e-ISSN:2602-2079

Volume 10
Issue 8
2026

JOURNAL of Surgery and Medicine

International Medical Journal

JOSAM

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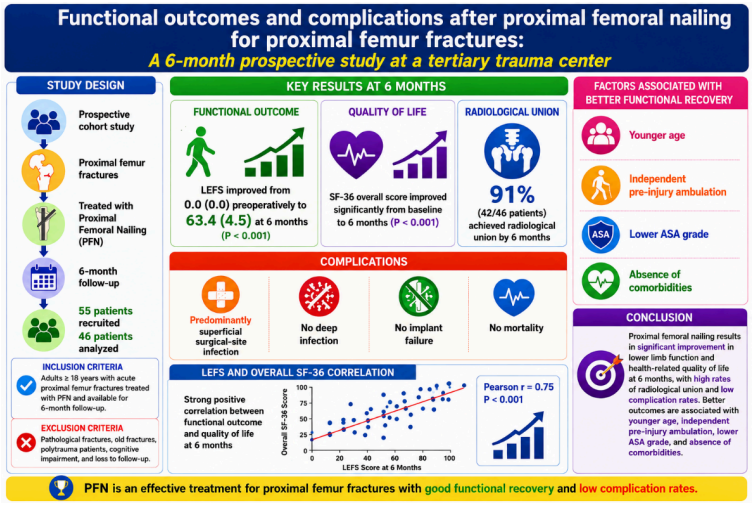
Vol. 10 No. 8 (2026)

Published: 2026-08-27

Research Article

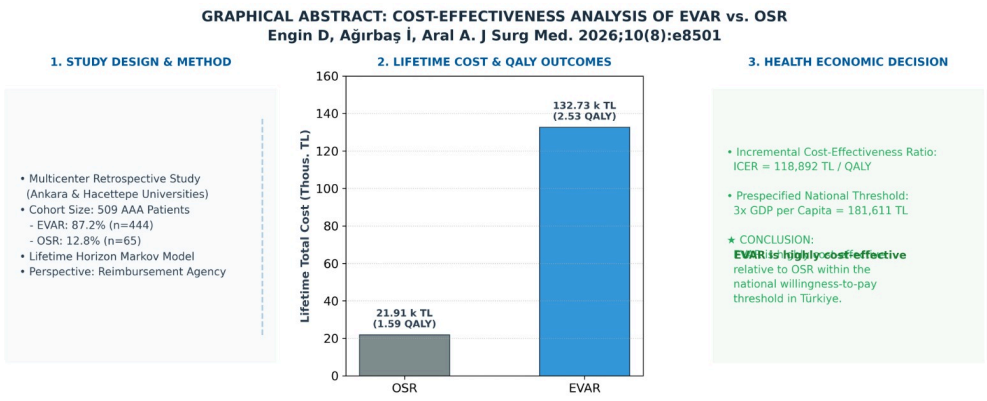


Early functional outcomes of proximal femur fractures treated with proximal femoral nailing in a tertiary trauma center

Proximal femur fractures treated with PFN

Kayode Odejobi, Kehinde Adesola Alatishe, Ugochuku Akpati

e8454

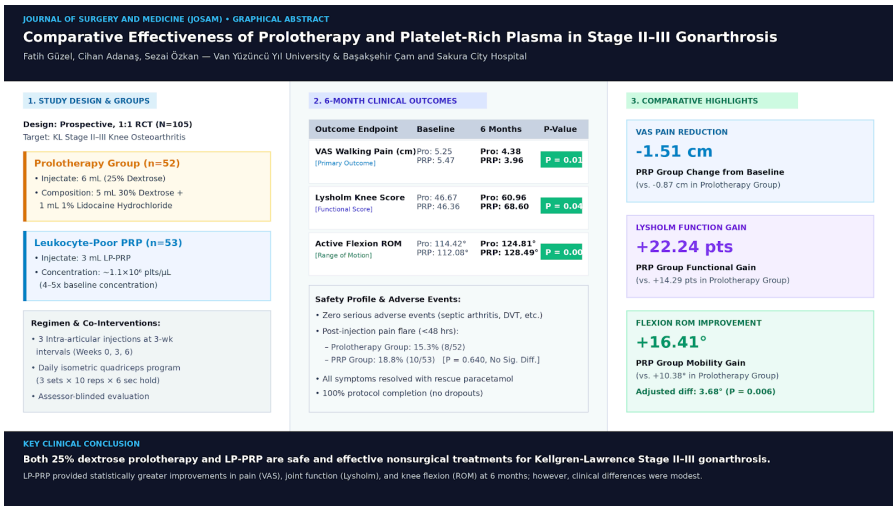


A multicenter cost-effectiveness analysis of endovascular versus open surgical repair for abdominal aortic aneurysm

Cost-effectiveness of EVAR versus OSR

Derya Engin, İsmail Ağırbaş, Atilla Aral

e8501

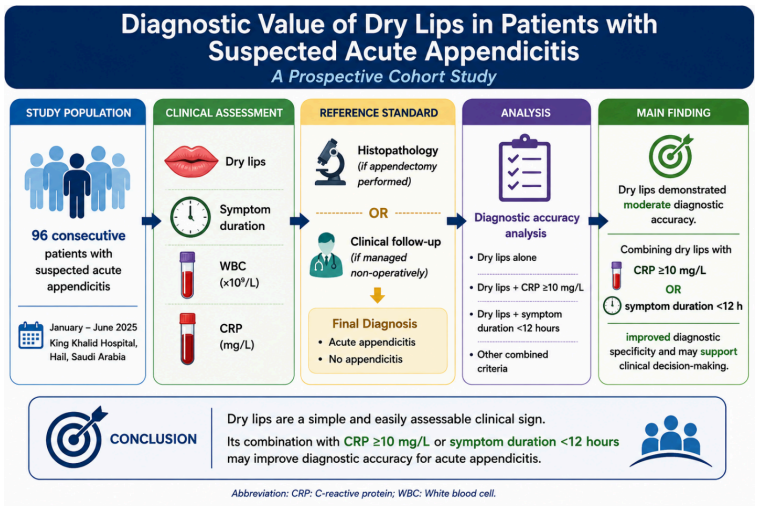


Comparative effectiveness of prolotherapy and platelet-rich plasma in patients with stage II–III gonarthrosis: A randomized controlled trial

Prolotherapy and platelet-rich plasma in patients with gonarthrosis

Fatih Güzel, Cihan Adanaş, Sezai Özkan

e8632



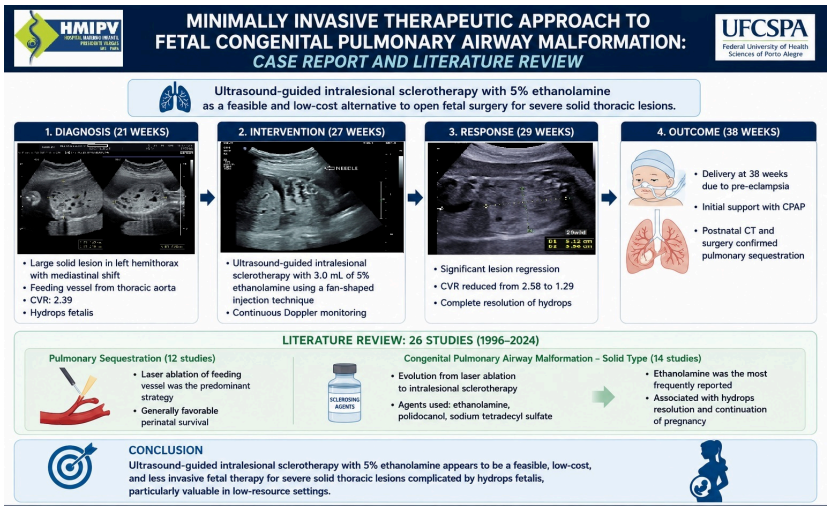
Diagnostic value of dry lips in patients with suspected acute appendicitis: A prospective cohort study

Dry lips in acute appendicitis diagnosis

Yahia Akeely, Nouf Alblowi, Wael Alanazi, Shabana Begum Patel, Nader Bokhari, Razan Alshaheen, Ali Afaifi

e8648

Case Report

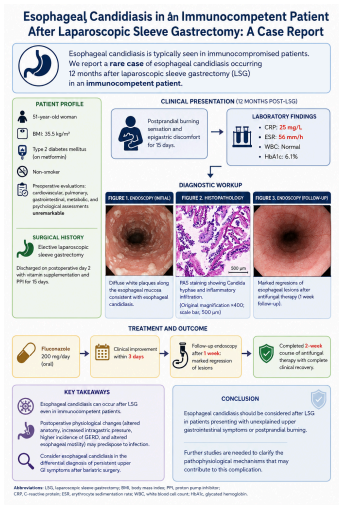


Minimally invasive therapeutic approach to fetal congenital pulmonary airway malformation: Case report and literature review

Fetal congenital pulmonary airway malformation

Alexandre Da Silva Rocha, Juliana Perotoni Dondé, Mariana Morais Pereira, Arthur Martiny, Andre Campos da Cunha, Jorge Bianchi Telles, Vinicius Toniolli

e8470

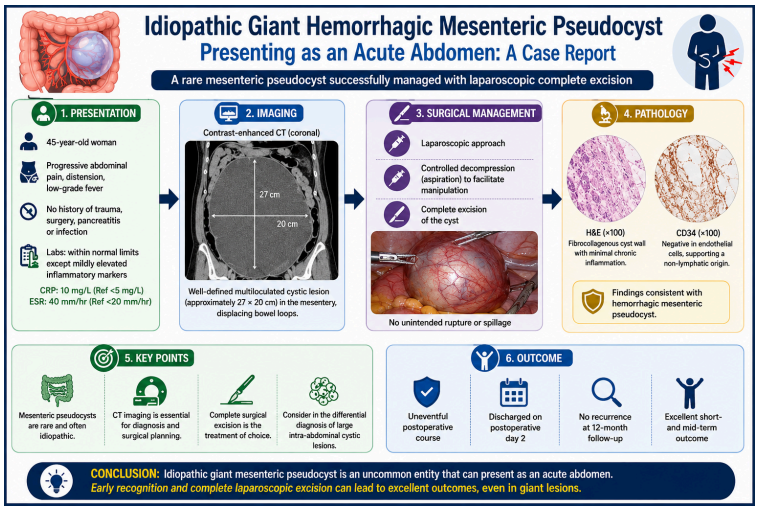


Esophageal candidiasis in an immunocompetent patient after laparoscopic sleeve gastrectomy: A case report

Esophageal candidiasis after laparoscopic sleeve gastrectomy

Abdulaziz Abouhosa, Layan Ghunaim, Beril Kaptan, Rabia Seray Barlak, Ufuk Utku Goktug, Tolga Muftuoglu, Zeyneb Tatar

e8504



Idiopathic giant hemorrhagic mesenteric pseudocyst presenting as an acute abdomen: A case report

Idiopathic giant hemorrhagic mesenteric pseudocyst

Abdulaziz Abouhosa, Beril Kaptan, Rabia Seray Barlak, Ezgi Vural, Layan Ghunaim, Ufuk Utku Goktug, Tolga Muftuoglu, Zeyneb Tatar

e8525

J Surg Med. 2026;10(8):e8632.
https://doi.org/10.28982/josam.8632

JOSAM

Research Article
https://jsurgmed.com/

Journal of Surgery and Medicine
e-ISSN: 2602-2079

Comparative effectiveness of prolotherapy and platelet-rich plasma in patients with stage II–III gonarthrosis: A randomized controlled trial

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Ethical Approval
Ethical approval was granted by the Van Yüzüncü Yıl University Clinical Research Ethics Committee on November 25, 2020 (Decision No: 2020/11-04).

Informed consent: Written informed consent was obtained from all participants.

Trial registration: Not registered in a public clinical trial registry; national thesis repository ID: 684210.

Conflict of Interest
No conflict of interest was declared by the authors.

Financial Disclosure
The authors declared that this study has received no financial support.

Published
2026 August 3

Abstract

Background/Aim: Gonarthrosis (knee osteoarthritis) is a common degenerative musculoskeletal condition that causes progressive joint pain, stiffness, and functional impairment. Conservative nonsurgical treatments primarily provide symptomatic relief, whereas regenerative orthobiologic interventions, including platelet-rich plasma (PRP) and hyperosmolar dextrose prolotherapy, have attracted interest because of their potential therapeutic effects. This study compared the clinical effectiveness of PRP and dextrose prolotherapy in patients with stage II–III gonarthrosis.

Methods: In this prospective, randomized, assessor-blinded controlled trial, 105 patients aged 40–70 years with Kellgren–Lawrence grade II–III gonarthrosis were enrolled between November 2020 and April 2021 and followed through October 2021. Participants received three intra-articular injections of either 25% dextrose prolotherapy (n = 52; 6 mL) or leukocyte-poor PRP (n = 53; 3 mL; estimated 4- to 5-fold baseline platelet concentration) at 3-week intervals. Both groups performed a standardized daily quadriceps-strengthening program. The prespecified primary outcome was the Visual Analog Scale (VAS) walking-pain score at 6 months. Secondary outcomes were the Lysholm Knee Score and active knee-flexion range of motion (ROM), assessed at baseline and at 3 and 6 months. Data were analyzed using linear mixed-effects models with 95% confidence intervals (CIs) and exact *P*-values.

Results: All 105 randomized participants completed the protocol. Both groups showed significant improvements in pain and function from baseline to 6 months ($P < 0.001$). At 6 months, PRP produced greater improvement than prolotherapy in the VAS pain score (adjusted mean difference, 0.42 cm; 95% CI, 0.08–0.76; $P = 0.015$; group-by-time interaction, $P = 0.018$), Lysholm score (adjusted mean difference, 7.64 points; 95% CI, 0.32–14.96; $P = 0.041$; interaction, $P = 0.024$), and knee-flexion ROM (adjusted mean difference, 3.68°; 95% CI, 0.51–6.85; $P = 0.006$). No serious adverse events occurred. Transient postinjection soreness occurred in 15.3% of prolotherapy recipients and 18.8% of PRP recipients ($P = 0.640$).

Conclusion: Both leukocyte-poor PRP and 25% dextrose prolotherapy were safe and effective nonsurgical treatments for early- to moderate-stage knee osteoarthritis. PRP provided statistically greater improvements in pain, function, and mobility at 6 months; however, the between-group differences were modest and should be interpreted in relation to clinically important thresholds.

Keywords: gonarthrosis, knee osteoarthritis, platelet-rich plasma, prolotherapy, randomized controlled trial

How to cite: Güzel F, Adanaş C, Özkan S. Comparative effectiveness of prolotherapy and platelet-rich plasma in patients with stage II–III gonarthrosis: A randomized controlled trial. J Surg Med. 2026;10(8):e8632.

Introduction

Osteoarthritis (OA) is a chronic degenerative joint disorder characterized by progressive articular cartilage loss, subchondral bone remodeling, synovial inflammation, and periarticular tissue degradation [1, 2]. Clinical manifestations include persistent joint pain, morning stiffness, swelling, reduced range of motion (ROM), and progressive loss of physical independence, all of which can substantially impair health-related quality of life [1]. The knee is the most frequently affected weight-bearing joint, and symptomatic gonarthrosis has been reported in 10%–30% of individuals older than 50 years [2, 3].

Current conservative management guidelines emphasize symptom relief, preservation of physical function, and postponement of joint replacement [4]. Standard nonsurgical treatments include oral paracetamol, nonsteroidal anti-inflammatory drugs (NSAIDs), physical therapy, structured quadriceps exercises, and intra-articular corticosteroid or hyaluronic acid injections [1, 4]. Over the past decade, regenerative orthobiologic approaches, particularly platelet-rich plasma (PRP) and hyperosmolar dextrose prolotherapy, have emerged as minimally invasive treatment options [5, 6].

Autologous PRP is prepared from peripheral venous blood and concentrated by centrifugation to isolate a high density of platelets and associated alpha-granule growth factors, including transforming growth factor beta, platelet-derived growth factor, vascular endothelial growth factor, and fibroblast growth factor [6, 7]. These bioactive proteins may modulate intra-articular inflammatory pathways, promote extracellular matrix synthesis, and support tissue homeostasis [6]. Dextrose prolotherapy acts through a distinct hyperosmolar mechanism. Intra-articular administration of hypertonic dextrose, usually at a concentration of 20%–25%, induces localized osmotic stress and a controlled transient inflammatory response that may stimulate tissue repair and growth-factor release [8, 9].

Although prospective studies have evaluated PRP and prolotherapy separately against saline placebo or viscosupplementation [10-13], randomized head-to-head comparisons of PRP and dextrose prolotherapy in gonarthrosis remain limited [4, 14]. Existing comparative evidence is further constrained by small sample sizes, heterogeneous injection protocols, incomplete orthobiologic characterization, and reliance on cross-sectional pairwise analyses [4, 15].

Therefore, this prospective, assessor-blinded randomized controlled trial aimed to compare the clinical effectiveness of intra-articular leukocyte-poor PRP (LP-PRP) and 25% dextrose prolotherapy in patients with Kellgren–Lawrence grade II–III gonarthrosis over 6 months using longitudinal linear mixed-effects modeling.

Materials and methods

Study design and ethical considerations

This prospective, assessor-blinded, 1:1 parallel-group randomized controlled trial was conducted at the Orthopedics and Traumatology Outpatient Clinic of Van Yüzüncü Yıl University Dursun Odabaş Medical Center. Ethical approval was obtained from the Van Yüzüncü Yıl University Clinical Research Ethics Committee on November 25, 2020 (Decision No: 2020/11-04). All procedures were performed in accordance with the principles of the Declaration of Helsinki. Written informed consent was obtained from all participants before enrollment. Participants were recruited from November 2020 through April 2021, and the 3- and 6-month follow-up assessments were completed by October 2021.

