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Clinical Outcomes in Initial Hirudotherapy versus Standard Treatment in Idiopathic Granulomatous Mastitis: A Comparative Cohort Study

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ABSTRACT

Objective: Idiopathic granulomatous mastitis (IGM) is a chronic inflammatory disease characterized by a high risk of recurrence and fistula formation. Spontaneous remission has been reported in up to 50% of cases, particularly in mild forms, within 6–24 months without intervention, but inadequate management may allow disease progression. The aim of this study was to compare the clinical outcomes of patients who initially preferred hirudotherapy (leech therapy) with those managed with evidence-based stepwise conventional care.

Materials and Methods: We retrospectively analyzed histopathologically confirmed IGM patients. Patients were divided into two groups: Group 1 who delayed conventional treatment for ≥ 6 months because they initially chose hirudotherapy, and Group 2 who received standardized stepwise management (steroids, aspiration, or surgery). Clinical outcomes included complete remission, overall recurrence/persistence, clinically significant (extensive/severe) recurrence, fistulizing/complicated recurrence, and the need for surgical intervention.

Results: The study included 298 patients, with 41 (13.8%) in Group 1 and 257 (86.2%) in Group 2. Median delay to presentation was significantly longer in Group 1 (15 vs. 1.5 months; $p < 0.001$). Complete remission was achieved in only 4.9% (2/41) of Group 1 compared to 59.1% (152/257) in Group 2 ($p < 0.001$). Overall recurrence/persistence rates were 95.1% in Group 1 versus 21.8% in Group 2 ($p < 0.001$). Among patients who experienced recurrence or persistence, clinically significant (extensive or severe) recurrence occurred in 89.7% (35/39) of Group 1 compared with 42.9% (24/56) of Group 2 ($p < 0.001$), while fistulizing/complicated recurrence was significantly higher in Group 1 (26.8% vs. 5.4%; $p < 0.001$). In multivariable analysis, hirudotherapy use [odds ratio (OR): 6.7; $p < 0.001$] and fistula presence (OR: 9.3; $p < 0.001$) were independent predictors of surgical intervention.

Conclusion: Initial exclusive reliance on hirudotherapy was associated with markedly lower remission rates, substantially higher rates of clinically significant recurrence, longer delays before medical evaluation, and increased surgical needs despite comparable baseline severity. These findings suggest that hirudotherapy alone does not appear to modify the immune-mediated course of IGM and may result in a higher proportion of refractory cases presenting to hospital settings, as milder cases in the community may resolve spontaneously without seeking care. Early adherence to standardized stepwise care may therefore be important to prevent progression to severe recurrence and reduce the need for surgery. However, further prospective studies are required to confirm these findings.

Keywords: Idiopathic granulomatous mastitis; hirudotherapy; spontaneous remission; complete remission; recurrence; fistula

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KEY POINTS

- Initial hirudotherapy (leech therapy) in idiopathic granulomatous mastitis (IGM) was linked to lower complete remission rates and substantially higher recurrence rates compared with standard stepwise treatment.
- Patients who started with hirudotherapy experienced substantially more frequent clinically significant and fistulizing recurrences, along with a higher need for surgical intervention.
- Exclusive reliance on hirudotherapy caused a median treatment delay of 15 months, which appears to contribute to disease progression and worse clinical outcomes.
- Early evidence-based stepwise care appears crucial for minimizing severe recurrence and limiting the need for surgical intervention in IGM.

Introduction

Idiopathic granulomatous mastitis (IGM) is a rare inflammatory breast disease that primarily affects women of reproductive age. The etiology of IGM remains unclear, and it is characterized by non-necrotizing granulomatous inflammation. Patients typically present with a painful mass, abscess, or fistula formation. The clinical presentation of IGM may mimic breast cancer or infectious mastitis, creating a diagnostic and therapeutic challenge (1, 2). IGM is considered a potentially self-limiting condition, with spontaneous remission reported in up to 50% of patients, particularly in mild cases, within 6–24 months without intervention (3). Nevertheless, even though spontaneous resolution is possible in some IGM cases, the disease often follows a prolonged clinical course. IGM is associated with high recurrence rates, and progression to complicated forms may occur when the condition is not adequately managed (3-5).

Multicenter studies have shown that a history of pregnancy, breastfeeding, prior breast infection and smoking are associated with an increased risk of recurrence (3). These observations illustrate the importance of addressing modifiable risk factors during IGM treatment. The pathogenesis of IGM is not fully understood. However, several mechanisms have been proposed, including autoimmune reactions, immune responses to ductal secretions, and possible microbial or traumatic triggers (2).

