measurements or microbiological sampling, no long-term recurrence data beyond one month, and the open-label design inherent to surgical and topical interventions. Future multicentre trials with blinded assessors, microbiological endpoints, and extended follow-up are recommended.

V. CONCLUSION

This randomized comparative trial demonstrates that adjuvant local application of *Trivratyadi Taila* following the IFTAK procedure provides statistically and clinically superior postoperative outcomes in complex fistula-in-ano compared to IFTAK alone. Group B achieved markedly higher relief across all parameters, pain (84%), discharge (82.86%), itching (83.87%), and swelling (86.79%), with highly significant inter-group differences at trial completion ($p < 0.0001$). The convergent antimicrobial, anti-inflammatory, and tissue-regenerative pharmacological actions of *Trivratyadi Taila*'s constituent herbs[16] justify its inclusion as a standardized adjuvant in postoperative care protocols for *Bhagandara* managed by IFTAK. Multicentre trials with larger cohorts, objective wound assessment, and extended follow-up are warranted to confirm these findings.

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Conflict Of Interest

The authors declare no conflict of interest. The study received no commercial funding. *Trivratyadi Taila* was prepared specifically for this research without commercial interest.

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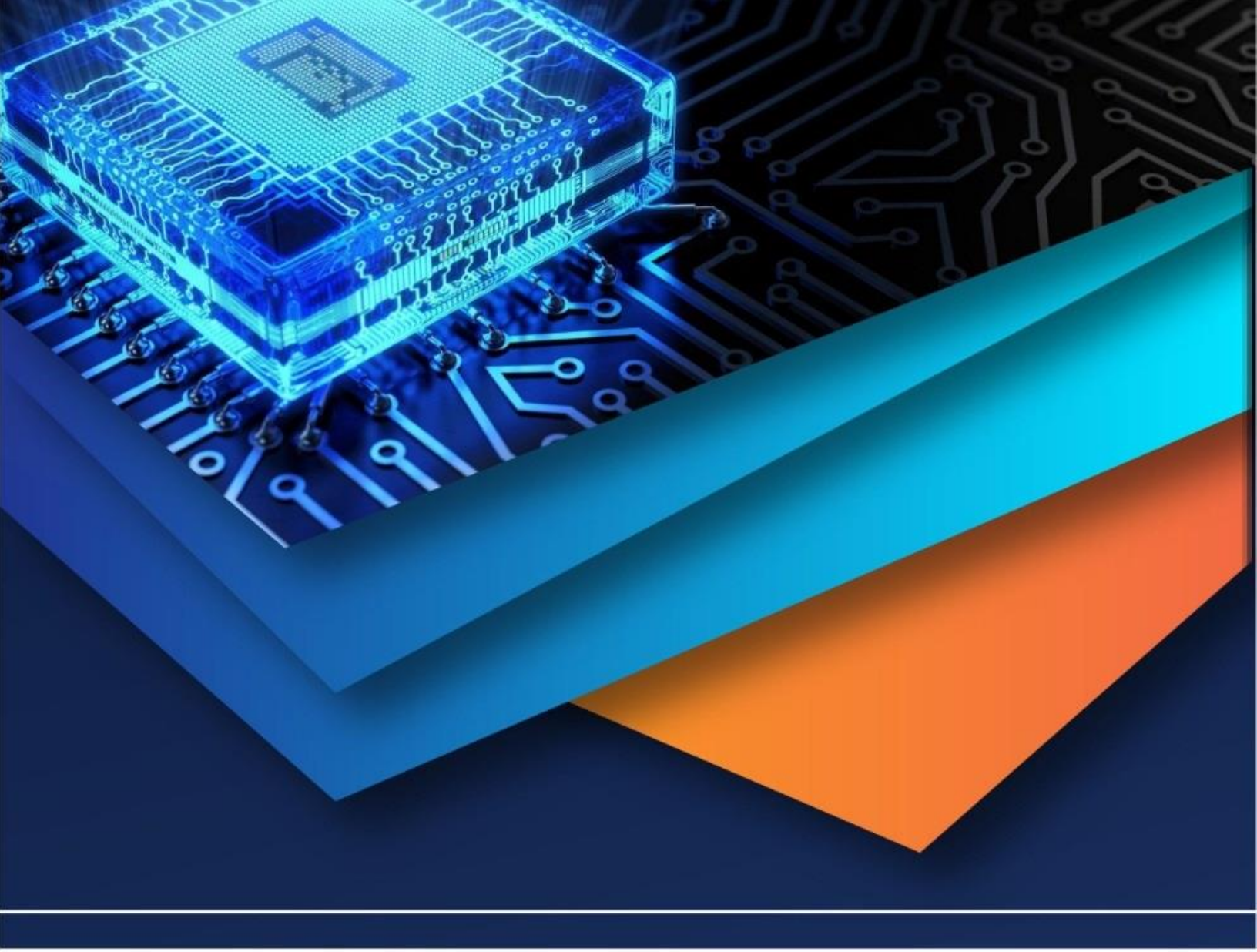

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