Participants and eligibility criteria

A total of 105 ambulatory patients aged 40–70 years with symptomatic idiopathic knee OA were enrolled. Eligible patients had a clinical and weight-bearing radiographic diagnosis of Kellgren–Lawrence grade II or III gonarthrosis, knee pain lasting longer than 6 months, a baseline VAS walking-pain score of at least 4 cm, and willingness to comply with the injection and follow-up schedules. For patients with bilateral symptomatic gonarthrosis, the knee identified by the patient as more painful was selected for treatment and evaluation.

Patients were excluded if they had secondary knee OA caused by an inflammatory rheumatic disease, such as rheumatoid arthritis, ankylosing spondylitis, or gout; an active local joint or systemic infection; lower-limb mechanical-axis malalignment greater than 5° of varus or valgus or another structural knee deformity; previous knee surgery or arthroscopy; knee trauma within the previous 6 months; an intra-articular corticosteroid, hyaluronic acid, or orthobiologic injection in either knee within the previous 6 months; a severe systemic comorbidity, including uncontrolled diabetes mellitus, active malignancy, hepatic or renal impairment, or a bleeding disorder; or regular use of oral anticoagulant or antiplatelet medication.

Randomization, allocation concealment, and masking

Eligible participants were randomly assigned in a 1:1 ratio to 25% dextrose prolotherapy (n = 52) or LP-PRP (n = 53). An independent statistician generated the allocation sequence using computer-generated block randomization with variable block sizes of four and six. Sequentially numbered, opaque, sealed envelopes containing group assignments were prepared and stored securely to maintain allocation concealment. An unblinded research nurse opened the assigned envelope immediately before preparation of the procedure.

Complete double-blinding was not feasible because of the visible procedural differences between groups, including venous blood collection and differences in injectate color and volume. Nevertheless, assessor blinding was maintained. All clinical outcome assessments, including the VAS, Lysholm score, and goniometric ROM measurements, were performed by a blinded physical therapist who had no access to treatment allocation, injection procedures, or patient medical records.

Interventions and orthobiologic characterization

All injections were administered under strict aseptic conditions by one senior orthopedic surgeon using a standardized anterolateral intra-articular approach. Patients were placed supine with the knee supported in 20° of flexion by a popliteal cushion.

Patients in the prolotherapy group received three intra-articular dextrose injections at 3-week intervals (weeks 0, 3, and 6). Each 6-mL dose consisted of 5 mL of 30% dextrose and 1 mL of 1% lidocaine hydrochloride, yielding a final dextrose concentration of 25%.

Patients in the PRP group received three intra-articular injections according to the same schedule. For each treatment, 20 mL of peripheral venous blood was collected into vacuum tubes

containing acid citrate dextrose solution A anticoagulant. A standardized double-spin protocol was used. The first centrifugation at 1,500 rpm (approximately 300 × g) for 10 minutes separated red blood cells from the plasma and buffy-coat layers. The upper plasma and buffy-coat fraction was transferred to a second sterile tube and centrifuged at 3,600 rpm (approximately 1,200 × g) for 15 minutes. The upper platelet-poor plasma was discarded, leaving 3 mL of concentrated LP-PRP with an estimated 4- to 5-fold increase over the baseline platelet concentration (approximately 1,100,000 platelets/μL) and minimal leukocyte contamination. No exogenous activator, such as thrombin or calcium chloride, was added. PRP was injected within 10 minutes after preparation.

Co-interventions and postprocedural care

After each injection, patients were observed for 30 minutes. Participants were instructed to avoid NSAIDs for 2 weeks before enrollment and throughout the 6-month study period. Oral paracetamol was permitted for transient postinjection discomfort at a maximum dose of 2 g/day, and daily use was recorded in patient diaries. All participants were instructed to perform a standardized home-based isometric quadriceps-strengthening program consisting of three sets of 10 repetitions daily, with each contraction held for 6 seconds. Adherence was monitored using self-reported exercise logs reviewed during clinic visits.

Outcome measures

Assessments were performed at baseline (week 0, before injection) and at 3 and 6 months after treatment.

The primary outcome was the VAS walking-pain score measured on a 10-cm horizontal line, where 0 cm indicated no pain and 10 cm indicated unbearable pain. The prespecified primary endpoint was the VAS walking-pain score at 6 months.

Secondary outcomes were the Lysholm Knee Score and active knee-flexion ROM. The Lysholm score ranges from 0 to 100 and assesses pain, instability, locking, swelling, stair climbing, and squatting; the validated Turkish version was used [16]. Active knee-flexion ROM was measured in degrees in the supine position with a standard 30-cm universal goniometer by the blinded assessor, and the mean of three consecutive measurements was recorded.

Local and systemic adverse events, including postinjection pain flare, joint effusion, warmth, hematoma, infection, and vasovagal events, were evaluated systematically at each follow-up visit.

Sample size calculation

The sample size was determined before trial initiation using G*Power version 3.1. Based on previous studies of intra-articular regenerative treatment for knee OA, an effect size of d = 0.55 was anticipated for the primary outcome. With a two-sided α of 0.05 and 80% power (1 − β), at least 42 participants were required in each group (84 in total). To allow for a potential loss to follow-up of 20%, 105 participants were enrolled.

Statistical analysis

Statistical analyses were performed using SPSS version 27.0 (IBM Corp., Armonk, NY, USA). The distribution of continuous variables was evaluated using the Kolmogorov–Smirnov test and visual inspection of Q–Q plots. Continuous variables are presented as mean (standard deviation [SD]), and categorical variables are presented as number (percentage).

Correlated repeated measurements within participants were analyzed using linear mixed-effects models with a participant-level random intercept. Fixed effects were treatment group (prolotherapy or PRP), time (baseline, 3 months, or 6 months), and the group-by-time interaction. Models were adjusted for the baseline value of the corresponding outcome. Treatment effects are reported as adjusted between-group mean differences with 95% CIs and exact *P*-values. Post hoc pairwise comparisons were adjusted for multiplicity using the Holm–Bonferroni procedure. Categorical variables were compared using Pearson's chi-square test or Fisher's exact test, as appropriate. A two-sided *P*-value < 0.05 was considered statistically significant.

Results

Participant flow and baseline characteristics

All 105 eligible patients were randomized, received all three scheduled injections, and completed the 3- and 6-month assessments. The prolotherapy group included 52 participants, and the PRP group included 53. There were no reported dropouts or protocol deviations. All randomized participants were included in the analysis under the intention-to-treat principle, and no outcome data were missing.

The cohort included 82 women (78.1%) and 23 men (21.9%), and the overall mean age was 55.14 (9.12) years. Baseline characteristics, including age, sex, body mass index (BMI), Kellgren–Lawrence grade, symptom duration, treated knee, and paracetamol use, were clinically comparable between the treatment groups (Table 1).

Table 1. Baseline demographic and clinical characteristics

Baseline characteristic	Prolotherapy group (n = 52)	PRP group (n = 53)
Age, years, mean (SD)	56.62 (9.32)	53.70 (8.77)
BMI, kg/m², mean (SD)	30.73 (5.31)	31.57 (5.32)
Sex, n (%)	Women: 38 (73.1) Men: 14 (26.9)	Women: 44 (83.0) Men: 9 (17.0)
Kellgren–Lawrence grade n (%)	Grade II: 28 (53.8) Grade III: 24 (46.2)	Grade II: 29 (54.7) Grade III: 24 (45.3)
Symptom duration months, mean (SD)	34.2 (14.5)	36.8 (15.1)
Treated knee, n (%)	Right: 27 (51.9) Left: 25 (48.1)	Right: 29 (54.7) Left: 24 (45.3)
Baseline paracetamol use days/week, mean (SD)	3.2 (1.1)	3.4 (1.2)

Abbreviations: BMI: body mass index, PRP: platelet-rich plasma, SD: standard deviation. Baseline significance *P*-values are not presented.

Primary outcome: VAS pain score

Baseline VAS walking-pain scores were 5.25 (1.05) cm in the prolotherapy group and 5.47 (0.89) cm in the PRP group. Linear mixed-effects analysis showed significant reductions in pain from baseline to 6 months in both groups: −0.87 cm with prolotherapy and −1.51 cm with PRP ($P < 0.001$ for both). At the prespecified 6-month endpoint, the mean VAS pain score was lower in the PRP group than in the prolotherapy group (3.96 vs. 4.38 cm). The adjusted between-group difference was 0.42 cm (95% CI, 0.08–0.76; $P = 0.015$). The group-by-time interaction was also significant ($P = 0.018$), indicating greater pain reduction over time with PRP (Table 2).

Table 2. Visual Analog Scale walking-pain scores by treatment group

Time point	Prolotherapy mean (SD)	PRP mean (SD)	Adjusted difference (95% CI)*	*P*-value*
Baseline	5.25 (1.05)	5.47 (0.89)	—	—
Month 3	5.17 (1.13)	4.75 (1.09)	0.42 (0.02–0.82)	0.037
Month 6 (primary endpoint)	4.38 (0.99)	3.96 (0.88)	0.42 (0.08–0.76)	0.015
Baseline-to-month 6 change	−0.87 (1.47)	−1.51 (1.00)	0.64 (0.12–1.16)	0.018

Abbreviations: CI: confidence interval, PRP: platelet-rich plasma, SD: standard deviation, VAS: Visual Analog Scale. *Derived from a linear mixed-effects model adjusted for baseline values and the group-by-time interaction. Negative change indicates pain reduction. A positive adjusted difference favors PRP. $P < 0.05$ was considered statistically significant.

Secondary outcomes: Lysholm score and knee-flexion ROM

Baseline Lysholm scores were similar in the prolotherapy and PRP groups (46.67 and 46.36 points, respectively). Both groups showed progressive functional improvement over 6 months ($P < 0.001$). At 6 months, the Lysholm score was higher with PRP than with prolotherapy (68.60 vs. 60.96 points), with an adjusted between-group difference of 7.64 points (95% CI, 0.32–14.96; $P = 0.041$). The group-by-time interaction was significant ($P = 0.024$) (Table 3).

Table 3. Lysholm Knee Scores by treatment group

Time point	Prolotherapy mean (SD)	PRP mean (SD)	Adjusted difference (95% CI)*	*P*-value*
Baseline	46.67 (18.32)	46.36 (17.73)	—	—
Month 3	53.31 (18.70)	60.11 (22.26)	6.80 (−1.12–14.72)	0.134
Month 6	60.96 (20.12)	68.60 (17.55)	7.64 (0.32–14.96)	0.041
Baseline-to-month 6 change	14.29 (18.74)	22.24 (14.45)	7.95 (1.42–14.48)	0.018

Abbreviations: CI: confidence interval, PRP: platelet-rich plasma, SD: standard deviation. *Derived from a linear mixed-effects model adjusted for baseline values. Positive change indicates functional improvement, and a positive adjusted difference favors PRP. $P < 0.05$ was considered statistically significant.

Baseline active knee-flexion ROM was 114.42° in the prolotherapy group and 112.08° in the PRP group. At 6 months, ROM had improved in both groups and was greater with PRP (128.49° vs. 124.81°). The adjusted between-group difference was 3.68° (95% CI, 0.51–6.85; $P = 0.006$), and the difference in baseline-to-6-month change was significant ($P = 0.011$) (Table 4).

Table 4. Active knee-flexion range of motion by treatment group

Time point	Prolotherapy mean (SD)	PRP mean (SD)	Adjusted difference (95% CI)*	*P*-value*
Baseline	114.42 (10.92)	112.08 (11.66)	—	—
Month 3	117.88 (9.97)	119.06 (8.61)	1.18 (−2.41–4.77)	0.532
Month 6	124.81 (10.19)	128.49 (6.01)	3.68 (0.51–6.85)	0.006
Baseline-to-month 6 change	10.38 (11.88)	16.41 (12.10)	6.03 (1.41–10.65)	0.011

Abbreviations: CI: confidence interval, PRP: platelet-rich plasma, ROM: range of motion, SD: standard deviation. *Derived from a linear mixed-effects model adjusted for baseline values. Positive change indicates improved ROM, and a positive adjusted difference favors PRP. $P < 0.05$ was considered statistically significant.

Adverse events and safety

No serious adverse events, including septic arthritis, deep vein thrombosis, tendon rupture, or anaphylaxis, occurred in either group. Transient postinjection joint pain and fullness lasting less than 48 hours occurred in eight patients (15.3%) in the prolotherapy group and 10 patients (18.8%) in the PRP group, with no significant between-group difference ($P = 0.640$). All minor symptoms resolved spontaneously or with limited rescue paracetamol (maximum permitted dose of 2 g/day for up to 48 hours post-injection). All participants completed the three planned injection sessions.

Discussion

This randomized controlled trial compared intra-articular LP-PRP and 25% dextrose prolotherapy in 105 patients with Kellgren–Lawrence grade II–III gonarthrosis over 6 months using longitudinal linear mixed-effects modeling. Both treatments were associated with improvements in pain, function, and joint mobility. In the head-to-head comparison, PRP produced statistically greater improvements than prolotherapy at the 6-month endpoint for the primary and secondary outcomes.

These findings should be interpreted by distinguishing statistical significance from clinical importance. For walking pain measured on a 10-cm VAS, the reported minimal clinically important improvement is approximately 1.5–2.0 cm [17]. In this trial, the within-group reduction with PRP was 1.51 cm, whereas the reduction with prolotherapy was 0.87 cm; however, the net between-group difference favoring PRP was only 0.42 cm (95% CI, 0.08–0.76). The observed between-group difference in the Lysholm score was 7.64 points (95% CI, 0.32–14.96), and the between-group difference in knee-flexion ROM was 3.68° (95% CI, 0.51–6.85). Therefore, although PRP was statistically superior, the magnitude of the relative benefit was modest, and both interventions may have clinical utility as nonsurgical options.

The potential effects of PRP have been attributed to its concentration of autologous growth factors, including transforming growth factor beta, platelet-derived growth factor, and insulin-like growth factor 1, and anti-inflammatory mediators that may suppress synovial inflammation, downregulate matrix metalloproteinases, and promote extracellular matrix synthesis [6, 7]. Hyperosmolar dextrose prolotherapy may induce transient local osmotic stress and a controlled inflammatory response, thereby recruiting fibroblasts and growth factors involved in tissue repair [8, 9]. Because this trial evaluated clinical outcomes without structural magnetic resonance imaging or histopathologic biomarkers, these mechanisms remain hypothetical explanations rather than demonstrated structural effects.

The findings should also be considered in relation to previous comparative evidence. Eroğlu et al. [4] compared PRP, prolotherapy, and saline in a smaller randomized cohort and found no significant superiority of either active treatment over placebo or over each other. By contrast, systematic reviews by Meheux et al. [10] and Laudy et al. [13] reported that intra-articular PRP may provide more durable symptomatic benefit than hyaluronic acid or corticosteroid injections over 6–12 months. The present study adds a randomized head-to-head comparison using longitudinal statistical modeling but does not establish a large clinically important advantage of PRP.

Methodological strengths include the prospective randomized design, complete reported follow-up, standardized injection techniques, characterization of the LP-PRP preparation, assessor blinding, and analysis using linear mixed-effects models.

Several limitations should be acknowledged. First, the trial did not include a saline placebo or sham-injection group; therefore, nonspecific contextual and placebo effects could not be separated from treatment effects. Second, complete double-blinding was not feasible because of differences in injectate appearance and the blood-collection procedure, although outcome assessors were blinded. Third, the 6-month follow-up period precludes conclusions about durability at 12–24 months. Fourth, women comprised 78.1% of the cohort, which may limit generalizability by sex. Finally, the Lysholm score was developed originally for ligamentous knee injuries rather than OA-specific assessment. Although a validated Turkish version is available

[18], disease-specific instruments such as the Western Ontario and McMaster Universities Osteoarthritis Index or the Knee injury and Osteoarthritis Outcome Score may have been more appropriate.

In conclusion, LP-PRP and 25% dextrose prolotherapy were safe and well tolerated and were associated with improvements in pain and knee function in patients with Kellgren–Lawrence grade II–III gonarthrosis. PRP produced statistically greater improvements at 6 months, but the between-group differences were modest. Multicenter randomized trials with a registered protocol, placebo control, longer follow-up, structural imaging, and OA-specific outcome instruments are needed.

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J Surg Med. 2026;10(8):e8501.
https://doi.org/10.28982/josam.8501

JOSAM

Research Article
https://jsurgmed.com/

Journal of Surgery and Medicine
e-ISSN: 2602-2079

A multicenter cost-effectiveness analysis of endovascular versus open surgical repair for abdominal aortic aneurysm

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Abstract

Background/Aim: Abdominal aortic aneurysm carries substantial clinical and economic consequences, and the long-term economic value of the available repair strategies remains important for reimbursement decisions. This study evaluated the cost-effectiveness of endovascular aneurysm repair (EVAR) and open surgical repair (OSR) for abdominal aortic aneurysm using actual hospital invoice data.
Methods: This retrospective multicenter study included 509 patients treated with EVAR or OSR at Ankara University and Hacettepe University Hospitals between 2011 and 2020. Cost data were derived from actual hospital invoices. Quality of life was assessed using the EQ-5D-3L questionnaire, HeartQoL, and a visual analog scale. Cost-effectiveness was evaluated using a Markov model, and a budget impact analysis was performed.
Results: The 1-year total cost was 58,732.38 TL ($8,386.24) for EVAR and 15,638.25 TL ($2,232.95) for OSR, while the corresponding lifetime costs were 132,726.00 TL ($18,951.65) and 21,906.23 TL ($3,127.94), respectively. The cost per quality-adjusted life-year (QALY) was 52,460.87 TL ($7,490.77) for EVAR and 13,777.50 TL ($1,967.26) for OSR. The incremental cost-effectiveness ratio was 118,892 TL ($16,976.33) per QALY gained, below the threshold of 181,611.00 TL ($25,931.83).
Conclusion: EVAR was a cost-effective alternative to OSR within the threshold used in this analysis.