IGM treatment typically follows a stepwise approach based on clinical severity. Management options may range from observation or local steroid therapy in mild cases to more aggressive approaches such as systemic corticosteroids, immunosuppressive agents, drainage, and surgical interventions in refractory or fistulizing disease (3-6). Although a universal international consensus guideline is lacking, a recent expert consensus report has proposed standardized diagnostic and treatment criteria for IGM, providing a framework for clinical decision-making in regions where the disease is relatively prevalent (5). Nevertheless, treatment strategies remain heterogeneous across centers (3, 4, 7). Early initiation of evidence-based therapy has been associated with improved remission rates and a lower likelihood of surgical intervention (6).

Recent proposals include treatment algorithms based on clinical and ultrasound-based classifications, such as the Pittsburgh classification. These systems categorize disease severity from minimal irritation to widespread involvement, and studies have shown that higher complete response rates are achieved when management follows the recommended algorithm (7).

Cultural beliefs and traditional medicine practices significantly influence health-seeking behavior in certain regions of Türkiye and the Middle East. Despite well-documented potential complications such as secondary bacterial infections, hirudotherapy (medicinal leech therapy) is widely perceived as a natural, low-risk, and religiously compatible treatment modality (8, 9). In addition, traditional beliefs may delay patients' presentation to medical care, which can result in more advanced disease at diagnosis and poorer outcomes (10). Hirudotherapy has shown efficacy in specific conditions, including venous congestion and microvascular disorders (8, 11). However, despite its frequent use, the role of hirudotherapy as an initial treatment modality in inflammatory breast diseases such as IGM has not yet been systematically evaluated in comparative clinical studies.

The aim of this retrospective study was to compare clinical outcomes between patients who initially opted for exclusive hirudotherapy for ≥ 6 months and those who received timely institutionally preferred stepwise conventional treatment after a biopsy-confirmed diagnosis of IGM. The ≥ 6 -month threshold was selected to identify patients who had meaningfully delayed evidence-based care, rather than those who had only briefly explored traditional remedies, and is consistent with the lower bound of the reported spontaneous remission window for IGM (6–24 months), beyond which persistent disease is unlikely to resolve without intervention (3). All patient data were extracted retrospectively from hospital records, outpatient files, and telephone follow-up conducted after the care period had concluded; no prospective data collection or intervention assignment was performed. We hypothesized that prolonged reliance on hirudotherapy would be associated with delayed access to evidence-based care, increased disease severity, higher complication rates, and greater need for surgical intervention.

Materials and Methods

This retrospective cohort study included female patients diagnosed with IGM by needle core biopsy between January 2020 and December 2024. The study was approved by the İstanbul Medipol University Non-Interventional Clinical Research Ethics Committee (approval no: E-10840098-772.02-3000, date: 24.06.2021) and conducted in accordance with the Declaration of Helsinki.

Patient Selection and Diagnostic Criteria

A total of 313 female patients were screened. In all cases, the diagnosis of IGM was confirmed by histopathological examination of tissue obtained via ultrasound-guided tru-cut biopsy. Ultrasound was the primary imaging modality for all patients, while magnetic resonance imaging was reserved for cases with suspected extensive disease or complex fistulizing patterns.

According to institutional protocols before establishing the diagnosis of IGM, tuberculosis (purified protein derivative test, culture, polymerase chain reaction, and chest imaging when indicated), malignancy, sarcoidosis, Wegener's granulomatosis, fungal or bacterial infections, and other secondary granulomatous causes were ruled out.

Patients were included if they had biopsy-proven lobulocentric non-caseating granulomatous inflammation consistent with IGM and had at least 12 months of follow-up. Patients with infectious, malignant, and systemic granulomatous etiologies and secondary granulomatous mastitis (tuberculosis, sarcoidosis, fungal or bacterial infections, cystic neutrophilic granulomatous mastitis, or other identifiable causes) were excluded from the study.

Data were collected from electronic hospital records, outpatient files and telephone follow-up interviews. Three patients (1%) were lost to follow up and excluded from analysis. Therefore, the analyzable cohort consisted of 310 patients. Of these, 12 patients who continued treatment outside the city were recorded for follow-up data but were not included in the standard care group, resulting in a comparative cohort of 298 patients. The patient selection process is illustrated in Figure 1.

Patient Groups

Patients were categorized based on their initial treatment preference following biopsy-confirmed diagnosis.

Group 1 (Leech Therapy Group, $n = 41$)

This group consisted of patients who exclusively underwent hirudotherapy for ≥ 6 months after diagnosis and declined conventional medical treatment during that period.

Hirudotherapy was performed in non-medical traditional settings by independent practitioners. The number of sessions, duration of application, and leech species were not standardized, as these interventions occurred outside institutional clinical control (8, 10). Hirudotherapy exposure was verified through two complementary sources: (1) institutional records documenting the absence of any conventional treatment during the ≥ 6 -month post-diagnosis period; and (2) direct patient contact. Patients who did not attend scheduled post-biopsy follow-up appointments were actively contacted by telephone by the study team. This active outreach confirmed hirudotherapy use and allowed collection of outcome data for non-attending patients. Exposure was therefore corroborated by the documented absence of institutional treatment and was not based solely on patient self-report.

Seven patients initially declined in-person hospital follow-up after diagnosis. Outcome information for these patients was obtained through telephone interviews conducted at least 12 months after their last known hospital visit. They were included in the outcome analyses based on the available follow-up data (recurrence, persistence, fistula development, or remission status).

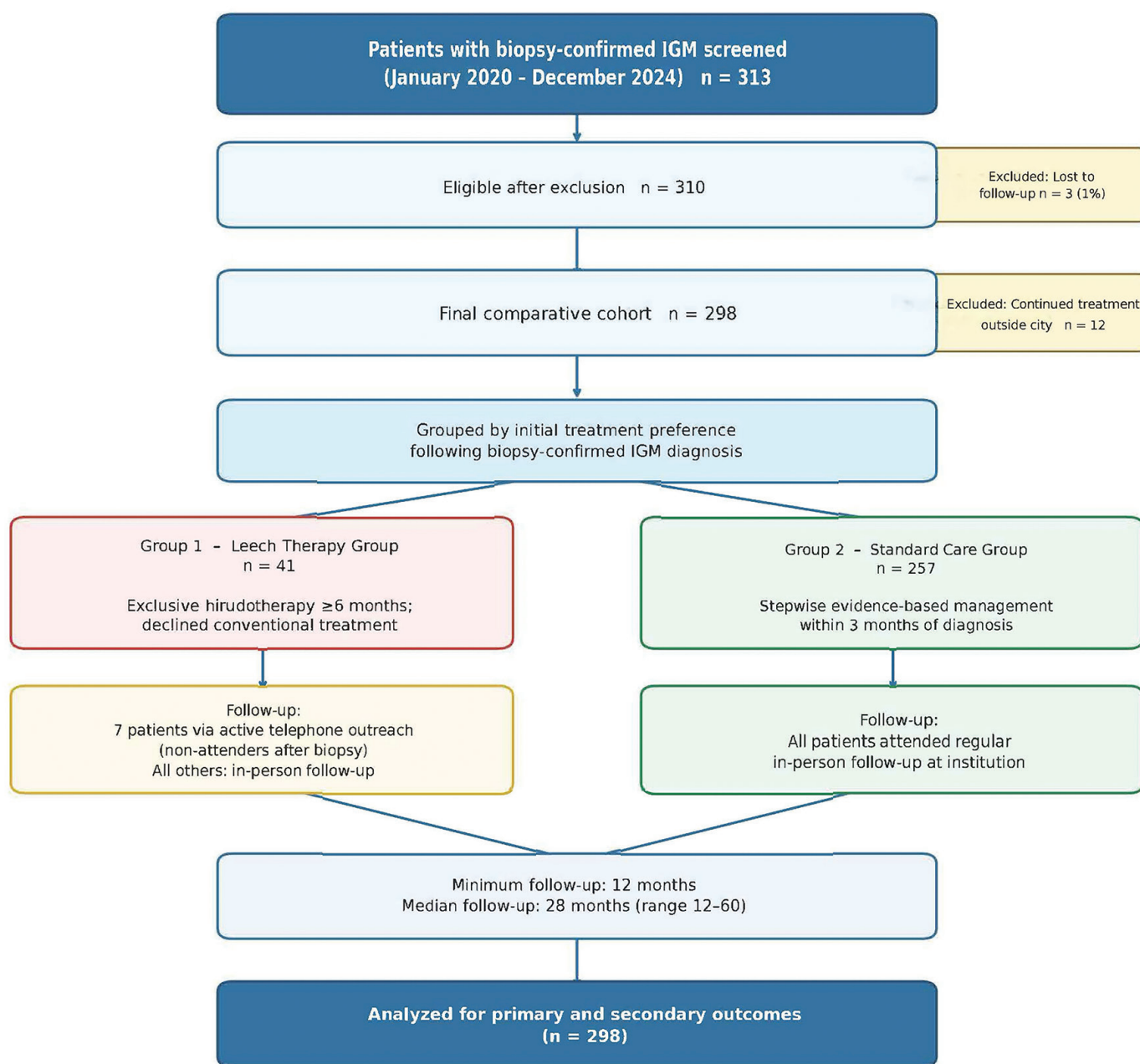
Group 2 (Standard Care Group, $n = 257$)

The second group consisted of patients who received stepwise evidence-based management within three months of diagnosis and attended regular, in-person follow-ups.