Keywords: abdominal aortic aneurysm, cost-effectiveness analysis, health economics, quality of life

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Ethics Committee Approval
The study was approved by the Hacettepe University Non-Interventional Clinical Research Ethics Committee on September 7, 2021 (GO 21/899).
All research procedures were conducted in accordance with the Declaration of Helsinki.

Conflict of Interest
No conflict of interest was declared by the authors.

Financial Disclosure
The authors declared that this study has received no financial support.

Published
2026 August 5

How to cite: Engin D, Ağırbaş İ, Aral A. A multicenter cost-effectiveness analysis of endovascular versus open surgical repair for abdominal aortic aneurysm. J Surg Med. 2026;10(8):e8501.

Introduction

Cardiovascular diseases, including coronary heart disease and stroke, are leading causes of noncommunicable mortality worldwide and impose a substantial clinical and economic burden on patients and society [1, 2]. Within this spectrum, aortic aneurysms, defined as permanent localized arterial dilatation of 50% or more and usually exceeding 30 mm, carry a high risk of mortality if left untreated [3]. Abdominal aortic aneurysm (AAA), the most common aortic pathology, becomes more frequent with advancing age and remains asymptomatic in approximately 75% of cases until complications such as rupture or embolization occur [4].

Although endovascular aneurysm repair (EVAR) and open surgical repair (OSR) are established treatment modalities, evidence regarding their relative long-term economic impact on reimbursement agencies remains limited in the context of current healthcare expenditures. This study aimed to address this gap by evaluating the cost-effectiveness of EVAR and OSR from the perspective of the reimbursement agency and to provide evidence that may inform healthcare decision-makers.

Materials and methods

Study design and cost data

A comparative cost-effectiveness analysis was performed to determine the relative cost-effectiveness of EVAR and OSR for the treatment of AAA. A budget impact analysis was also conducted to estimate the burden of these treatment methods on the national budget.

The unit prices of health resources used in the model were obtained from the Ministry of Health Drug Price List and the Social Security Institution Health Implementation Communiqué. Cost data for both treatment methods were derived from patient invoices obtained from the hospital databases. Treatment costs were classified as surgery, anesthesia, blood products, medications, examinations, laboratory services, supplies, medical imaging, hospital beds, and other services. Costs were analyzed from the reimbursement agency perspective using actual hospital invoice data.

One-year follow-up costs after discharge were determined by analyzing invoice amounts from outpatient visits to the relevant departments. The unit costs of drugs used after discharge were calculated from the current price list of the Turkish Medicines and Medical Devices Agency. Public discount rates were applied, and 1 euro was accepted as 3,815.5 TL [5].

Quality-of-life assessment

Two scales were used to determine the health-related quality of life of treated patients. The first was the EQ-5D-3L scale developed by the EuroQol Group [6]. The Turkish version of the scale was administered by telephone interview, and German EQ-5D-3L utility weights were used in the base-case analysis. The second was the HeartQoL scale, which was developed for cardiac disorders and consists of 14 questions. A visual analog scale was also administered by telephone to assess the patients' health status.

Because comparative cost-effectiveness analyses require balanced baseline disease severity, the Charlson Comorbidity Index was used to evaluate pretreatment comorbidity burden. The Charlson Comorbidity Index, developed by Charlson et al. [7], is a widely used clinical scoring system that estimates prognosis according to patients' comorbidities.

Modeling and budget impact analysis

A Markov model was developed to calculate the cost-effectiveness ratio using the cost and effectiveness data obtained. For modeling purposes, study data were used as inputs for a hypothetical cohort of 1,000 patients, and lifetime health-state transitions were derived from a literature review. The health states specified in the model and the transitions between these states were simulated separately for EVAR- and OSR-treated patients in 1-month cycles over a lifetime horizon. A 3% discount rate was applied after the first year. The incremental cost-effectiveness ratio (ICER) was calculated and compared with a threshold of three times gross domestic product (GDP) per capita. One-way sensitivity analyses were then performed, and the impact of both treatment modalities on the national budget was analyzed.

The AAA patient population in Türkiye was used as the basis for the budget impact analysis. The prevalence of AAA in the general population was obtained from the study by Sampson et al. [8]. In 2010, the global age-specific prevalence per 100,000 individuals was reported as 9,506.84 among people aged 25 years or older, whereas the incidence was reported as 850.70. According to the Turkish Statistical Institute (TurkStat), the population of Türkiye in 2020 was 83,614,362, including 53,614,362 individuals aged 25 years or older [9]. Based on these data, the target population was calculated as 5,097,031.61 individuals according to prevalence and 456,097.38 individuals according to incidence.

Treatment for AAA is recommended only for individuals with an aortic diameter of 5.5 cm or greater. To estimate the proportion of the target population eligible for treatment, the probability of an aortic diameter of 5.5 cm or greater (8.11%), as reported by Lederle et al. [10], was used. Accordingly, the budget impact analysis assumed that 8.11% of the target population would undergo treatment.

Statistical analysis

SPSS Version 22.0 was used for all statistical analyses. Descriptive data are presented as number (%), mean (SD), or median, as appropriate. Independent samples t-test and Mann-Whitney U test were used for continuous variables, while the Chi-square test was used for categorical variables. All statistical tests were two-sided, and the significance threshold was set at $P < 0.05$. Patients with missing data were excluded from the analysis due to the high volume of incomplete records.

Cost-effectiveness outcomes were estimated using the Markov model described above, with 1-month cycles over a lifetime horizon. Costs and outcomes beyond the first year were discounted at 3%. The ICER was compared with a threshold of three times GDP per capita, and one-way sensitivity analyses were performed to evaluate model robustness.

Ethics

Ethical approval was obtained from the Hacettepe University Non-Interventional Clinical Research Ethics Committee on September 7, 2021 (GO 21/899). The study was conducted in accordance with the Declaration of Helsinki. Informed consent was obtained from all participants before direct patient contact for the questionnaire assessment.

Results

Of the 509 patients included in the study, 89.2% were male and 10.8% were female. Patients younger than 65 years accounted for 15.1% of the cohort, while 84.9% were aged 65 years or older. Regarding length of hospitalization, 62.9% of patients were hospitalized for fewer than 10 days and 37.1% for 10 days or longer. Patients treated with EVAR constituted 87.2% of the study group (n = 444), whereas those treated with OSR constituted 12.8% (n = 65). In this two-center study, 70.3% of patients were treated at Ankara University Hospital and 29.7% at Hacettepe University Hospital. The descriptive findings are presented in Table 1.

Effectiveness of treatment methods

In this study, 112 patients treated with EVAR and 35 patients treated with OSR were contacted, and 147 patients completed the questionnaires. The visual analog scale and HeartQoL scale were also administered. Using German weights, the mean QALY value was 0.90 (0.20) in the EVAR group and 0.80 (0.34) in the OSR group. The visual analog scale score ranged from 10 to 100 in the EVAR group, with a mean of 70.49 (16.94), and from 20 to 100 in the OSR group, with a mean of 60.28 (19.92). The mean HeartQoL score was 30.75 (10.59) in the EVAR group and 27.62 (12.57) in the OSR group. Patients in the EVAR group had significantly higher QALY values than those in the OSR group ($P = 0.035$). The visual analog scale score was also significantly higher in the EVAR group ($P = 0.005$), whereas the difference in HeartQoL score was not statistically significant ($P = 0.236$). The quality-of-life findings are presented in Table 2.

Costs

Table 3 presents the cost distribution of EVAR and OSR by expense type. The mean invoice cost for EVAR was 57,891.48 TL ($8,266.20), with medical materials accounting for the largest share at 84.44% (48,884.83 TL/$6,980.16). Medical imaging (5.56%) and medications (3.73%) were the next largest expense categories. In contrast, the mean invoice cost for OSR was substantially lower at 15,253.34 TL ($2,177.99). Unlike EVAR, OSR costs were distributed more evenly among medical materials (26.53%), surgery (21.26%), medications (17.60%), and blood products (14.49%).

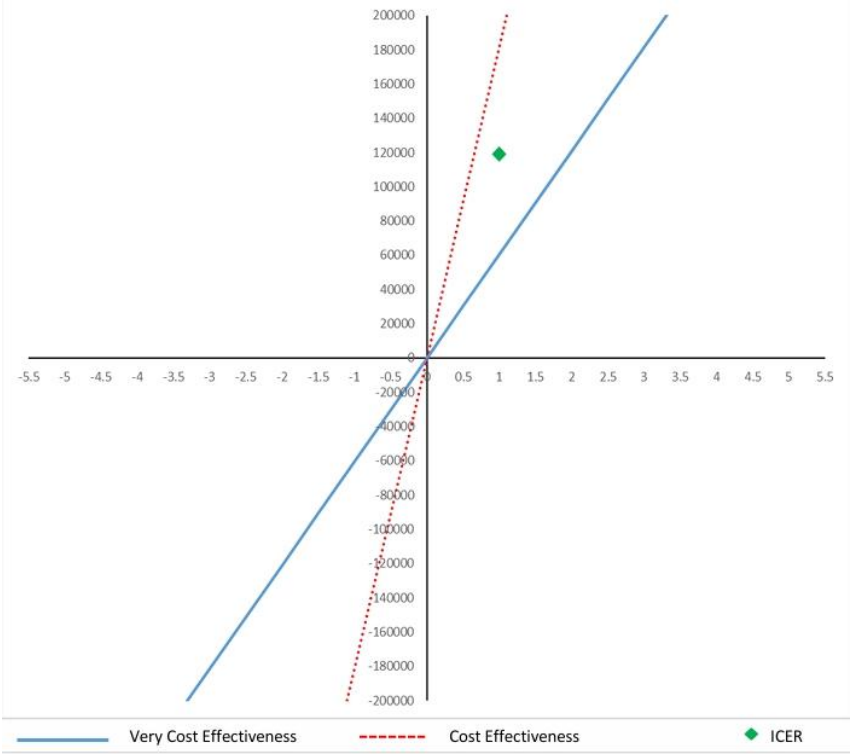
A marked difference was observed in blood-related expenses, which accounted for 0.74% of EVAR costs compared with 14.49% of OSR costs. Post-discharge outpatient expenses were 490.70 TL ($70.06) for EVAR and 189.45 TL ($27.05) for OSR. These findings indicate that the primary driver of the cost difference between the two methods was the high price of the stent-grafts used in EVAR.

The drug cost per patient after EVAR was 350.20 TL ($50.00), compared with 195.46 TL ($27.91) after OSR. When drug costs were added to outpatient clinic costs, the 1-year follow-up cost was 840.90 TL ($120.07) for EVAR and 384.91 TL ($54.96) for OSR. When these follow-up costs were added to the initial treatment costs, the 1-year total cost was 58,732.38 TL ($8,386.24) for EVAR and 15,638.25 TL ($2,232.95) for OSR. In the Markov model, the median costs used as inputs for patients in the good-health state were 49,760.48 TL ($7,105.18) for EVAR and 11,580.56 TL ($1,653.56) for OSR.

Cost-effectiveness analysis

In the cost-effectiveness analysis, the Markov model showed that the EVAR group remained in the model longer than the OSR group (279 vs 192 months), primarily because of lower mortality. Consequently, EVAR provided greater clinical effectiveness in terms of both life-years (2.84 vs 1.98) and QALYs (2.53 vs 1.59). Although EVAR provided better quality of life, its substantial lifetime cost resulted in a higher cost per QALY than OSR. The ICER was 118,892 TL per QALY gained, as detailed in Table 4.

Figure 1. Representation of the ICER on the cost-effectiveness plane.



ICER: Incremental cost-effectiveness ratio.

Table 1. Descriptive findings of the study group

Category	Variable	Number	Percentage
Gender	Male	454	89.2
	Female	55	10.8
Age	<65 years	77	15.1
	≥65 years	432	84.9
Hospitalization duration	<10 days	320	62.9
	≥10 days	189	37.1
Treatment type	Endovascular aneurysm repair	444	87.2
	Open surgical repair	65	12.8
Hospital	Ankara University Hospital	358	70.3
	Hacettepe University Hospital	151	29.7

Table 2. Quality of life of patients undergoing EVAR and OSR

Outcome	EVAR min	EVAR max	EVAR mean (SD)	OSR min	OSR max	OSR mean (SD)	*P* value
EQ-5D-3L Utility Score (Germany)	-0.21	1	0.90 (0.20)	-0.21	1	0.80 (0.34)	0.035
VAS score	10	100	70.49 (16.94)	20	100	60.28 (19.92)	0.005
HeartQoL	1	42	30.75 (10.59)	4	42	27.62 (12.57)	0.236

EVAR: Endovascular aneurysm repair, OSR: Open surgical repair, QALY: Quality-adjusted life-year, VAS: Visual analog scale. *P < 0.05 was considered statistically significant.

Table 3. Mean costs of EVAR and OSR methods

Expense type	EVAR (TL)	EVAR ($)	EVAR share (%)	OSR (TL)	OSR ($)	OSR share (%)
Operation	393.34	56.16	0.68	3,243.41	463.12	21.26
Anesthesia	529.96	75.67	0.92	874.98	124.94	5.74
Medicine	2,160.23	308.45	3.73	2,684.00	383.24	17.60
Blood	426.62	60.92	0.74	2,210.58	315.64	14.49
Laboratory	1,238.45	176.84	2.14	565.31	80.72	3.71
Material	48,884.83	6,980.16	84.44	4,046.94	577.85	26.53
Examination	31.58	4.51	0.05	42.34	6.05	0.28
Medical imaging	3,216.05	459.21	5.56	247.48	35.34	1.62
Bed	495.70	70.78	0.86	825.50	117.87	5.41
Other	514.72	73.50	0.89	512.77	73.22	3.36
Total	57,891.48	8,266.20	100	15,253.34	2,177.99	100

Table 4. Cost-effectiveness analysis results

Treatment	Total cost (TL)	Life-years	Clinical effectiveness (QALY)	Additional cost (TL)	Additional effectiveness (life-years)	Additional effectiveness (QALYs)	ICER per life-year	ICER per QALY
EVAR	132,726.00	2.84	2.53	110,819.76	0.86	0.93	129,180	118,892
OSR	21,906.23	1.98	1.59	-	-	-	-	-

EVAR: Endovascular aneurysm repair, OSR: Open surgical repair, QALY: Quality-adjusted life-year, ICER: Incremental cost-effectiveness ratio.

Table 5. One-way sensitivity analysis results

Variable	Exchange	ICER (TL/QALY)
EVAR treatment cost	When it decreases by 10%	105,231.64
EVAR treatment cost	When it decreases by 20%	91,571.65
EVAR treatment cost	When it decreases by 30%	77,911.66
EVAR treatment cost	When it decreases by 40%	64,251.67
Cost calculations	When calculated based on averages	136,458.82
Discount rate	When 0% is used	114,530.88
Discount rate	When 6% is used	122,979.19
Efficacy data	When the Netherlands weights are used	116,998.07
Efficacy data	When the United States weights are used	114,209.25

EVAR: Endovascular aneurysm repair, QALY: Quality-adjusted life-year, ICER: Incremental cost-effectiveness ratio.

Table 6. Budget impact analysis findings

Variable	Endovascular aneurysm repair	Open surgical repair
Number of patients	413,369.26	413,369.26
Average cost (TL)	57,891.48 TL	15,253.34 TL
Average cost ($)	8,266.20 $	2,177.99 $
Total cost (TL)	23,930,558,454.64 TL	6,305,261,922.80 TL
Total cost ($)	3,416,993,006.53 $	900,314,122.37 $
Spending difference between methods (2020)	17,625,296,531.84 TL ($2,516,677,292.72)	17,625,296,531.84 TL ($2,516,677,292.72)

TL: Turkish lira.

To determine whether EVAR was cost-effective, the ICER was compared with the prespecified threshold of three times GDP per capita. According to TurkStat, GDP per capita in 2020 was 60,537.00 TL ($8,643.94) [11]. Therefore, three times GDP per capita, 181,611.00 TL ($25,931.83), was used as the cost-effectiveness threshold. Because the ICER remained below this threshold, EVAR was considered cost-effective. The results are presented on the cost-effectiveness plane in Figure 1.

One-way sensitivity analysis

One-way sensitivity analyses were performed to examine the robustness of the EVAR findings under changes in treatment cost, the use of mean rather than median costs, different discount rates, and the use of country-specific quality-of-life weights from the United States and the Netherlands instead of German weights.

As the cost of EVAR decreased, the ICER also decreased and approached the very cost-effective threshold of 60,537.00 TL ($8,643.94). When mean costs were used instead of median values, the ICER increased but remained below the cost-effectiveness threshold of 181,611.00 TL ($25,931.83). Across all one-way sensitivity analyses, the ICER ranged from 64,251.67 TL ($9,174.35) to 136,458.82 TL ($19,484.65), remaining below the threshold in every scenario. These findings are presented in Table 5.

Budget impact analysis

In 2020, the target population for AAA was calculated as 5,097,031.61 individuals according to prevalence. Assuming that 8.11% of the target population would undergo treatment, treating all patients with EVAR would cost 23,930,558,454.64 TL ($3,416,993,006.53), whereas treating all patients with OSR would cost 6,305,261,922.80 TL ($900,314,797.73). The

difference in expenditure between the two methods was 17,625,296,531.84 TL ($2,516,678,208.81). These data are presented in Table 6.

Discussion

Until 1991, open conventional surgery was the only available method for aortic aneurysm repair. In 1991, Parodi et al. [12] first performed endovascular repair in high-risk patients. With advances in interventional radiology, the number of open surgical procedures performed for AAA has decreased, whereas the use of endovascular procedures has increased in Türkiye, as in the rest of the world. In the present study, 87% of 509 patients were treated with EVAR and 13% with OSR.