Initial Clinical Severity Classification at Patient Presentation

Patients were classified into three severity groups at the time of initial presentation according to severity and corresponding treatment approach. The classification reflected the stepwise treatment approach used in routine clinical practice and was defined retrospectively, as follows (5, 7, 8):

- Mild severity (limited mass, minimal inflammation, no fistula/abscess/ulceration, mild or absent skin changes, no multifocality): patients managed with observation (watch-and-wait) or only with topical/intralesional steroids (12, 13);
- Moderate severity (prominent mass, moderate inflammation, possible localized abscess or skin changes, no fistula/ulceration, limited multifocality): Systemic steroids (dose of 0.5–0.8 mg/kg/day methylprednisolone, followed by gradual tapering over 8 to 12 weeks based on clinical response) or intralesional steroids as first-line therapy, combined with aspiration for abscess drainage when indicated;
- Severe/complicated (fistula/sinus presence, multiple abscesses, widespread inflammation, skin ulceration, multifocal/bilateral involvement, treatment resistance, or high recurrence risk):



* 12 patients excluded from comparative analysis (continued treatment outside city) but were retained for follow-up data recording purposes.

Figure 1. Patient selection flowchart. CONSORT-style diagram illustrating the screening, exclusion, and group allocation of patients included in the comparative cohort analysis. Patients were grouped based on their initial treatment preference following biopsy-confirmed IGM diagnosis. Active telephone outreach was performed for patients who did not attend scheduled follow-up after biopsy, ensuring complete outcome ascertainment

IGM: Idiopathic granulomatous mastitis

Systemic steroids as first-line therapy with the addition of immunosuppressive agents (methotrexate or azathioprine) in resistant cases. Aspiration or drainage was performed when abscess formation was present and surgical intervention (wide local excision or drainage) was performed as a last resort in refractory cases (14, 15).

To ensure consistency across participating centers, the initial clinical severity classification was performed according to a predefined standardized protocol applied by the participating surgeons at each center. All cases were assessed using the same severity criteria based on clinical findings, imaging reports, and pathology data.

Data Collection and Outcome Measures

Demographic characteristics (age, bilaterality, multifocality), time from diagnosis to first conventional treatment, total disease duration and the need for surgical intervention were recorded. Clinical outcomes included complete remission (complete clinical and radiological resolution) and recurrence or persistence of disease (new episode or ongoing disease) after treatment. For analytical purposes, recurrence events were further evaluated according to clinical severity. Clinically significant recurrence was defined as extensive or severe recurrence, including persistent severe inflammatory attacks, refractory disease course, multiple recurrences, or fistulizing/complicated presentations, such as sinus tract formation with abscess. These events were analyzed as a subgroup of overall recurrence.

Statistical Analysis

Continuous variables are presented as median (range) or mean $\pm$ standard deviation, and categorical variables as frequencies (%). Inter-group comparisons were performed using the Mann-Whitney U test, chi-square test, or Fisher's exact test as appropriate. Independent predictors of surgical intervention were identified using multivariable binary logistic regression (backward stepwise). A p -value <0.05 was considered statistically significant. All analyses were conducted using SPSS, version 28.0 (IBM Inc., Armonk, NY, USA).

Results

For comparative analysis, 298 patients were included after excluding 12 patients who continued treatment in different cities. The final comparative analysis included two groups: Group 1 (Leech Therapy Group, $n = 41$) and Group 2 (Standard Care Group, $n = 257$).

Baseline Characteristics at Initial Presentation

Baseline demographic and clinical characteristics are summarized in Table 1. The two groups were comparable with respect to age, body mass index, smoking status, parity, number of deliveries, time since last delivery, breastfeeding history, and duration of breastfeeding (all $p > 0.05$). The distribution of initial clinical severity (mild, moderate, or severe/complicated) did not differ significantly between groups (χ^2 test, $p = 0.92$), indicating similar baseline clinical status.

Leech Therapy Group Follow-up Details

Seven patients initially declined in-person hospital attendance after diagnosis. Among these patients, four later presented with complicated fistula formation, two continued leech therapy due to recurrent abscess episodes, and one reported symptom improvement and did not seek further hospital care. All remaining patients attended in-person hospital follow-up. No

additional loss to follow-up occurred beyond the three patients excluded during cohort formation.

Follow-up Duration

All patients had a minimum follow-up of 12 months. The median follow-up duration was 28 months (range 12–60) in the full cohort. Median follow-up was 26 (12–58) months in the standard care group and 32 (12–60) months in the leech therapy group ($p = 0.008$). The longer median follow-up in the leech group reflects the extended disease duration and delayed presentation, as well as the inclusion of late-presenting cases.

Median time from diagnosis to presentation was 15 (6–24) months in the leech therapy group versus 1.5 months in the standard care group ($p < 0.001$). Total disease duration was significantly longer in the leech therapy group (median of 22 months vs. 9 months; $p < 0.001$).

Clinical Outcomes

Clinical outcomes are presented in Table 2. Complete remission was markedly lower in the leech therapy group compared with the standard care group (4.9% vs. 59.1%, $p < 0.001$). Overall recurrence or persistent disease was significantly more frequent in the leech therapy group than in the standard care group (95.1% vs. 21.8%, $p < 0.001$). Among patients with recurrence, clinically significant recurrence (extensive or severe recurrence) occurred in 35 of 39 patients (89.7%) in the leech therapy group compared with 24 of 56 patients (42.9%) in the standard care group ($p < 0.001$). Fistulizing or complicated recurrence represented a subset of these events and was significantly more frequent in the leech therapy group (26.8% vs. 5.4%, $p < 0.001$) (Figure 2).

Multivariable logistic regression analyses identified initial exclusive leech therapy [odds ratio (OR) 6.7, 95% confidence interval (CI) 2.9–15.6, $p < 0.001$] and presence of fistula at presentation (OR 9.3, 95% CI 3.1–28.1, $p < 0.001$) as independent predictors of surgical intervention. Other covariates were not statistically significant.

Discussion and Conclusion

This study provides one of the first comparative cohort analyses examining the clinical impact of exclusive initial hirudotherapy in biopsy-proven IGM. The principal finding was the markedly lower remission rate and substantially higher recurrence and surgical intervention rates among patients who initially relied on hirudotherapy, despite similar baseline demographic and disease severity characteristics.

Complete remission was achieved in only 4.9% of the leech therapy group compared with 59.1% in the standard care group ($p < 0.001$), while overall recurrence/persistence occurred in 95.1% versus 21.8% ($p < 0.001$). The markedly higher recurrence/

Table 1. Baseline characteristics at initial presentation

Characteristic	Leech therapy (n = 41)	Standard care (n = 257)	p-value
Age, median (range), years	36 (24–52)	37 (22–58)	0.51
BMI, mean ± SD, kg/m ²	27.8±4.2	27.4±4.5	0.62
Smoking (current or former), n (%)	8 (19.5%)	48 (18.7%)	0.89
Parity (≥1 delivery), n (%)	35 (85.4%)	220 (85.6%)	0.97
Number of deliveries, median (range)	2 (0–5)	2 (0–6)	0.78
Time since last delivery, median (range), years	6 (1–18)	7 (1–20)	0.44
History of breastfeeding, n (%)	32 (78.0%)	198 (77.0%)	0.88
Duration of breastfeeding, median (range), months	18 (0–60)	16 (0–72)	0.55
Initial severity classification, n (%)			0.92*
- Mild	12 (29.3%)	75 (29.2%)	
- Moderate	14 (34.1%)	90 (35.0%)	
- Severe/complicated	15 (36.6%)	92 (35.8%)	

*Chi-square test; SD: Standard deviation; BMI: Body mass index

Table 2. Clinical outcomes

Outcome	Leech therapy (n = 41)	Standard care (n = 257)	p-value
Complete remission, n (%)	2 (4.9%)	152 (59.1%)	<0.001
Overall recurrence or persistence, n (%)	39 (95.1%)	56 (21.8%)	<0.001
Extensive or severe recurrence*, n (%)	35 (85.4%)	24 (9.3%)	<0.001
Fistulizing/complicated recurrence†, n (%)	11 (26.8%)	14 (5.4%)	<0.001

*Subset of overall recurrence or persistence; †Subset of extensive or severe recurrence

persistence in the leech therapy group is consistent with known risk factors for IGM recurrence, including potential delays in effective immunomodulatory therapy, and is consistent with multicenter data linking recurrence to factors such as history of pregnancy, breastfeeding, prior breast infection, and smoking (3). Importantly, the distribution of initial clinical severity did not differ significantly between groups ($p = 0.92$), suggesting that the observed divergence in outcomes cannot be explained by differences in baseline disease burden. Patients in the leech therapy group experienced a substantial delay in presentation for conventional care, accompanied by significantly prolonged total disease duration compared to the standard care group (1, 2).

IGM is widely regarded as an immune-mediated inflammatory condition characterized by granulomatous lobulitis (2). Early initiation of corticosteroid or immunomodulatory therapy has been associated with better disease control and lower risk of progression to fistulizing or refractory forms (16). In contrast, hirudotherapy does not directly target the underlying granulomatous inflammatory cascade. Medicinal leeches have a well-established role in reconstructive and plastic surgery, where they are used to relieve venous congestion in replanted

digits, pedicled and free flaps, and nipple-areola complex congestion following breast surgery (8, 11). Their anticoagulant and vasodilatory secretions, including hirudin, calin, and destabilase, are effective in reversing localized venous stasis in these vascular contexts (11). The perception of hirudotherapy as a broadly applicable, natural, and low-risk treatment may stem in part from its genuine efficacy in such settings, combined with its long-standing use in traditional Unani and Islamic medicine frameworks (10). However, these mechanisms are mechanistically distinct from the immune-mediated granulomatous inflammation that drives IGM pathology. While medicinal leeches have recognized utility in selected surgical contexts (7, 10), their biological effects, which are primarily anticoagulant with limited local anti-inflammatory activity, are unlikely to modify the immune-driven pathology of IGM.