The mean initial hospital invoice cost was 57,891.48 TL ($8,266.20) for EVAR and 15,253.34 TL ($2,177.99) for OSR. After 1-year follow-up costs were included, the corresponding total costs were 58,732.38 TL ($8,386.24) and 15,638.25 TL ($2,232.95). The lifetime costs were 132,726.00 TL ($18,951.65) for EVAR and 21,906.23 TL ($3,127.94) for OSR. Material costs accounted for the largest share of total EVAR expenditure, reaching 48,884.83 TL ($6,980.16).

Patients treated with EVAR had a shorter hospital stay than those treated with OSR. This finding is clinically plausible because EVAR requires a smaller incision and causes less tissue trauma than conventional open surgery. In addition, the EVAR group had better QALY and visual analog scale results, whereas HeartQoL scores were only modestly higher and did not differ significantly.

The Charlson Comorbidity Index indicated that the pretreatment comorbidity burden was similar between the two groups. This supports the comparability of the groups in terms of baseline disease severity and strengthens the interpretation of the observed differences in quality-of-life and cost outcomes.

The international literature includes several studies evaluating the cost-effectiveness of EVAR and OSR. Early analyses by Patel et al. and Bosch et al. supported EVAR as a clinically effective and cost-effective alternative to OSR, emphasizing its less invasive nature and favorable quality-adjusted survival [13, 14]. However, later long-term economic evaluations produced more complex findings.

Epstein et al. highlighted considerable uncertainty regarding the long-term cost-effectiveness of EVAR, whereas Stroupe et al. reported better early survival despite initial cost differences [15, 16]. Burgers et al. further suggested that the high graft cost of EVAR could be partly offset by shorter hospital stays [17]. In the present study, however, EVAR treatment costs remained clearly higher than OSR costs, and nearly 85% of total EVAR expenditure was attributable to material costs. This difference likely reflects institutional cost structures and the reimbursement perspective used in the analysis.

Long-term evidence also suggests that the early survival and morbidity advantages of EVAR may diminish over time. Lederle et al. reported no significant difference in survival or quality of life after 9 years of follow-up, as costs often converged because of continued surveillance and secondary interventions in the EVAR group [18]. In younger patient populations, OSR has also been reported to be more cost-effective, underscoring the importance of patient age and long-term monitoring costs [19]. More recent evidence, including the systematic review by Nargesi et al. and the large-scale study by Yei et al., indicates that although EVAR provides important early benefits, late complications and reinterventions remain major barriers to long-term cost-effectiveness [20, 21].

Taken together, the available literature shows that the economic profile of EVAR depends strongly on perspective, follow-up duration, and local cost structure. In the present study, EVAR was cost-effective over a lifetime horizon using hospital-based evidence. Moreover, one-way sensitivity analyses consistently kept EVAR below the national threshold, supporting the robustness of the main finding.

However, the budget impact analysis revealed a substantial difference of more than 17.6 billion TL between universal EVAR adoption and universal OSR adoption. This gap was driven primarily by the high cost of stent-grafts, which represented nearly 85% of EVAR expenditure. Therefore, although EVAR appeared cost-effective for suitable candidates, strategic price negotiations for medical materials and careful patient selection remain essential for the long-term sustainability of the reimbursement system.

The ultimate goal of endovascular aneurysm treatment is to reduce mortality, morbidity, and hospital stay compared with standard surgical treatment. Although studies, including the present analysis, suggest that EVAR shortens hospitalization and reduces blood-related resource use, the cost of new-generation endovascular stent-grafts remains high. Because these costs vary substantially among countries and healthcare systems, direct one-to-one comparisons between settings should be interpreted cautiously.

Limitations

Although this study was based on multicenter data, the findings reflect hospital-level costs and may not be generalizable to all healthcare settings. In addition, quality-of-life data were obtained from a subset of patients. Nevertheless, the use of real-world data and a long-term modeling approach provides valuable insight into both clinical and economic outcomes.

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J Surg Med. 2026;10(8):e8648.
https://doi.org/10.28982/josam.8648

JOSAM

Research Article
https://jsurgmed.com/

Journal of Surgery and Medicine
e-ISSN: 2602-2079

Diagnostic value of dry lips in patients with suspected acute appendicitis: A prospective cohort study

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Ethical Approval
This prospective observational cohort study was approved by the Institutional Review Board of Security Forces Hospital Program, Riyadh, Saudi Arabia (Research No. 24-722-19; KACST IRB Registration No. H-01-R-069) on September 12, 2024. All procedures involving human participants were conducted in accordance with the ethical standards of the institutional research committee and the 1964 Declaration of Helsinki and its later amendments.

Informed Consent
Written informed consent was obtained from all participants before enrollment.

Conflict of Interest
No conflict of interest was declared by the authors.

Financial Disclosure
The authors declared that this study has received no financial support.

Published
2026 August 8

Abstract

Background/Aim: Acute appendicitis is a common surgical emergency, but accurate diagnosis remains challenging. Simple bedside findings may complement established diagnostic strategies. This study aimed to evaluate the diagnostic accuracy of dry lips as a bedside clinical sign in adults presenting with suspected acute appendicitis.

Methods: This prospective observational cohort study was conducted in the emergency department of a tertiary care hospital from June 2024 to May 2025. Consecutive adults presenting with suspected acute appendicitis were enrolled. Dry lips were assessed during the initial examination before intravenous fluid administration, laboratory testing, or imaging. Histopathological examination confirmed appendicitis in operated patients, whereas non-operated patients were classified as not having appendicitis based on negative computed tomography findings and/or an uneventful 30-day clinical follow-up. Sensitivity, specificity, predictive values, likelihood ratios, and 95% confidence intervals (CIs) were calculated.

Results: Of 115 patients screened, 96 met the eligibility criteria and were included. Acute appendicitis was confirmed in 44 patients (45.8%), and dry lips were present in 36 (37.5%). Dry lips had a sensitivity of 54.6% (95% CI, 38.8-69.6%) and a specificity of 76.9% (95% CI, 63.2-87.5%). The positive likelihood ratio was 2.36 (95% CI, 1.34-4.16), and the negative likelihood ratio was 0.59 (95% CI, 0.41-0.84). Combining dry lips with a C-reactive protein level of at least 10 mg/L increased specificity to 93.9% (95% CI, 84.4-98.0%) and the positive likelihood ratio to 6.61 (95% CI, 2.24-22.49).

Conclusion: Dry lips showed moderate specificity but limited sensitivity for diagnosing acute appendicitis. This finding is not sufficiently accurate for use as a standalone test but may provide a rapid, cost-free adjunct to bedside assessment when interpreted with inflammatory markers and other clinical findings. Larger multicenter studies are needed to validate these results.

Keywords: acute appendicitis, dry lips, physical examination, diagnostic accuracy, dehydration

How to cite: Akeely YY, Alfaifi A, Patel SB, Bokhari NN, Alblowi NS, Alshaheen R, Alanazi WA. Diagnostic value of dry lips in patients with suspected acute appendicitis: A prospective cohort study. J Surg Med. 2026;10(8):e8648.

Introduction

Acute appendicitis is among the most common abdominal surgical emergencies, with an annual incidence of approximately 100 cases per 100,000 adults worldwide [1]. Despite advances in laboratory testing and diagnostic imaging, accurate diagnosis remains challenging because clinical presentations range from nonspecific abdominal pain to generalized peritonitis [1, 2]. Delayed diagnosis increases the risk of perforation and postoperative morbidity, whereas overdiagnosis may lead to unnecessary appendectomy. Timely and accurate diagnosis therefore remains a major objective in emergency and surgical practice.

The diagnosis of acute appendicitis relies on a combination of clinical assessment, laboratory investigations, and imaging. Clinical prediction tools, including the Alvarado score and the Appendicitis Inflammatory Response score, can support risk stratification but cannot consistently confirm or exclude appendicitis when used alone [3-5]. Similarly, inflammatory biomarkers such as the white blood cell count and C-reactive protein (CRP) level should be interpreted within the broader clinical context because normal values do not reliably exclude the disease [6].

Computed tomography (CT) provides excellent diagnostic accuracy, with reported sensitivity and specificity above 95%. However, routine CT use is associated with radiation exposure, cost, and limited availability in some settings [7]. Additional studies of clinical scoring systems have likewise shown that bedside scores are most useful for risk stratification rather than as independent definitive tests [8-11]. CRP has also been investigated as a diagnostic adjunct, but it should not be interpreted in isolation [12, 13].

These limitations sustain interest in simple bedside findings that may improve early assessment. Patients with acute appendicitis commonly experience anorexia, nausea, vomiting, and reduced oral intake, which may contribute to dehydration. Dry lips are readily observable and may reflect this physiological state. Unlike laboratory tests or imaging, their assessment requires no equipment, incurs no additional cost, and can be performed immediately during the initial clinical evaluation.

Evidence regarding the diagnostic value of dry lips is limited. A previous adult study reported an association between dry lips and acute appendicitis, and an earlier pediatric study evaluated the same finding [14, 15]. Prospective validation in an independent adult cohort remains limited. This study therefore aimed to evaluate the diagnostic accuracy of dry lips as a bedside clinical sign in adults presenting with suspected acute appendicitis, using histopathological confirmation for operated patients and negative CT findings and/or 30-day clinical follow-up for non-operated patients.

Materials and methods

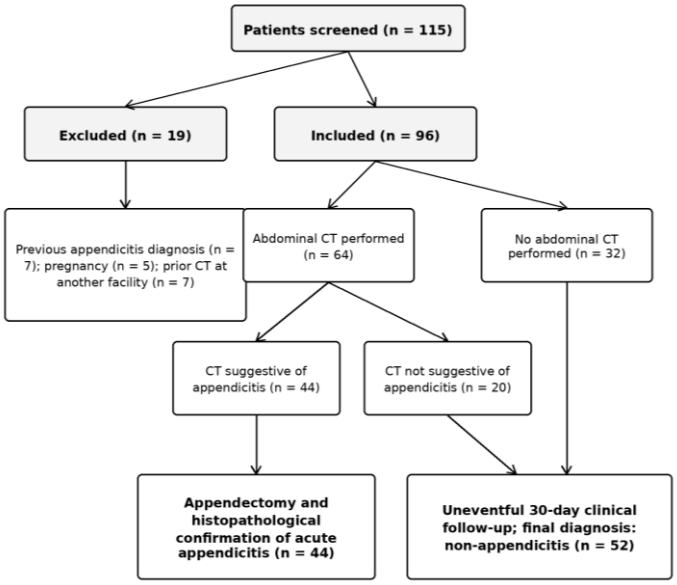
Study design and setting

This prospective observational cohort study was conducted in the emergency department of Security Forces Hospital Program, Riyadh, Saudi Arabia, from June 2024 to May 2025. The study evaluated the diagnostic accuracy of dry lips as a bedside clinical sign in adults presenting with suspected acute appendicitis. Reporting followed the Standards for Reporting Diagnostic Accuracy Studies recommendations where applicable.

Study population

All consecutive adults aged 18 years or older who presented to the emergency department with suspected acute appendicitis during the study period were screened. Of 115 patients screened, 19 were excluded: seven had a previous diagnosis of appendicitis, five were pregnant, and seven had undergone abdominal CT at another healthcare facility before presentation. The final cohort comprised 96 prospectively enrolled patients (Figure 1).

Figure 1. STARD flow diagram of participant enrollment and diagnostic classification



Abbreviations: CT: computed tomography, STARD: Standards for Reporting Diagnostic Accuracy Studies.

Index test

The index test was the presence of dry lips during the initial clinical assessment. Dry lips were defined a priori as visible dryness, fissuring, or cracking on direct inspection. Emergency physicians assessed the finding before intravenous fluid administration, laboratory testing, or imaging and recorded it as present or absent. The physicians were blinded to laboratory and imaging findings at the time of examination. Outcome assessment and data analysis were performed independently by investigators who were not involved in the initial clinical evaluation.

Reference standard and follow-up

A composite reference standard was used because not all participants underwent surgery. For patients who underwent appendectomy, acute appendicitis was confirmed by histopathological examination. Patients who did not undergo surgery were classified as not having appendicitis based on negative CT findings and/or an uneventful 30-day clinical follow-up. Follow-up included review of electronic medical records and telephone contact. All participants completed follow-up, and none were lost to follow-up. Patients without recurrent symptoms or subsequent appendectomy were considered not to have appendicitis.

Clinical management was independent of the study protocol. Treating physicians determined the need for laboratory testing, imaging, surgical consultation, hospital admission, or appendectomy according to routine practice. The dry-lips assessment was not used to guide clinical decisions.

Laboratory investigations included the white blood cell count and CRP level. A CRP threshold of at least 10 mg/L was selected a priori based on previous literature.

Outcomes

The primary outcome was the diagnostic accuracy of dry lips for acute appendicitis. Secondary outcomes were the diagnostic performance of dry lips when combined with a CRP level of at least 10 mg/L and with symptom duration.

Statistical analysis

Data were analyzed using IBM SPSS Statistics for Windows, version 23.0 (IBM Corp., Armonk, NY, USA). Continuous variables are presented as mean (standard deviation), and categorical variables as frequency and percentage. Diagnostic accuracy was evaluated by calculating sensitivity, specificity, positive predictive value, negative predictive value, positive likelihood ratio, and negative likelihood ratio with 95% CIs. A 2 × 2 contingency table was constructed for dry lips and the final diagnosis. Combined analyses used an AND rule; a positive result required both dry lips and the specified criterion. Where inferential analyses were applicable, a two-sided $P < 0.05$ was considered statistically significant. No inferential hypothesis tests were prespecified for the primary diagnostic-accuracy analysis.

Results

Participant characteristics

During the study period, 115 consecutive adults with suspected acute appendicitis were screened. Nineteen were excluded according to the predefined criteria, and 96 were included in the final analysis (Figure 1). The mean age was 27.9 (9.8) years, and 50 participants (52.1%) were female. Dry lips were present in 36 participants (37.5%), and 87 (90.6%) presented at least 12 hours after symptom onset. Baseline characteristics are presented in Table 1, and the final clinical classification and laboratory findings are presented in Table 2.

Table 1. Baseline characteristics of the study population (n = 96)

Variable	Value
Age, years, mean (SD)	27.9 (9.8)
Female sex, n (%)	50 (52.1)
Male sex, n (%)	46 (47.9)
Symptom duration ≥12 h, n (%)	87 (90.6)
Dry lips present, n (%)	36 (37.5)

Abbreviation: SD: standard deviation.

Table 2. Final clinical classification and laboratory findings (n = 96)

Variable	Value
Acute appendicitis, n (%)	44 (45.8)
Non-appendicitis, n (%)	52 (54.2)
Operated patients, n (%)	44 (45.8)
WBC, ×10^9/L, mean (SD)	8.17 (6.24)
CRP, mg/L, mean (SD)	31.39 (61.68)

Abbreviations: CRP: C-reactive protein, SD: standard deviation, WBC: white blood cell count.

Acute appendicitis was confirmed in 44 participants (45.8%), all of whom underwent appendectomy with histopathological confirmation. The remaining 52 participants (54.2%) were classified as not having appendicitis based on negative CT findings and/or an uneventful 30-day clinical follow-up. No participant was lost to follow-up.

Diagnostic performance of dry lips

The 2 × 2 contingency table is shown in Table 3. Dry lips had a sensitivity of 54.6% and a specificity of 76.9% for acute appendicitis. When dry lips were combined with a CRP level of at least 10 mg/L, specificity increased to 93.9% and the positive likelihood ratio to 6.61, whereas sensitivity remained limited. Detailed diagnostic-accuracy estimates and 95% CIs are shown in Table 4. Estimates for participants presenting within 12 hours of symptom onset should be interpreted cautiously because this subgroup was small.

Table 3. Two-by-two contingency table for dry lips and the final diagnosis of acute appendicitis

Dry-lips assessment	Appendicitis	Non-appendicitis	Total
Dry lips present	24	12	36
Dry lips absent	20	40	60
Total	44	52	96

Table 4. Diagnostic accuracy of dry lips alone and in combination with C-reactive protein level and symptom duration for acute appendicitis

Index test	Sensitivity, % (95% CI)	Specificity, % (95% CI)	PPV, % (95% CI)	NPV, % (95% CI)	LR+ (95% CI)	LR- (95% CI)
Dry lips	54.6 (38.8-69.6)	76.9 (63.2-87.5)	66.7 (49.0-81.4)	66.7 (53.3-78.3)	2.36 (1.34-4.16)	0.59 (0.41-0.84)
Dry lips + CRP ≥10 mg/L	40.5 (27.7-55.6)	93.9 (84.4-98.0)	85.0 (65.4-95.0)	64.8 (54.1-75.1)	6.61 (2.24-22.49)	0.63 (0.49-0.81)
Dry lips + symptom duration <12 h	4.5 (1.3-15.2)	92.3 (82.1-97.1)	33.3 (9.7-70.0)	53.3 (43.4-63.0)	0.59 (0.13-2.63)	1.03 (0.95-1.10)

Abbreviations: CI: confidence interval, CRP: C-reactive protein, LR+: positive likelihood ratio, LR-: negative likelihood ratio, NPV: negative predictive value, PPV: positive predictive value. Combined tests used an AND rule.

Discussion

In this prospective diagnostic-accuracy study, dry lips showed moderate specificity but limited sensitivity in adults presenting with suspected acute appendicitis. The finding alone was insufficient to diagnose or exclude the disease. When dry lips were interpreted with an elevated CRP level, specificity and the positive likelihood ratio increased substantially. These results suggest that dry lips may contribute incremental information within a broader clinical assessment rather than function as an independent diagnostic test.

Acute appendicitis remains a clinical diagnosis supported by laboratory and imaging findings. CT provides excellent diagnostic accuracy but may be constrained by radiation exposure, cost, availability, and emergency department workflow [7]. Clinical prediction tools improve risk stratification but cannot reliably confirm or exclude appendicitis in isolation [3-5, 8-11]. Careful bedside examination therefore remains important during the initial evaluation.

The rationale for assessing dry lips is biologically plausible. Anorexia, nausea, vomiting, fever, and reduced oral intake may cause dehydration in patients with acute appendicitis. Dry lips may reflect this state but are nonspecific and may occur in many medical and surgical conditions. The finding should therefore be interpreted with the history, physical examination, laboratory findings, and imaging results.

Our findings differ from those of Mohammadi Tofigh et al. [14], who reported substantially higher sensitivity for dry lips. Their study included a much higher proportion of patients with confirmed appendicitis, which may have affected diagnostic estimates. Differences in patient selection, disease severity, healthcare setting, and assessment methods may also explain the discrepancy. Nevertheless, both studies indicate that dry lips may have a supportive role in patients with suspected appendicitis.

The improved diagnostic performance observed when dry lips were combined with elevated CRP was clinically relevant. The coexistence of these findings increased the probability of

appendicitis, but sensitivity remained modest. The absence of dry lips, even when interpreted with CRP, should therefore not be used to exclude the diagnosis. These findings support the use of simple bedside observations as complements to established diagnostic strategies.

The strengths of this study include its prospective design, consecutive enrollment, assessment of the index test before laboratory and imaging results were available, blinding of assessors to subsequent diagnostic information, complete 30-day follow-up, and independent outcome assessment. Histopathological confirmation in all operated patients further strengthened the final diagnosis.

Limitations

This study has several limitations. First, it was conducted at a single tertiary care center and included a relatively modest sample, which may limit generalizability. Second, a composite reference standard was required because histopathological confirmation was available only for patients who underwent appendectomy. Classification of non-operated patients by negative CT findings and/or 30-day follow-up may have introduced verification bias.

Third, dry lips were assessed by visual judgment using a predefined definition, but formal observer training and interobserver agreement were not evaluated. Observer variability therefore cannot be excluded. Fourth, dry lips are a nonspecific manifestation of dehydration and may be influenced by vomiting, reduced oral intake, fever, mouth breathing, environmental conditions, medications, or chronic lip disorders. These potential confounders were not systematically recorded. Finally, subgroup analyses, particularly among participants presenting within 12 hours, included small numbers and should be interpreted cautiously.

Conclusion

Dry lips showed moderate specificity but limited sensitivity for acute appendicitis. Although this bedside finding cannot diagnose or exclude appendicitis when used alone, it may provide useful adjunctive information when interpreted with clinical assessment and inflammatory markers, particularly CRP. As a rapid, noninvasive, and cost-free observation, dry lips may support early bedside risk stratification, especially where immediate imaging is unavailable. Larger multicenter diagnostic-accuracy studies are needed to validate these findings and clarify the role of dry lips in contemporary diagnostic pathways.

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J Surg Med. 2026;10(8):e8454.
https://doi.org/10.28982/josam.8454

JOSAM

Research Article
https://jsurgmed.com/

Journal of Surgery and Medicine
e-ISSN: 2602-2079

Early functional outcomes of proximal femur fractures treated with proximal femoral nailing in a tertiary trauma center

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Ethics Committee Approval
The study was approved by the Ethics Committee of the National Orthopaedic Hospital, Igbobi, Lagos, Nigeria (reference no. OH/90/C/IX) on January 17, 2023. All research procedures were conducted in accordance with the Declaration of Helsinki.

Conflict of Interest
No conflict of interest was declared by the authors.

Financial Disclosure
The authors declared that this study has received no financial support.

Published
2026 August 12

Abstract

Background/Aim: Proximal femur fractures are common and often debilitating, particularly in older adults with osteoporosis and a high risk of falls. In younger individuals, these injuries usually result from high-energy trauma. Proximal femoral nailing has gained acceptance as a reliable fixation method that may enable early mobilization and functional recovery. This study evaluated the early functional outcomes and complications of proximal femoral nailing in patients managed at a tertiary trauma center.

Methods: This prospective cohort included 55 patients with proximal femur fractures treated with proximal femoral nailing; 46 patients completed follow-up and were included in the final analysis. Functional outcomes were assessed over 6 months using the Lower Extremity Functional Scale and the Short Form-36 health survey, together with clinical and radiological evaluation. Data were analyzed using IBM SPSS Statistics for Windows, version 23. Continuous variables were summarized as mean (SD), and categorical variables as frequencies and percentages. Appropriate parametric and nonparametric tests were used, with statistical significance set at $P < 0.05$.

Results: The mean age was 57.9 (13.0) years, and the male-to-female ratio was 1.7:1. The radiological union rate was 91%, with a mean time to union of 3.9 (0.2) months. Lower Extremity Functional Scale and Short Form-36 scores improved progressively during follow-up. Poorer functional outcomes were associated with comorbidities, pre-injury use of walking aids, female sex, older age, higher American Society of Anesthesiologists grade, and surgery delayed beyond 48 hours. Complications occurred in 13% (n = 6) of patients, predominantly superficial surgical site infections. Surgical site infection was associated with comorbidities ($P = 0.040$) and showed a borderline association with increasing age ($P = 0.048$).

Conclusion: Proximal femoral nailing provided reliable fixation, a high union rate, and meaningful early functional recovery in this cohort. Patient baseline characteristics and timing of surgery were associated with recovery. Larger multicenter studies with longer follow-up are needed to confirm these findings.

Keywords: proximal femur fracture, proximal femoral nailing, functional outcome, lower extremity functional scale, short form-36 health survey

How to cite: Odejobi K, Alatishe KA, Akpati U. Early functional outcomes of proximal femur fractures treated with proximal femoral nailing in a tertiary trauma center. J Surg Med. 2026;10(8):e8454.

Introduction

Proximal femoral fractures encompass femoral neck, intertrochanteric, and subtrochanteric fractures, each with distinct biomechanical challenges and healing potential. They represent a major global health burden, particularly among older adults with osteoporosis and an elevated risk of falls. These injuries often mark a turning point in patients' lives, with only 40-60% of older individuals regaining pre-injury mobility and independence within a year [1]. In younger patients, proximal femoral fractures usually result from high-energy trauma, such as motor vehicle collisions, falls from height, or industrial accidents [2].

The global incidence of hip fractures varies geographically. Northern Europe and the United States report the highest rates, with Norwegian data indicating annual incidences of 920 per 100,000 in women and 399 per 100,000 in men [3]. Variations across regions have been attributed to population demographics, cultural practices, and environmental factors. In contrast, African studies remain sparse, with much lower reported incidences, ranging from 2 per 100,000 in Nigeria [4] to fewer than 90 per 100,000 in other sub-Saharan African countries [5, 6]. In Nigeria and other developing regions, the burden is compounded by delays in presentation, limited access to surgical implants, and reliance on traditional bone setters, which may contribute to poor outcomes.

Although nonoperative treatment may be considered for patients with poor functional prospects or prohibitive medical risks, surgical fixation remains the standard of care because it enables early mobilization and reduces complications associated with prolonged immobility. Several implants are available, including dynamic hip screws and proximal femoral plates, but cephalomedullary nails, particularly the proximal femoral nail (PFN) introduced by the AO/ASIF group in 1996 [7], have gained increasing popularity. Compared with extramedullary devices, intramedullary fixation offers biomechanical advantages, reducing bending forces on the implant by 23-30% and facilitating early weight-bearing [8].

Multiple studies from Europe and Asia have demonstrated favorable outcomes with PFN, particularly in unstable fracture patterns, with durable fixation and relatively low complication rates [9, 10]. However, local data from sub-Saharan Africa are limited and focus mainly on epidemiology rather than clinical and functional outcomes. Given the rising use of PFN in our setting, evaluating its effectiveness is important. In particular, the influence of patient-related factors, such as age, comorbidities, and pre-injury functional status, on outcomes remains underexplored. This study aimed to determine the early functional outcomes of proximal femoral fracture treatment with PFN at the study center. Secondary objectives were to determine the union rate, time to union, and the most common complications associated with PFN use.

Materials and methods

This prospective cohort study was conducted at a tertiary referral center for orthopedics and trauma. Consecutive patients presenting with proximal femur fractures and managed with PFN between February 2023 and January 2024 were recruited. The study was conducted in accordance with the principles of the Declaration of Helsinki, and ethical approval (reference no. OH/90/C/IX) was obtained from the institutional review board before study commencement. Written informed consent was obtained from all participants. Inclusion criteria were adults aged 18-75 years with closed pertrochanteric or subtrochanteric fractures (AO 31-A1, A2, or A3) treated with PFN within 3 months of injury. Patients with metastatic disease, multiple or open fractures, severe cognitive impairment, inability to walk before injury, incomplete clinical records or inadequate radiographic documentation, or ipsilateral hip osteoarthritis were excluded. Sample size was calculated based on the number of cases managed at the study center in the previous year, while ensuring a power of 0.80 and a significance level of 0.05. Ultimately, 55 patients were recruited, and 46 completed follow-up and were included in the analysis. A structured pro forma captured demographic characteristics, mechanism of injury, comorbidities, intraoperative data, and complications. Pre-injury lower limb function and health-related quality of life were assessed using the Lower Extremity Functional Scale (LEFS) and the Short Form-36 (SF-36), respectively. Anteroposterior and lateral radiographs of the pelvis and femur were obtained for classification using the AO/OTA system. Follow-up assessments were performed at 6 weeks, 3 months, and 6 months, with clinical and radiological evaluation of union, function using LEFS and SF-36, and complications.

All patients underwent a comprehensive history and physical examination. Initial management followed Advanced Trauma Life Support (ATLS) protocols, with resuscitation and stabilization prioritized. Once life-threatening injuries were excluded, informed consent was obtained from patients meeting the study inclusion criteria. Baseline investigations included complete blood count, serum electrolytes, urea and creatinine, fasting blood glucose, and viral hepatitis and retroviral screening. Additional assessments were performed for patients older than 40 years and those with hypertension or diabetes, including chest radiography and electrocardiography. Patients with abnormal electrocardiographic findings or a previously abnormal echocardiogram underwent echocardiography. All patients had plain radiographs of the pelvis and ipsilateral femur in anteroposterior and lateral views for fracture classification and preoperative planning. Subcutaneous enoxaparin was withheld 12 hours before surgery and resumed 12 hours postoperatively. Preoperative fasting guidelines were observed.

Anesthesia was provided using a subarachnoid block, with or without epidural anesthesia. Prophylactic intravenous third-generation cephalosporin was administered at induction and continued for 24 hours. Patients were positioned supine on a fracture table, and closed reduction was initially attempted with traction, internal rotation, and abduction under fluoroscopic guidance. Reduction quality was confirmed on anteroposterior (AP) and lateral views, with attention to the femoral neck, inferomedial calcar, and sagittal alignment. When closed reduction was inadequate, percutaneous or open techniques using pointed forceps, bone levers, or Steinmann pins as joysticks were used.

After preparation with chlorhexidine, povidone-iodine, and methylated spirit, sterile draping was applied from the anterior superior iliac spine to the knee. A 3-5 cm proximal incision was

made above the greater trochanter and extended as required in patients with obesity or for open reductions. The fascia lata was divided in line with the incision. For open reductions, a longer incision allowed direct visualization while preserving periosteal integrity. Entry was made with an awl through the tip of the greater trochanter. Guidewire placement was confirmed in both planes: centrally on the anteroposterior view and slightly anterior to the trochanter-shaft axis on the lateral view. The entry was reamed while avoiding eccentric widening of the trochanter. The nail, preassembled with its targeting device, was introduced over the guidewire under fluoroscopic control. The lag-screw guidewire was advanced into the femoral head and neck, aiming for a center-center or slightly inferior position on the anteroposterior view and a central position on the lateral view. Position was adjusted to achieve a tip-apex distance <25 mm. After measurement and reaming, the lag screw and antirotational hip pin were inserted. Distal interlocking was performed in static mode for unstable or multifragmentary fractures and in dynamic mode for transverse or stable configurations. Traction was released before distal locking to prevent iatrogenic limb lengthening in intertrochanteric fractures and after locking in subtrochanteric fractures to allow impaction.

The proximal femoral nails used at the study center (NEBULA, Gujarat, India) were available in short (200 mm) and long (up to 440 mm) configurations, with diameters of 10, 11, and 12 mm. All nails incorporated a 6° proximal mediolateral bend to facilitate lateral entry. Fixation of the femoral neck was achieved with an 8.0 mm load-bearing lag screw (80-120 mm) complemented by a 6.5 mm antirotational hip pin (60-110 mm). Distal fixation was achieved by static or dynamic locking with 4.9 mm bolts, depending on fracture morphology.

Wounds were irrigated, and hemostasis was secured. The fascia was closed with absorbable sutures, and the skin was approximated with staples. Wound drains were placed selectively for open reductions, patients with obesity, or extensive soft tissue dissection. Final implant position was confirmed fluoroscopically.

Immediate postoperative AP and lateral radiographs were obtained, and reduction quality was graded using the Chang reduction quality criteria [11]. Analgesia consisted of intravenous pentazocine (30 mg every 6 hours) and paracetamol (1 g every 6 hours) for the first 48 hours. Intravenous antibiotics were continued for 24 hours. Drains, when used, were removed at 48 hours, and skin staples were removed 2 weeks after surgery. Deep vein thrombosis prophylaxis was continued for 2 weeks postoperatively using pharmacologic agents and early mobilization. Isometric quadriceps, hamstring, and gluteal exercises commenced on the first postoperative day. Patients were mobilized with a walking frame within 24 hours and permitted weight-bearing as tolerated under physiotherapist supervision.

Discharge criteria included medical stability and independent ambulation with support, typically achieved by the fifth postoperative day. Rehabilitation continued in outpatient physiotherapy clinics.

The primary outcomes were functional outcome, assessed using the Lower Extremity Functional Scale (LEFS), and quality of life, assessed using the Short Form-36 (SF-36) health survey. Both instruments were administered preoperatively and at 6 weeks, 3 months, and 6 months postoperatively. Higher scores indicated better functional status and quality of life, respectively. Secondary outcomes included time to radiological union and complications. Radiological union was defined as bridging callus across at least three cortices on AP and lateral radiographs.

Statistical analysis

Data were analyzed using IBM SPSS Statistics for Windows, version 23 (IBM Corp., Armonk, NY, USA). Continuous variables were summarized as mean (SD), and categorical variables as frequencies and percentages. Comparisons were performed using paired t-tests, chi-square tests, and analysis of variance, as appropriate. Pearson correlation analysis was used to assess the relationship between lower extremity function and quality of life. A *P*-value < 0.05 was considered statistically significant.

Results

A total of 55 patients underwent proximal femoral nailing during the recruitment period. Seven patients older than 75 years and two patients lost to follow-up were excluded. Forty-six patients were therefore included in the final analysis. The mean age was 57.9 (13.0) years, with a male-to-female ratio of 1.7:1. Most patients (59%, n = 27) were young or middle-aged adults, and 87% (n = 40) were independent ambulators before injury. Baseline demographic characteristics are summarized in Table 1. The distribution of fracture classes is shown in Figure 1, and perioperative characteristics are summarized in Table 2.

Table 1. Demographic and baseline clinical data (n = 46)

Age group	Frequency, n	Percentage, %
25-34	1	2.20
35-44	7	15.20
45-54	8	17.40
55-64	11	23.90
>64	19	41.30
Sex		
Female	18	39.10
Male	28	60.90
Laterality		
Right	29	63
Left	17	37
ASA grade		
I	23	50.00
II	15	32.60
III	8	17.40

ASA: American Society of Anesthesiologists.

Table 2. Descriptive perioperative statistics

Variable	Minimum	Maximum	Mean (SD)
Preoperative days of admission	1.00	12.00	4.50 (2.10)
Duration of surgery (min)	94.00	190.00	121.60 (17.90)
Blood loss (mL)	80.00	950	235.90 (185.80)
Time to ambulation (days)	1.00	21.00	3.60 (2.95)
Postoperative days of admission	5.00	28.00	9.60 (4.70)

Figure 1. Distribution of fracture classes according to the AO/OTA classification.

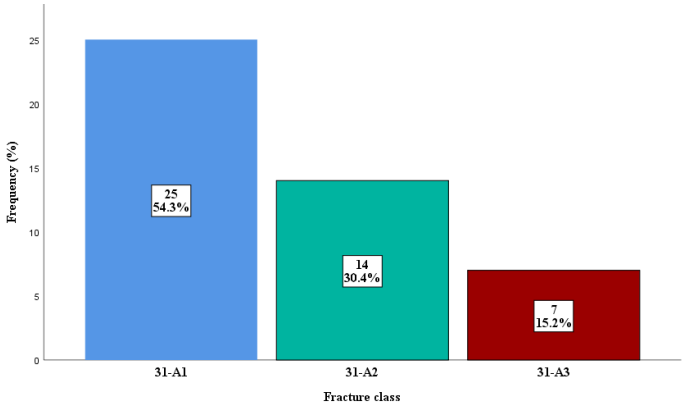
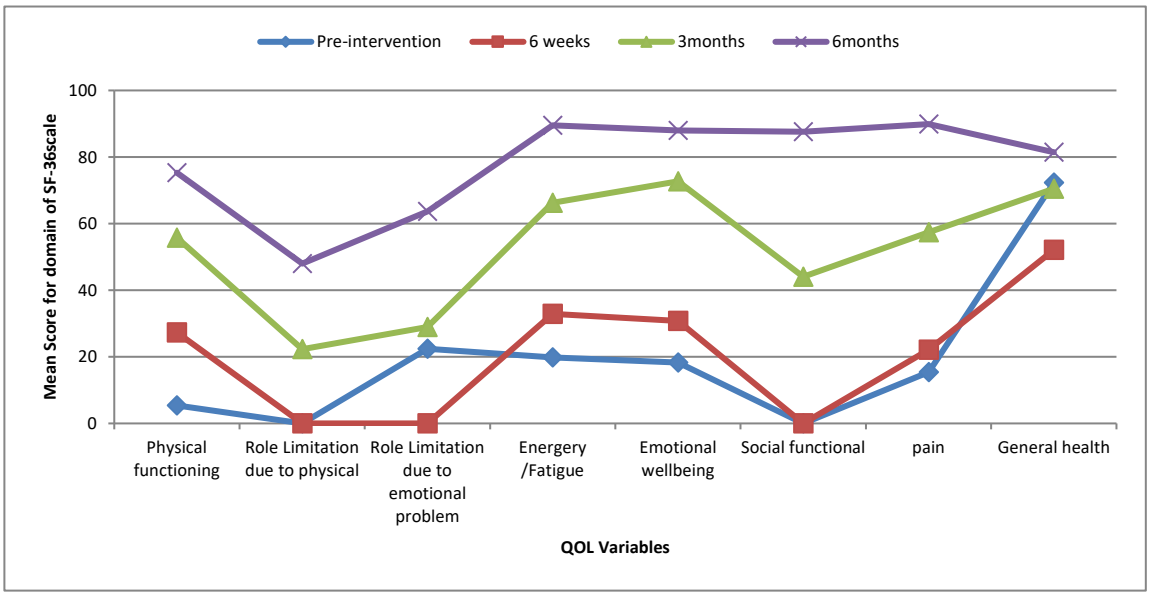


Figure 2. Quality of life of participants.