Spontaneous remission is a well-recognized feature of IGM. Several studies report spontaneous resolution in up to 50% of patients, particularly in mild forms without any intervention, typically within 6–24 months (3-5). This natural course has important implications when interpreting outcomes of non-evidence-based therapies. Mild cases that resolve spontaneously in the community may never present to hospital, whereas

patients with persistent disease are more likely to eventually seek medical care. In the present cohort, patients who initially relied on hirudotherapy presented after a prolonged delay (median 15 months), suggesting that the hospital-based hirudotherapy group may have been enriched with more persistent or treatment-resistant cases. Consistent with this interpretation, among the 39 patients with recurrence or persistence in the leech therapy group, 35 (89.7%) developed clinically significant forms, including fistulizing or extensive/severe recurrence.

The markedly higher rates of fistulizing/complicated and extensive/severe recurrence in the leech therapy group further support the hypothesis that delaying evidence-based treatment may permit progression to more destructive disease phenotypes (3). Multivariable analysis demonstrated that exclusive initial leech therapy was independently associated with the need for surgical intervention (OR 6.7), even after adjustment for baseline severity and other covariates. The presence of fistula at presentation was the strongest predictor (OR 9.3), consistent with prior literature showing fistulizing disease as a marker of advanced inflammatory burden (9).

In Türkiye, hirudotherapy is not reimbursed by the social security institution, even when performed in public facilities, and remains fully out-of-pocket for patients, as the law excludes unlicensed traditional, complementary, and alternative medicine practices (17). Patients who prefer hirudotherapy often seek it directly through unregulated or traditional providers, leading to significant therapeutic delays. Consequently, those who eventually present to hospital are more likely to present with complicated IGM (e.g., fistulizing or severe-persistent disease), as evidenced by the high rate of serious/complicated recurrence at nearly 90% in the leech therapy group. This may contribute to progression to more severe IGM forms and increase the burden on the healthcare system through higher surgical intervention rates, prolonged hospitalizations, and greater treatment costs associated with fistulizing or refractory disease.

These findings must be interpreted within the context of several limitations. The retrospective design introduces potential selection bias, and the leech therapy sub-group was small, making up only about 14% of the whole study population. It is possible that patients who experienced spontaneous resolution following hirudotherapy never presented to hospital, which may