Mean Lower Extremity Functional Scale (LEFS) scores improved from 0 preoperatively to 23.80 (1.80) at 6 weeks, 43.55 (2.70) at 3 months, and 63.39 (4.50) at 6 months ($P < 0.001$). Improvement across assessment times is summarized in Table 3. Predictors of poorer LEFS at 6 months included comorbidities ($P < 0.001$), pre-injury use of walking aids ($P = 0.010$), female sex ($P < 0.001$), older age ($P = 0.020$), higher American Society of Anesthesiologists (ASA) grade ($P < 0.001$), and surgery delayed beyond 48 hours ($P = 0.020$). Fracture class and reduction quality showed no significant effect. SF-36 scores also improved in the physical, social, and emotional domains over follow-up (Figure 2).

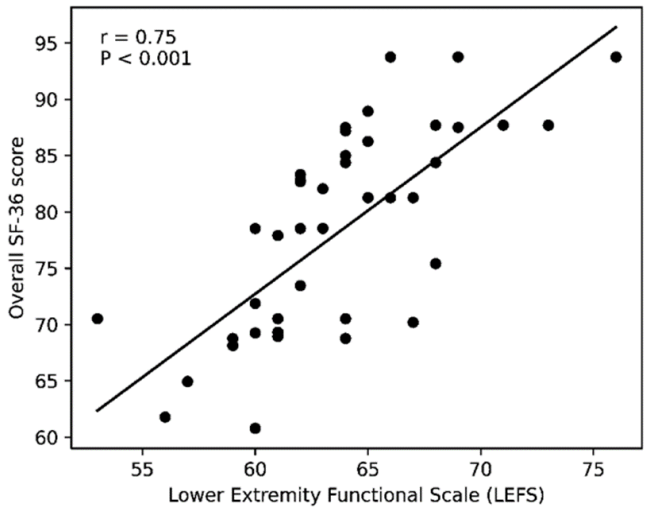
LEFS correlated positively with most SF-36 domains (r = 0.75 overall; $P < 0.001$), except social functioning, which showed a weak negative correlation (Figure 3).

Table 3. Mean Lower Extremity Functional Scale scores at assessment points

Time point	Mean (SD)	F	*P*-value
Preoperative	0.00	6913.17	<0.001
6 weeks postoperative	23.80 (1.80)		
3 months postoperative	43.55 (2.70)		
6 months postoperative	63.39 (4.50)		

LEFS: Lower Extremity Functional Scale, SD: standard deviation. *$P < 0.05$ was considered statistically significant.

Figure 3. Correlation between Lower Extremity Functional Scale and quality-of-life scores



Complications occurred in six patients (13%), predominantly superficial surgical site infections. One patient developed deep vein thrombosis. Surgical site infections were managed successfully with antibiotics and local wound care, whereas deep vein thrombosis was managed with anticoagulation and prolonged bed rest. Surgical site infection was associated with comorbidities ($P = 0.040$) and showed a borderline association with increasing age ($P = 0.048$). No reoperations, nonunion, or implant failures were reported.

By 6 months, 91% (n = 42) of patients achieved radiological union, with a mean union time of 3.9 (0.2) months. The remaining patients were considered to have delayed union and were not followed beyond the 6-month follow-up period. Sex, comorbidity, ASA grade, and reduction quality did not significantly affect time to union.

Discussion

Proximal femur fractures remain a major public health issue because of their association with disability, loss of independence, and increased mortality. With the aging global population, their incidence is expected to rise further. In this prospective cohort, proximal femoral nailing was associated with a high union rate and improvement in functional outcomes and quality of life within 6 months of surgery. Although proximal femur fractures predominantly occur in older populations, the study cohort was restricted to patients aged 75 years or younger to minimize confounding from age-related physiological decline. Despite this restriction, most participants were middle-aged or older adults. Road traffic crashes were the predominant mechanism of injury, consistent with the relatively younger profile of this cohort. This pattern reflects the burden of high-energy trauma in developing countries, where rapid urbanization and increased motor vehicle use have contributed to road traffic injuries. Consequently, trauma systems in these settings must increasingly address fractures traditionally associated with older populations but occurring in younger, economically active individuals, with implications for workforce productivity and healthcare resource use. Low-energy falls accounted for nearly one-quarter of cases and were more common among older female

participants, reflecting established associations with osteoporosis. These patterns contrast with large epidemiological studies by Zelenka et al. [12] and Bartoníček et al. [13], which reported mean ages above 75 years and a female predominance of 70-73%, largely because their cohorts included older populations with osteoporotic fractures. Comparable findings were reported by Hantouly et al. [14] in a retrospective epidemiological study of proximal femur fractures in younger patients (<60 years). They reported that 89.9% of their cohort was male, with falls from height and motor vehicle accidents as the most common mechanisms of injury.

Most fractures in this cohort were stable patterns (AO 31-A1 and A2), whereas unstable AO 31-A3 fractures were least frequent, similar to reports by Chang et al. [15] and Haslhofer et al. [16], both of which found A3 fractures to be relatively uncommon. As expected, A3 fractures were associated with longer operative times and greater blood loss in this series. This is consistent with findings from Song et al. [17] and Wang et al. [18], who noted that more complex fractures increase surgical complexity and intraoperative morbidity. These observations underscore the importance of preoperative planning, anticipating longer procedures, and optimizing perioperative support for complex fracture subtypes.

Functional recovery measured by LEFS improved steadily and meaningfully across follow-up points, reaching approximately 63 of 80 points at 6 months. The approximately 20-point difference between successive follow-up periods exceeded the minimal clinically important difference of 9 points reported by Mehta et al. [19] in their review of LEFS measurement properties. This result is comparable to the findings of Chopra et al. [20], who reported a mean LEFS of 70 after proximal femoral nailing. Predictors of higher LEFS scores in this study included younger age, male sex, pre-injury independent ambulation, ASA grade I, absence of comorbidities, and early surgery (<48 hours). These observations align with reports by Korkmaz et al. [21], Zahoor et al. [22], and van der Sijp et al. [23], which demonstrated the influence of baseline health and functional status on outcomes. Fracture class and reduction quality did not significantly affect LEFS, a finding also reported by Korkmaz et al. [21] but differing from Balachandran et al. [24], who identified reduction quality as an important determinant. These differences may reflect variation in surgical technique, sample size, and outcome assessment intervals across studies.

Quality of life improved across SF-36 domains, particularly pain and energy/fatigue, supporting the role of PFN in restoring not only limb function but also broader well-being. Verma et al. [25] reported similar improvements across multiple SF-36 domains. Although Guyver et al. [26] reported persistently low postoperative SF-36 scores, their cohort was older, included pathological fractures, and compared postoperative scores with normative values rather than preoperative baselines, which may account for the discrepancy. The strong relationship between LEFS and SF-36 underscores the interdependence of functional recovery and perceived quality of life. Pre-injury independent ambulation was also associated with better SF-36 outcomes, consistent with findings by Abdulkasem et al. [27].

Complications in this cohort were predominantly superficial surgical site infections. The observed infection rate was higher than the 3-4% reported by Haslhofer et al. [16] and Altintas et al. [28]; however, differences in sample size, surgical expertise, and institutional infection-control practices may explain this variation. Advanced age, comorbidities, and prolonged operative times were identified as important risk factors in this cohort. Older patients may have impaired immune responses, reduced tissue perfusion, and multiple chronic conditions that predispose them to postoperative infection and delayed wound healing. Diabetes mellitus, in particular, is associated with an increased risk of surgical site infection because of impaired leukocyte function and microvascular disease. Perioperative optimization strategies, such as glycemic control, appropriate antibiotic prophylaxis, meticulous surgical technique, and minimization of operative time, may help reduce infection risk in vulnerable patients [29, 30]. A recent systematic review and meta-analysis of orthopedic trauma surgery identified male sex, elevated body mass index, current smoking, open injury, higher wound class, and prolonged operative duration as risk factors for deep surgical site infection, while age was not significantly associated [31]. These findings reinforce the importance of early identification of high-risk patients and targeted perioperative optimization. The single case of deep vein thrombosis was managed successfully with anticoagulation and did not impede fracture union. No implant failures or reoperations were recorded, suggesting satisfactory implant performance in this cohort.

Ninety-one percent of patients achieved radiological union by 6 months, with a mean time to union comparable to reports by Patel et al. [32] and Gupta et al. [33], who reported mean union times of 10-18 weeks. A trend toward slower healing in unstable fracture types was noted, although it did not reach statistical significance. Time to union is multifactorial and may be influenced by patient demographics, comorbidities, fracture pattern, and perioperative management. Recognizing these variables can guide rehabilitation and help set realistic patient expectations.

Limitations

This prospective cohort study has several limitations. First, it was conducted at a single center with a relatively modest sample size, which may limit generalizability. Second, the 6-month follow-up period may underestimate late complications or longer-term functional decline. In addition, excluding patients older than 75 years resulted in a relatively younger cohort with better physiological reserve, which may partly explain the low complication rate. Hip fractures predominantly affect older adults with frailty and multiple comorbidities, factors associated with poorer functional recovery and higher postoperative complication rates [1, 23, 34]. Therefore, caution is warranted when extrapolating these findings to the oldest-old population. Finally, heterogeneity in patient characteristics, including age, fracture type, comorbidities, and pre-injury functional status, may have influenced functional outcomes.

Conclusion

This prospective study demonstrates that proximal femoral nailing provides reliable fixation for pertrochanteric and subtrochanteric fractures, with improvement in functional outcomes and quality of life within 6 months. Younger age, independent pre-injury ambulation, lower ASA grade, and absence of comorbidities were associated with better recovery.

The high union rate and overall complication profile support the effectiveness of this technique in the study population. Larger multicenter studies with longer follow-up are required to validate these findings.

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J Surg Med. 2026;10(8):e8504.
https://doi.org/10.28982/josam.8504

JOSAM

Case Report
https://jsurgmed.com/

Journal of Surgery and Medicine
e-ISSN: 2602-2079

Esophageal candidiasis in an immunocompetent patient after laparoscopic sleeve gastrectomy: A case report

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Informed Consent
Written informed consent was obtained from the patient for publication of this case report and any accompanying images. Patient anonymity has been preserved.

Conflict of Interest
No conflict of interest was declared by the authors.

Financial Disclosure
The authors declared that this study has received no financial support.

Published
2026 August 13

Abstract

Esophageal candidiasis is an opportunistic infection typically observed in immunocompromised individuals, whereas laparoscopic sleeve gastrectomy is a widely performed bariatric procedure with relatively low rates of infectious complications. We report the case of a 51-year-old immunocompetent woman who developed esophageal candidiasis one year after laparoscopic sleeve gastrectomy and presented with a postprandial burning sensation and epigastric discomfort. Upper gastrointestinal endoscopy revealed diffuse white plaques along the esophageal mucosa, and histopathological examination confirmed Candida hyphae. The patient was treated with oral fluconazole, resulting in rapid clinical and endoscopic improvement. This case highlights the importance of considering esophageal candidiasis in the differential diagnosis of upper gastrointestinal symptoms after bariatric surgery, even in immunocompetent patients.

Keywords: esophageal candidiasis, bariatric surgery, candida infection, laparoscopic sleeve gastrectomy, postoperative complications, immunocompetent patient

Introduction

Laparoscopic sleeve gastrectomy (LSG) has emerged as one of the most commonly performed bariatric procedures worldwide because of its proven efficacy and relatively low complication rates [1]. In contrast, esophageal candidiasis is an uncommon condition that is typically observed in immunocompromised individuals [2]. Esophageal candidiasis in immunocompetent patients after bariatric surgery is rare and has been infrequently reported. We present a case of an immunocompetent patient with morbid obesity who underwent elective LSG and was subsequently diagnosed with esophageal candidiasis. This case highlights the need to consider esophageal candidiasis in patients presenting with unexplained upper gastrointestinal symptoms after bariatric surgery and contributes to the limited literature on atypical infectious complications after LSG.

How to cite: Abouhosa A, Ghunaim L, Kaptan B, Barlak RS, Göktug UU, Müftüoglu T, Tatar Z. Esophageal candidiasis in an immunocompetent patient after laparoscopic sleeve gastrectomy: A case report. J Surg Med. 2026;10(8):e8504.

Case presentation

A 51-year-old woman with a history of type 2 diabetes mellitus presented with morbid obesity and a body mass index (BMI) of 35.5 kg/m². She was receiving metformin therapy and had no history of smoking. Preoperative cardiovascular, pulmonary, gastrointestinal, metabolic, and psychological assessments were unremarkable. The patient underwent elective laparoscopic sleeve gastrectomy and was discharged two days after surgery with vitamin supplementation and proton pump inhibitor therapy for 15 days.

Twelve months after surgery, she reported postprandial epigastric pain and a burning sensation. Routine laboratory investigations were otherwise within normal limits; however, inflammatory markers were elevated, with a C-reactive protein (CRP) level of 25 mg/L and an erythrocyte sedimentation rate (ESR) of 56 mm/h. After cardiac and pulmonary causes were excluded, upper gastrointestinal endoscopy was performed and revealed multiple adherent plaques consistent with esophageal candidiasis (Figure 1). Biopsy specimens were obtained from the esophageal lesions, and histopathological examination confirmed Candida hyphae with associated inflammatory infiltration (Figure 2). No clinical evidence of immunosuppression or endoscopic evidence of esophageal obstruction was identified, and serological testing for human immunodeficiency virus was negative. The patient was treated with oral fluconazole at 200 mg/day, resulting in marked symptomatic improvement within three days. Follow-up upper gastrointestinal endoscopy performed one week later demonstrated marked regression of the lesions after antifungal therapy (Figure 3). After completing a two-week course of antifungal therapy, the patient achieved complete clinical recovery.

Figure 1. Upper gastrointestinal endoscopy showing diffuse white plaques along the esophageal mucosa consistent with esophageal candidiasis.

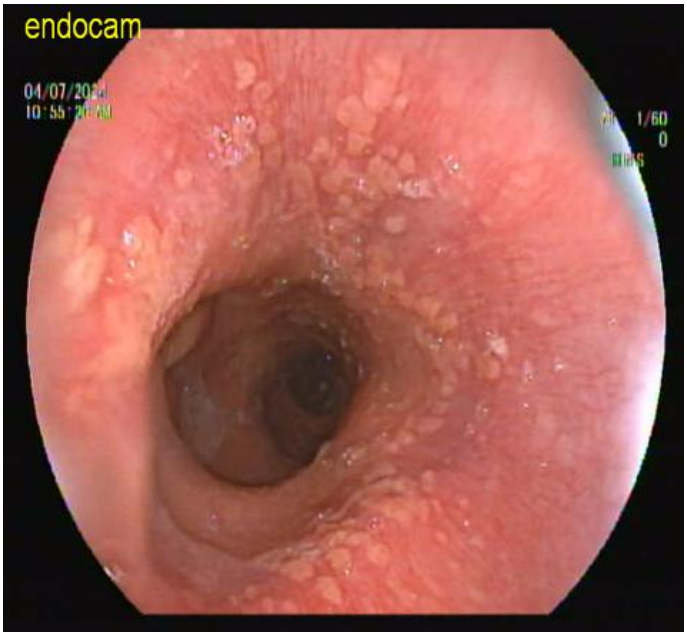


Figure 2. Histopathological examination of the esophageal biopsy showing Candida hyphae and inflammatory infiltration. Periodic acid–Schiff (PAS) staining, original magnification ×400

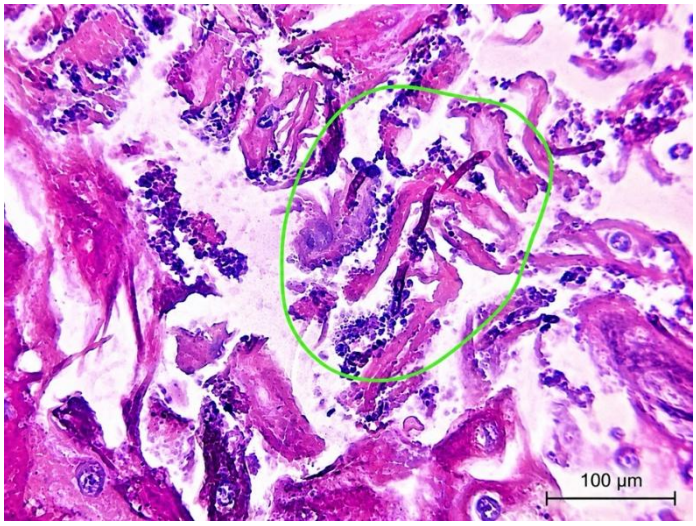
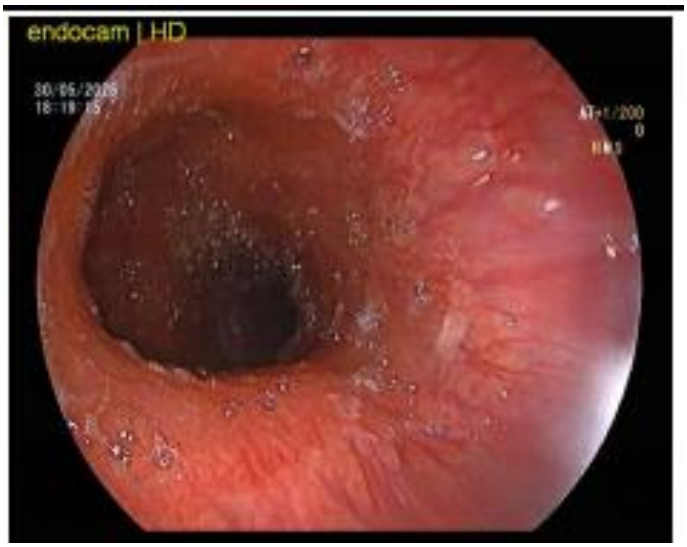


Figure 3. Follow-up upper gastrointestinal endoscopy showing marked regression of the esophageal lesions after antifungal therapy.



Discussion

Candida esophagitis is most commonly associated with immunocompromised states; however, it may also occur in immunocompetent individuals under certain predisposing conditions [2]. In the present case, the absence of classical immunosuppression highlights the importance of considering alternative risk factors, particularly in patients with a history of bariatric surgery. The pathogenesis of Candida esophagitis generally involves impaired host defense mechanisms or conditions that promote fungal overgrowth within the esophagus. These conditions may include esophageal stasis resulting from motility disorders or structural abnormalities, as well as alterations in the local microbial environment [3]. In this patient, no evidence of mechanical obstruction or a primary motility disorder was identified, suggesting that other contributing factors may have played a role.

Laparoscopic sleeve gastrectomy is associated with several postoperative physiological changes that may predispose patients to esophageal pathology. These include alterations in gastric anatomy, increased intragastric pressure, and a higher incidence of gastroesophageal reflux [4, 8, 9]. Changes in esophageal motility after LSG have also been reported and may contribute to impaired clearance of esophageal contents. Together,

these factors may disrupt the normal esophageal environment and facilitate fungal colonization.

Esophageal candidiasis after LSG has been reported in the literature but remains a rare postoperative complication [5]. In an outpatient series, prior gastric surgery and diabetes mellitus were among the reported predisposing factors for Candida esophagitis [6]. The patient's underlying type 2 diabetes mellitus may therefore have contributed to susceptibility to Candida infection. Diabetes has also been associated with increased gastrointestinal Candida colonization [7].

The present case is notable because of its delayed onset and occurrence in the absence of overt immunosuppression. The development of esophageal candidiasis one year after LSG suggests that long-term physiological changes may contribute to fungal overgrowth. The combination of postoperative anatomical and functional alterations, together with metabolic factors such as diabetes, may create an environment favorable to Candida colonization. This case underscores the importance of maintaining a high index of suspicion for atypical infectious etiologies in patients with persistent upper gastrointestinal symptoms after bariatric surgery. Early recognition and appropriate antifungal treatment can result in rapid clinical and endoscopic improvement, as demonstrated in this patient.

Conclusion

Esophageal candidiasis should be considered in patients who have undergone laparoscopic sleeve gastrectomy and present with unexplained upper gastrointestinal symptoms or postprandial burning sensations. Further studies are needed to clarify the pathophysiological mechanisms that may contribute to this complication.

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J Surg Med. 2026;10(8):e8525.
https://doi.org/10.28982/josam.8525

JOSAM

Case Report
https://jsurgmed.com/

Journal of Surgery and Medicine
e-ISSN: 2602-2079

Idiopathic giant hemorrhagic mesenteric pseudocyst presenting as an acute abdomen: A case report

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Informed Consent
Written informed consent was obtained from the patient for publication of this case report and any accompanying images. Patient anonymity has been preserved.

Conflict of Interest
No conflict of interest was declared by the authors.

Financial Disclosure
The authors declared that this study has received no financial support.

Published
2026 August 13

Abstract

Mesenteric pseudocysts are rare intra-abdominal lesions that may present with nonspecific symptoms and pose diagnostic challenges. We report a 45-year-old woman who presented with abdominal pain, distension, and low-grade fever. Contrast-enhanced computed tomography (CT) revealed a large cystic lesion measuring approximately 27 × 20 cm and occupying a substantial portion of the abdominal cavity. The patient underwent laparoscopic surgical management. Because of the lesion's size, controlled decompression was performed to facilitate manipulation, followed by complete excision. Histopathological examination confirmed a hemorrhagic mesenteric pseudocyst without evidence of malignancy. The postoperative course was uneventful, and no recurrence was identified during follow-up. This case highlights the importance of considering mesenteric pseudocysts in the differential diagnosis of large intra-abdominal cystic lesions and demonstrates that even giant lesions can be managed laparoscopically in selected patients.

Keywords: mesenteric cyst, mesenteric pseudocyst, acute abdomen, laparoscopy, abdominal cysts

Introduction

Mesenteric cysts are rare intra-abdominal lesions that often present with nonspecific symptoms and may mimic other abdominal conditions, making diagnosis challenging [1, 2]. Mesenteric pseudocysts represent an uncommon subgroup and are generally distinguished from true cysts by the absence of an epithelial lining. Secondary pseudocysts have been associated with trauma, infection, or hemorrhage, although cases without an identifiable cause have also been reported [2-4]. Giant mesenteric cysts are particularly uncommon and may present with acute symptoms because of hemorrhage, infection, rapid enlargement, or mass effect [1, 3-5]. We present a case of an idiopathic giant hemorrhagic mesenteric pseudocyst presenting as an acute abdomen that was successfully managed laparoscopically without bowel resection.

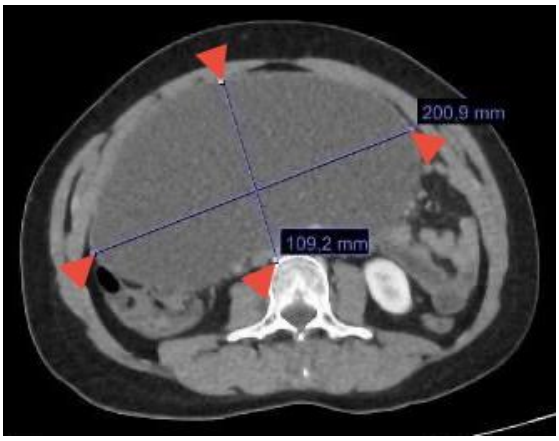
How to cite: Abouhosa A, Kaptan B, Barlak RS, Vural E, Ghunaim L, Göktuğ UU, Müftüoğlu T, Tatar Z. Idiopathic giant hemorrhagic mesenteric pseudocyst presenting as an acute abdomen: A case report. J Surg Med. 2026;10(8):e8525.

Case presentation

A 45-year-old woman presented with progressive abdominal distension accompanied by abdominal pain and low-grade fever. The symptoms had gradually worsened, prompting hospital admission. She had no significant medical or surgical history. On physical examination, the abdomen was distended, with a palpable mass occupying the central and lower abdominal regions. The mass was firm, mildly tender, and had limited mobility. There were no signs of peritoneal irritation, such as rebound tenderness or guarding. Laboratory investigations were largely within normal limits, with a C-reactive protein (CRP) level of 10 mg/L and an erythrocyte sedimentation rate (ESR) of 40 mm/h.

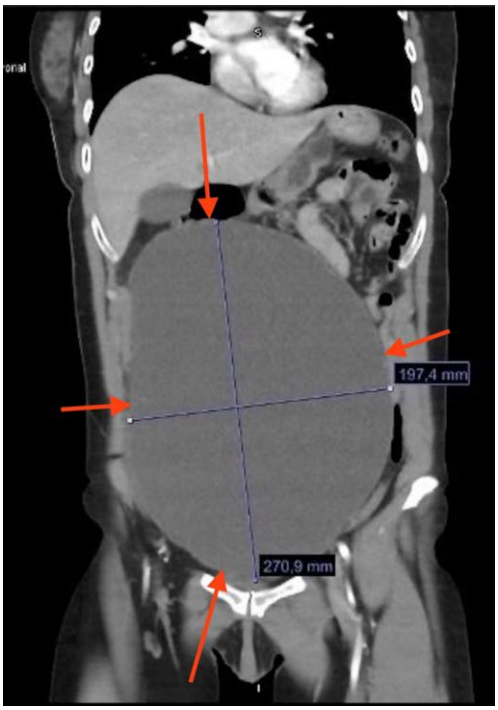
Contrast-enhanced CT revealed a large, well-defined cystic lesion occupying a substantial portion of the abdominal cavity and measuring approximately 27 × 20 cm, with internal heterogeneity suggestive of hemorrhagic content (Figures 1 and 2). The lesion exerted mass effect on adjacent bowel loops without clear evidence of invasion. Based on these findings, laparoscopic surgical intervention was planned.

Figure 1. Contrast-enhanced axial CT demonstrating a large cystic lesion occupying the abdominal cavity with displacement of adjacent bowel loops.



Abbreviations: CT: computed tomography.

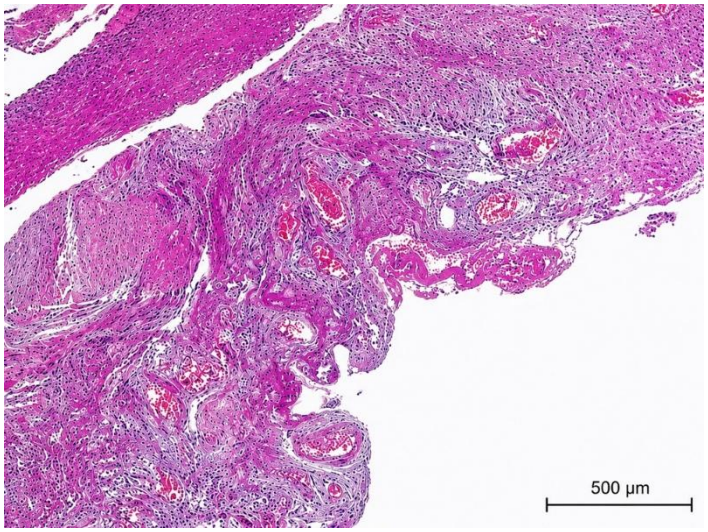
Figure 2. Coronal CT view showing the craniocaudal extent of the cystic lesion, extending from the upper abdomen to the pelvis.



Abbreviations: CT: computed tomography.

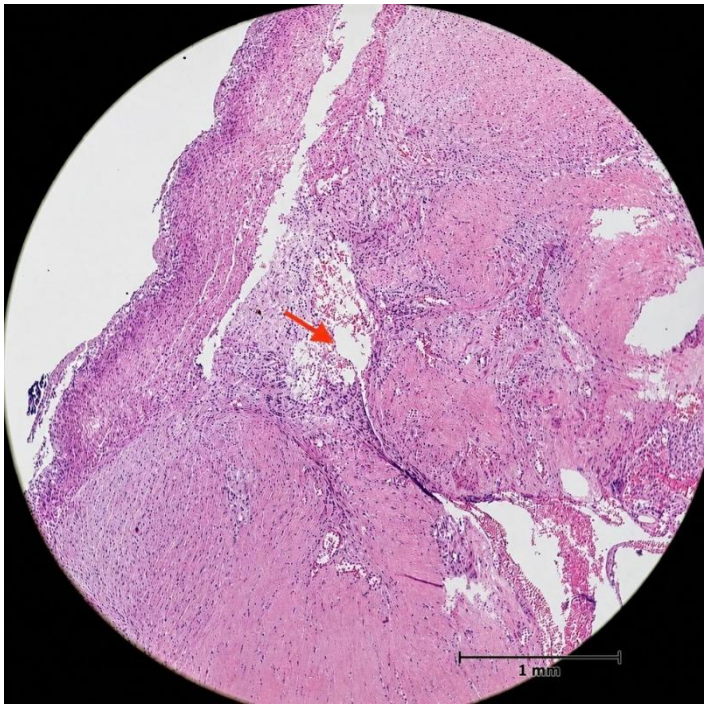
Intraoperatively, a large cystic mass occupying the abdominal cavity was identified. Because of its size, controlled decompression was performed to facilitate safe manipulation. After aspiration of the cyst contents, careful dissection revealed a well-defined plane between the cyst and the surrounding structures. Complete excision was achieved without unintended rupture or the need for bowel resection, as no involvement of adjacent bowel or mesenteric vessels was identified. The resected specimen was submitted for histopathological examination. Gross evaluation confirmed a large cystic lesion consistent with the intraoperative findings, while microscopic examination demonstrated a hemorrhagic mesenteric pseudocyst with no evidence of malignancy (Figures 3 and 4). The postoperative course was uneventful, and the patient was discharged in stable condition. At 1 month of postoperative follow-up, no evidence of recurrence or complications was observed.

Figure 3. Histopathological image (H&E) showing a fibrotic cyst wall with hemorrhage and vascular congestion. Original magnification ×100.



Abbreviations: H&E: hematoxylin and eosin.

Figure 4. Histopathological image (H&E) demonstrating fibrotic tissue with inflammatory infiltration and absence of an epithelial lining. Original magnification ×40.



Abbreviations: H&E: hematoxylin and eosin.

Discussion

Mesenteric cysts are rare clinical entities, and mesenteric pseudocysts represent an uncommon subgroup [1, 2]. Histopathological classification distinguishes pseudocysts from cysts of lymphatic, mesothelial, enteric, urogenital, and other origins [2]. Secondary pseudocysts have been associated with trauma, infection, or hemorrhage [2, 4]. The present lesion was considered idiopathic because the patient had no relevant medical or surgical history and no precipitating cause was identified.

The size and location of mesenteric cysts are highly variable. Large lesions can cause marked mass effect and may present with abdominal pain, distension, or an acute abdominal picture [1, 3]. In the present case, despite the lesion's size, adjacent bowel and major mesenteric vessels were not involved. A clear dissection plane therefore allowed complete excision without bowel resection. This is clinically relevant because complete excision is the preferred treatment, while resection of adjacent bowel may be required when the lesion is inseparable from surrounding structures [1, 3].

The differential diagnosis of a large intra-abdominal cystic lesion includes ovarian, pancreatic, retroperitoneal, and mesenteric lesions. In this patient, imaging defined the lesion's extent and relationship to surrounding structures, whereas the definitive diagnosis was established by histopathological examination.

Laparoscopic excision has been reported as feasible in selected patients with mesenteric cysts [3, 5]. In the present case, controlled decompression facilitated laparoscopic handling and was followed by complete excision without bowel resection. These findings support a minimally invasive approach in carefully selected patients when a safe dissection plane is present and the lesion can be removed without compromising adjacent bowel or mesenteric vessels [5].

Mesenteric pseudocysts should therefore remain in the differential diagnosis of large intra-abdominal cystic masses. This case also illustrates that giant lesions may be managed laparoscopically when the anatomy and surgical expertise permit.

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J Surg Med. 2026;10(8):e8470.
https://doi.org/10.28982/josam.8470

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Case Report
https://jsurgmed.com/

Journal of Surgery and Medicine
e-ISSN: 2602-2079

Minimally invasive therapeutic approach to fetal congenital pulmonary airway malformation: Case report and literature review

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Ethical Approval
This study was reviewed and approved by the Research Ethics Committee of Hospital Materno Infantil Presidente Vargas (HMIPV), Porto Alegre, Brazil, through Plataforma Brasil (CAAE No. 92927625.4.0000.5329; Ethics Committee Approval No. 7.981.838; approved on November 17, 2025). The study was conducted in accordance with the applicable Brazilian ethical and regulatory requirements for research involving human participants.

Informed Consent
Written informed consent for publication of this case was obtained from the child's legal guardian, who is directly responsible for the minor. The legal guardian voluntarily authorized the use and publication of the child's clinical data and medical images for scientific and educational purposes. The consent included authorization for dissemination in scientific presentations and publications, with preservation of the patient's anonymity and confidentiality. No information that could directly identify the child is disclosed in this manuscript.

Conflict of Interest
No conflict of interest was declared by the authors.

Financial Disclosure
The authors declared that this study has received no financial support.

Published
2026 August 18

Abstract

Congenital pulmonary airway malformation (CPAM) is a rare fetal condition associated with substantial morbidity and mortality, particularly when complicated by hydrops fetalis. Minimally invasive fetal therapies have emerged as alternatives to open fetal surgery, with the goals of reducing lesion volume, improving survival, and minimizing maternal morbidity. We report a hydropic fetus with a solid-appearing left thoracic lesion and a central feeding vessel, initially interpreted as a hybrid CPAM/pulmonary sequestration lesion. After maternal betamethasone failed to control disease progression, ultrasound-guided intralesional sclerotherapy with 5% monoethanolamine oleate (Ethamolin®; 50 mg/mL) was performed at 27 weeks' gestation. Follow-up ultrasonography showed a reduction in lesion size and a decrease in the CPAM volume ratio (CVR) from 2.58 to 1.29, with complete resolution of hydrops. The pregnancy progressed to term, and postnatal surgical resection and histopathologic examination confirmed pulmonary sequestration. To contextualize this experience, we also reviewed the literature on minimally invasive prenatal treatment of solid-appearing CPAM and pulmonary sequestration. Across the available reports, laser ablation predominated in pulmonary sequestration, whereas sclerotherapy progressively replaced laser therapy in solid CPAM. Among the reported sclerosants, ethanolamine appears to offer the most consistent balance of feasibility, low cost, and favorable fetal response, although careful Doppler-guided injection is essential to avoid intravascular complications.