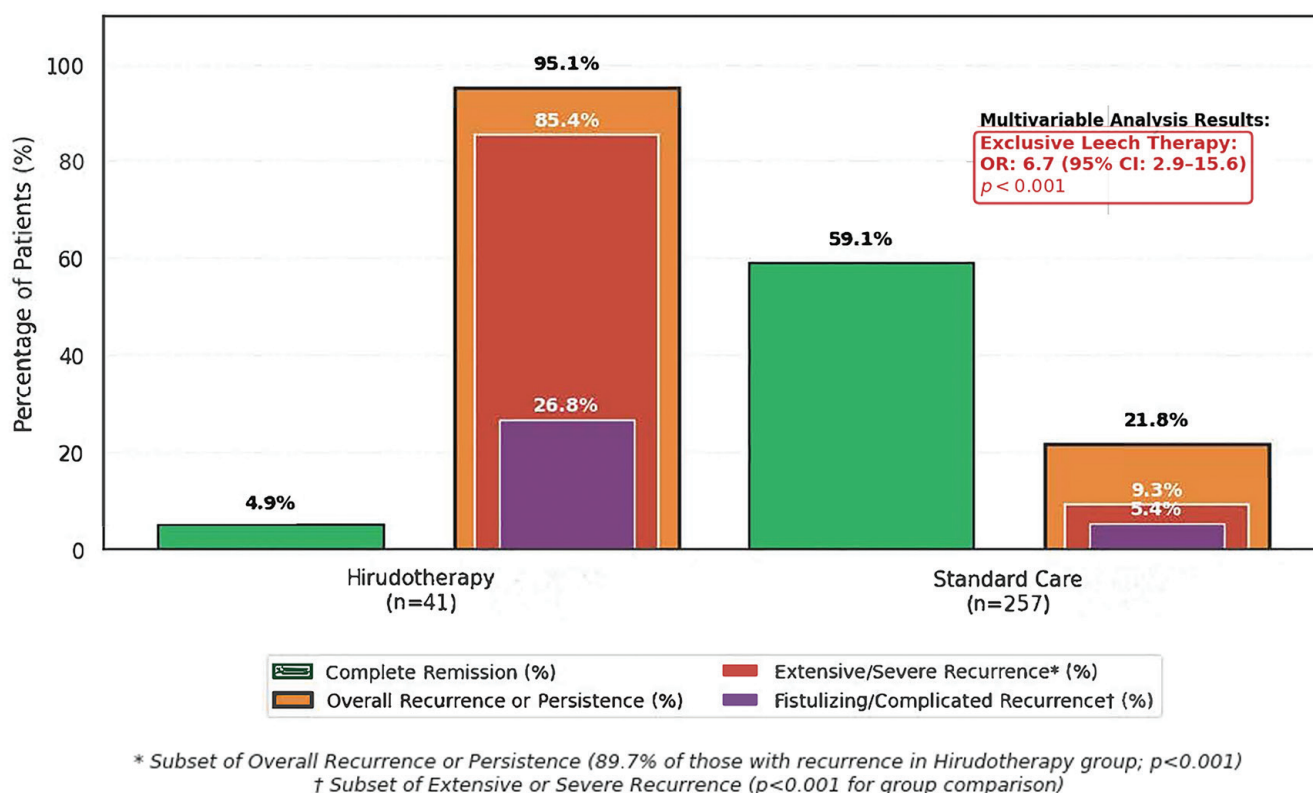


Figure 2. Comparison of remission and recurrence patterns in biopsy-proven IGM according to initial treatment strategy (hirudotherapy vs. standard care). Bars represent percentages of the total cohort. Hirudotherapy was associated with lower remission and higher rates of complicated recurrence, including clinically significant recurrence in 89.7% of those with recurrence ($p < 0.001$)

IGM: Idiopathic granulomatous mastitis; OR: Odds ratio; CI: Confidence interval

have increased the incidence of refractory cases in this group. As reported in multiple review and case series, spontaneous resolution without intervention occurs in up to 50% of IGM cases (16). This phenomenon is likely to occur similarly across both groups, given the comparable baseline severity distributions and the fact that our cohort captured consecutive biopsy-proven cases.

Undetected spontaneous resolutions in the community cannot be completely excluded. However, it is unlikely that such cases disproportionately affected the leech therapy group. Patients in this group presented with prolonged delay before seeking conventional care, and high rates of fistulizing/complicated and extensive/severe recurrence were observed. These findings argue against the possibility that the leech cohort appeared more refractory solely because of unrecognized spontaneous resolutions.

Follow-up for seven patients in the leech group was obtained via telephone interviews, introducing potential reporting bias. However, all included patients had at least 12 months of follow-up. Baseline characteristics were comparable between the groups, supporting the internal validity of the study. Marked differences were observed in remission rates, recurrence patterns, disease duration, and the need for surgical intervention. These findings suggest that the observed results are unlikely to be explained by selection bias alone.

Our findings suggest that prolonged exclusive reliance on non-evidence-based treatment in IGM may be associated with delayed access to effective immunomodulatory therapy, increased disease persistence, and higher surgical burden. Early and culturally sensitive patient counseling may therefore be important to prevent avoidable therapeutic delay and progression to complicated disease.

Relying solely on hirudotherapy as the first treatment for IGM was associated with poorer clinical outcomes. Remission rates were lower, recurrence was higher, especially fistulizing and severe forms, and more patients required surgery. Delays in initiating evidence-based therapy may allow the disease to progress to more complicated stages. Timely initiation of standard treatment therefore appears essential. Clinicians should inform patients about the risks of delaying therapy, and culturally sensitive education and early referral pathways may help bridge traditional practices with evidence-based medical care. Prospective studies are needed to understand the long-term impact of delayed treatment.

Ethics

Ethics Committee Approval: The study was approved by the Istanbul Medipol University Non-Interventional Clinical Research

Ethics Committee (approval no: E-10840098-772.02-3000, date: 24.06.2021) and conducted in accordance with the Declaration of Helsinki.

Informed Consent: This retrospective study was conducted using de-identified data obtained from medical records.

Footnotes

Authorship Contributions

Concept: M.T., K.C., M.B.A., M.Ö., A.G., R.C.A.O., H.K.; Design: M.T., K.C., M.B.A., M.Ö., A.G., R.C.A.O., H.K.; Data Collection and/or Processing: M.T., K.C., M.B.A., M.Ö., A.G., R.C.A.O.; Analysis and/or Interpretation: M.T., K.C., M.B.A., M.Ö., A.G., R.C.A.O., H.K.; Literature Search: M.T., K.C., M.B.A., M.Ö., A.G., R.C.A.O., H.K.; Writing: M.T., K.C., M.B.A., M.Ö., A.G., R.C.A.O., H.K.

Conflict of Interest: The authors have no conflicts of interest to declare.

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References

1. Aghajanzadeh M, Hassanzadeh R, Alizadeh Sefat S, Alavi A, Hemmati H, Esmaeili Delshad MS, et al. Granulomatous mastitis: presentations, diagnosis, treatment and outcome in 206 patients from the north of Iran. *Breast*. 2015; 24: 456-460. (PMID: 25935828) [Crossref]
2. Kaviani A, Vasigh M, Omranipour R, Mahmoudzadeh H, Elahi A, Farivar L, et al. Idiopathic granulomatous mastitis: looking for the most effective therapy with the least side effects according to the severity of the disease in 374 patients in Iran. *Breast J*. 2019; 25: 672-677. (PMID: 31087459) [Crossref]
3. Uysal E, Soran A, Sezgin E; Granulomatous Mastitis Study Group. Factors related to recurrence of idiopathic granulomatous mastitis: what do we learn from a multicentre study? *ANZ J Surg*. 2018; 88: 635-639. (PMID: 28749045) [Crossref]
4. Hasbahceci M, Kadioglu H. Use of imaging for the diagnosis of idiopathic granulomatous mastitis: a clinician's perspective. *J Coll Physicians Surg Pak*. 2018; 28: 862-867. (PMID: 30369380) [Crossref]
5. Emiroglu M, Akcan A, Velidedeoglu M, Girgin S, Aytac O, Canturk NZ, et al. Diagnosis, approach, and clinical classification of idiopathic granulomatous mastitis: consensus report. *Breast Care (Basel)*. 2024; 19: 243-251. (PMID: 39439860) [Crossref]
6. Ozmen V, Cantürk Z, Celik V, Güler N, Kapkaç M, Koyuncu A, et al. Breast disease. Ankara: Federation of Breast Diseases Society, Güneş Medical Publishing; 2012. p. 55-65. [Crossref]
7. Soran A, Tokoçin M, Aytaç HÖ, Nazlı MA, Özbaş S, Yiğit B, et al. Pittsburgh classification and treatment algorithm for idiopathic granulomatous mastitis: a multicenter cohort study. *Eur J Breast Health*. 2026; 22: 199-208. (PMID: 41874127) [Crossref]
8. Rajaram R, Cevik J, Bhindi N, Seth I, Rozen WM. The use of medicinal leeching in breast surgery: a systematic review. *J Clin Med*. 2024; 13: 1243. (PMID: 38592085) [Crossref]
9. Torresetti M, Peltristo B, Taddei FMJ, Di Benedetto G. *Aeromonas hydrophila* infection following leech therapy for the treatment of nipple-areola complex congestion after breast reduction: a case report. *Arch Plast Surg*. 2024; 51: 317-320. (PMID: 38737840) [Crossref]
10. Asnah A, Farouqi MA. An evidence based approach of Unani regimen: Irsal e Alaq (medicinal leech therapy). *Int J Unani Integr Med*. 2021; 5: 36-42. [Crossref]

11. Sig AK, Guney M, Uskudar Guclu A, Ozmen E. Medicinal leech therapy-an overall perspective. *Integr Med Res.* 2017; 6: 337-343. (PMID: 29296560) [\[Crossref\]](#)
12. Toktas O, Konca C, Trabulus DC, Soyder A, Koksall H, Karanlik H, et al. A novel first-line treatment alternative for noncomplicated idiopathic granulomatous mastitis: combined intralesional steroid injection with topical steroid administration. *Breast Care (Basel).* 2021; 16: 181-187. (PMID: 34012373) [\[Crossref\]](#)
13. Wijesinghe A, Lakmal K, Senevirathna J, Wijetilake B, Fernando JLTK, Jayarajah U, et al. The use of intralesional corticosteroids in idiopathic granulomatous mastitis: a systematic review. *Eur J Breast Health.* 2024; 20: 233-240. (PMID: 39323266) [\[Crossref\]](#)
14. Gulluoglu BM. Idiopathic granulomatous mastitis: do we really regard it as a surgical disease anymore? *World J Surg.* 2015; 39: 2724-2725. (PMID: 26243565) [\[Crossref\]](#)
15. Papila Kundaktepe B, Velidedeoğlu M, Mete B. The effect of methotrexate monotherapy on treatment-resistant idiopathic granulomatous mastitis patients. *Surgeon.* 2022; 20: e13-e19. (PMID: 33836950) [\[Crossref\]](#)
16. Dilaveri C, Degnim A, Lee C, DeSimone D, Moldoveanu D, Ghosh K. Idiopathic granulomatous mastitis. *Breast J.* 2024; 2024: 6693720. (PMID: 38304866) [\[Crossref\]](#)
17. Republic of Türkiye. Social insurance and general health insurance law no. 5510, Article 64(b). *Official Gazette.* 2006;(26200). [\[Crossref\]](#)