Keywords: congenital pulmonary airway malformation, pulmonary sequestration, fetal therapy, sclerotherapy, minimally invasive surgery, hydrops fetalis, ethanolamine

Introduction

Congenital pulmonary airway malformation (CPAM) and pulmonary sequestration (PS) are uncommon fetal thoracic lesions that may have similar prenatal imaging findings but differ in embryology, vascular anatomy, postnatal pathology, and therapeutic approach [1-4]. Both lesions may behave as expansile intrathoracic masses, compressing adjacent lung tissue, shifting the mediastinum, impairing venous return, and, in severe cases, progressing to hydrops fetalis with a very high risk of fetal or neonatal death [1, 3, 4].

Prenatal treatment is directed at reducing mass effect and restoring thoracic physiology. Current management options include maternal corticosteroids, thoracocentesis or thoracoamniotic shunting for macrocystic lesions, laser or embolization techniques for lesions with a dominant feeding vessel, and open fetal surgery in selected refractory cases [5-10]. Although open fetal resection can be lifesaving, it carries substantial fetal risk and clinically relevant maternal morbidity, including uterine scarring and implications for future pregnancies [6, 7].

For predominantly solid lesions complicated by hydrops that do not respond to corticosteroids, minimally invasive intralesional or intravascular therapies have gained attention as potentially effective alternatives to open surgery [11-36]. The aim of this report is to describe the management of a hydropic fetus with a solid-appearing thoracic lesion treated with ultrasound-guided ethanolamine sclerotherapy after failed corticosteroid therapy and to synthesize the literature on minimally invasive treatment for similar fetal presentations.

How to cite: Rocha ADS, Dondé JP, Pereira MM, Martiny A, da Cunha AC, Telles JB, Toniolli V. Minimally invasive therapeutic approach to fetal congenital pulmonary airway malformation: Case report and literature review. J Surg Med. 2026;10(8):e8470.

Case presentation

A 39-year-old pregnant woman (G2P1) was referred to the fetal medicine department of Hospital Materno Infantil Presidente Vargas on January 17, 2024, at 21 weeks and 1 day of gestation, with fetal hydrops and a hyperechoic heterogeneous lesion in the left hemithorax measuring 6.1 × 4.5 × 3.3 cm. The lesion caused rightward mediastinal deviation, and the CPAM volume ratio (CVR) was 2.39. Doppler assessment demonstrated a central feeding vessel arising from the thoracic aorta, raising the initial diagnostic hypothesis of a hybrid CPAM with a sequestration component. A detailed fetal ultrasound examination was performed on February 15, 2024, at 25 weeks and 2 days of gestation (Figure 1), confirming persistence of the lesion with features suggestive of hybrid CPAM/sequestration and ongoing hydrops.

Maternal betamethasone was administered on January 17 and January 25, 2024; however, no significant clinical or sonographic improvement was observed. Because hydrops persisted and the lesion remained clinically significant, ultrasound-guided intralesional sclerotherapy with 5% monoethanolamine oleate (Ethamolin®; 50 mg/mL) was indicated. The procedure was performed on February 27, 2024, at 27 weeks' gestation, when the lesion measured 5.5 × 5.2 × 4.6 cm and the CVR was 2.58. Under maternal sedation to minimize maternal and fetal movement, a 22-gauge needle was introduced into the lesion, and 3.0 mL of 5% monoethanolamine oleate (Ethamolin®; 50 mg/mL) was injected using a fan-shaped technique under continuous Doppler monitoring. Figure 2 shows an ultrasound image obtained during sclerotherapy.

Ultrasound follow-up on March 12, 2024, at 29 weeks' gestation showed a reduction in lesion size to 5.1 × 3.9 × 3.5 cm, with a CVR of 1.29 and complete resolution of hydrops (Figure 3). The pregnancy subsequently progressed to 38 weeks, when cesarean delivery was indicated because of preeclampsia. A male newborn was delivered on May 14, 2024, with Apgar scores of 6 and 8 at 1 and 5 minutes, respectively, and a birth weight of 2,890 g. Mechanical ventilation was not required; continuous positive airway pressure was used only during the first hours of life.

Postnatal computed tomography performed on May 21, 2024, demonstrated a heterogeneous lesion in the posterior basal segment of the left lower lobe measuring 4.0 × 3.0 × 3.5 cm. The newborn underwent thoracotomy with segmentectomy on June 17, 2024. Histopathologic examination confirmed pulmonary sequestration measuring 5.1 × 4.2 × 3.4 cm. The infant was discharged in good clinical condition on July 1, 2024 (Figure 4).

Literature review strategy

A literature review was conducted in MEDLINE, Embase, and LILACS in May 2025, without restrictions on publication year, language, or country. The search combined MeSH terms and free-text keywords related to CPAM, pulmonary sequestration, fetal therapy, minimally invasive treatment, laser ablation, sclerotherapy, radiofrequency, and percutaneous intervention (Supplementary material 1). After duplicate removal and eligibility assessment, 26 studies were included: 14 concerning predominantly solid CPAM and 12 concerning PS (Figure 5).

Figure 1. Prenatal sonographic appearance of the thoracic mass.

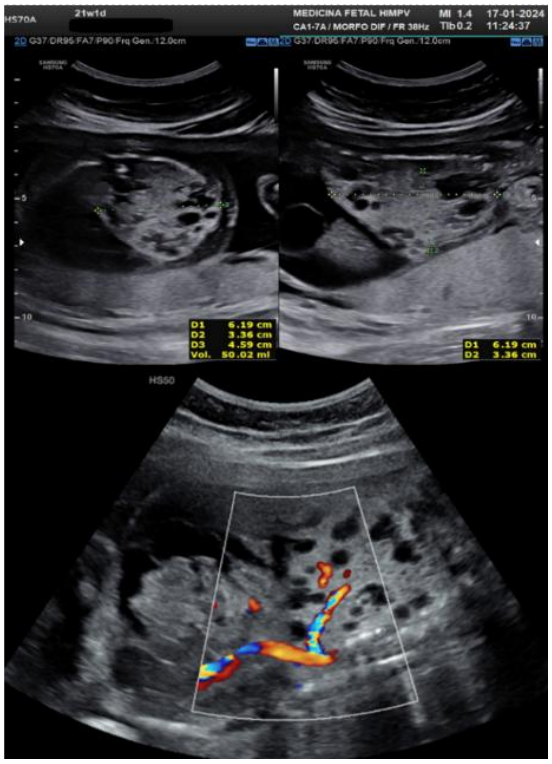

Figure 2. Ultrasound image obtained during sclerotherapy.

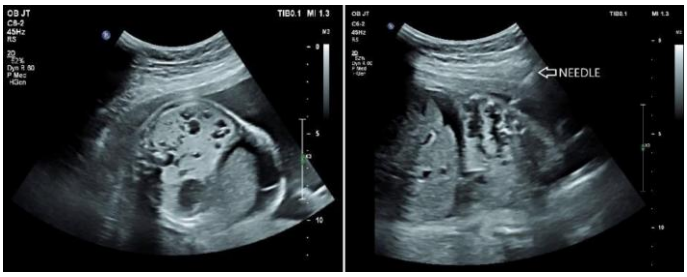

Figure 3. Ultrasound follow-up 2 weeks after sclerotherapy.

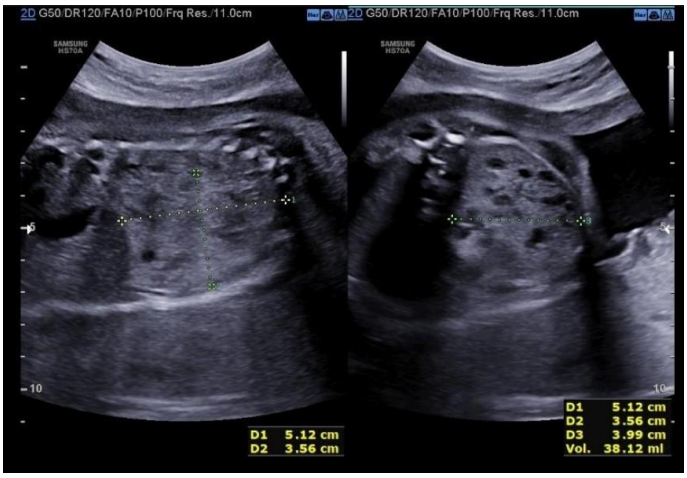

Figure 4. Postnatal computed tomography scan of the neonatal thorax.

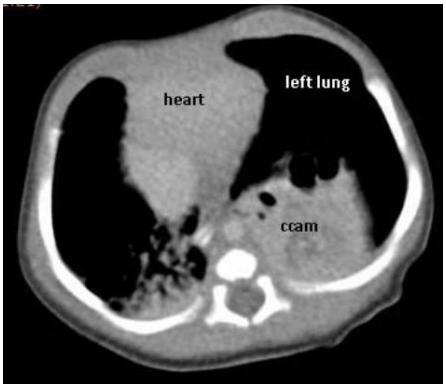

Figure 5. Flowchart of study selection.

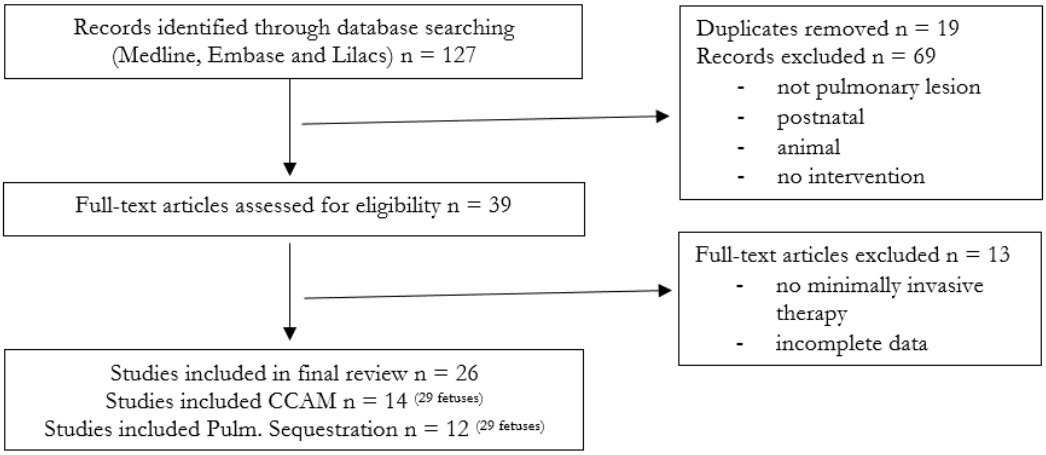

Table 1. Literature review of minimally invasive treatment for predominantly solid CPAM.

First author – year – journal	Type of study / sample	Fetal ultrasound diagnosis	CVR	Steroid use	Minimally invasive therapy	GA at therapy (weeks)	Intervention details	Therapy results
Fortunato SJ et al. (1997) Am J Obstet Gynecol [13]	Case report (n=1)	Type III CCAM	Not reported	No	Laser ablation	21 and 23	YAG laser therapy was performed using 16 W at 21 and 23 weeks of gestation (double dose).	Cardiac axis returned to normal; lung growth documented.
Bruner JP et al. (2000) Fetal Diagn Ther [14]	Case report (n=1)	Type III CCAM	Not reported	No	Laser ablation	23 and 24	YAG laser therapy was performed using 15 W at 23 and 24 weeks (double dose).	Fetal demise at 25 weeks.
Davenport M et al. (2004) J Pediatr Surg [15]	Retrospective case series (n=3)	Type II–III CCAM	Not reported	No	Laser ablation (n=1)	19–31	YAG laser therapy at 19 and 31 weeks (double dose).	Hydrops resolution and uneventful birth at 38 weeks (two other cases did not receive therapy).
Ong SS et al. (2006) Fetal Diagn Ther [16]	Case report (n=1)	Type III CCAM	Not reported	No	Laser ablation	22	YAG laser therapy was performed using 45 W.	Term birth; lobectomy 48 h after birth.
Cavoretto P et al. (2008) Ultrasound Obstet Gynecol [17]	Case report (n=1)	Type III CCAM	Not reported	No	Laser ablation	23 and 31	YAG laser therapy was performed using 30–50 W (double dose).	Term birth and neonatal demise due to pulmonary hypoplasia.
Bermúdez C et al. (2008) Fetal Diagn Ther [18]	Retrospective case series (n=3)	Type II and III CCAM	Not reported	No	Sclerotherapy with polidocanol 3% or ethanolamine oleate 5%	21–26	Case 1: ethanolamine oleate 5%, 1.5 mL. Cases 2 and 3: polidocanol 3%, 2 mL.	Cases 1 and 3: term birth and normal newborn. Case 2: term birth, neonatal lobectomy, death from nosocomial sepsis.
Sepulveda W et al. (2010) J Ultrasound Med [19]	Case report (n=1)	Hybrid type III CCAM and PS	Not reported	No	Embolization with N-butyl-2-cyanoacrylate	22	NBCA 2 mL injected into the largest vessel supplying the tumor.	Hydrops resolution at 25 weeks and term birth.
Lee FL et al. (2012) Fetal Diagn Ther [20]	Retrospective case series (n=3)	Type II–III CCAM	Case 1: 7.8; Case 2: 3.4; Case 3: 3.9	Yes (n=1)	Sclerotherapy with ethanolamine oleate 5%	19–33	Cases 1 and 2: ethanolamine oleate 5%, 2 mL. Case 3: ethanolamine oleate 5%, 4 mL.	Cases 1 and 3: hydrops resolution and term birth. Case 2: term birth, low Apgar score, minor neurological sequelae.
Ruano R et al. (2012) Prenat Diagn [21]	Retrospective case series (n=3)	Type III CCAM	Not reported	No	Laser ablation	<32	YAG laser therapy was performed using 30–40 W.	Fetal death after the procedure (n=1) and premature birth followed by neonatal death (n=2).
Juárez-García L et al. (2015) Ginecol Obstet Mex [22]	Case report (n=1)	Type II CCAM	Not reported	No	Sclerotherapy with polidocanol 3%	24	Polidocanol 3%, 1.5 mL.	Born at 39+4 weeks and required ventilatory support; postnatal lobectomy; hydrops persisted until term.
Cruz-Martínez R et al. (2015) Fetal Diagn Ther [23]	Case report (n=1)	Type III CCAM (bronchial atresia?)	4.2	Yes	Fetal bronchoscopy	30	Clearance of the upper airway with a 3-mm endoscope and laser ablation of the bronchial membrane at 10 W.	Born at 38+6 weeks; no ventilatory support or lesion resection required.
Chon AH et al. (2018) Prenat Diagn [24]	Retrospective case series (n=8)	Type II–III CCAM	1.7 to 7.8	Yes (n=4)	Sclerotherapy with ethanolamine oleate 5%	19–31	Ethanolamine oleate 5%, 2.0 to 10.0 mL (average 5.5 mL).	Six favorable outcomes; one death after intravascular injection; one death following severe preprocedural bradycardia.
Abbasi N et al. (2020) Fetal Diagn Ther [25]	Case report (n=1)	Type III CCAM	2.78	Yes	Sclerotherapy with sodium tetradecyl sulfate 3%	23	STS 3%, 2 mL.	Term birth with normal Apgar score.
Klinkner DB et al. (2022) Fetal Diagn Ther [26]	Case report (n=1)	Giant mixed II–III CCAM	1.9	Yes	Radiofrequency ablation	22	Three ablation points, from 50 W to 80 W, monitored by local gas release.	Term birth with a low Apgar score (1–8).

Abbreviations: CCAM: congenital cystic adenomatoid malformation, CPAM: congenital pulmonary airway malformation, CVR: CPAM volume ratio, GA: gestational age, NBCA: N-butyl-2-cyanoacrylate, PS: pulmonary sequestration, STS: sodium tetradecyl sulfate, YAG: yttrium aluminum garnet.

Table 2. Literature review of minimally invasive treatment for pulmonary sequestration.

First author – year – journal	Type of study / sample	Fetal ultrasound diagnosis	CVR	Steroid use	Minimally invasive therapy	GA at therapy (weeks)	Intervention details	Therapy results
Ruano R et al. (2007) J Ultrasound Med [28]	Case report (n=1)	Pulmonary sequestration	Not reported	No	Laser ablation of feeding artery	29	YAG laser therapy was performed using 35 W.	Term birth and neonatal lobectomy on day 15.
Oepkes D et al. (2007) Ultrasound Obstet Gynecol [29]	Case report (n=1)	Pulmonary sequestration	Not reported	No	Laser ablation of feeding artery	23	YAG laser therapy was performed using 20–50 W.	Term birth and no tumor resection performed.
Bermúdez C et al. (2007) Ultrasound Obstet Gynecol [27]	Case series (n=3)	Pulmonary sequestration	Not reported	No	Sclerotherapy with polidocanol 3% (feeding artery)	24–26	1 mL polidocanol 3% injected into the feeding artery.	Hydrops resolution and term birth; one death after lobectomy complications.
Witlox RSGM et al. (2009) Ultrasound Obstet Gynecol [30]	Case report (n=1)	Pulmonary sequestration	Not reported	No	Laser ablation of feeding artery + drainage	23	Nd:YAG laser at 20 W, followed by drainage of hydrothorax and hydramnios through the same needle.	Term birth with normal Apgar score.
Rammos KS et al. (2010) Interact Cardiovasc Thorac Surg [31]	Case report (n=2)	Extralobar pulmonary sequestration	Not reported	No	Laser ablation of feeding artery + pleural drainage/shunt	28 and 31	Prenatal laser treatment with pleural drainage and pleuroamniotic shunt; second laser session in one case.	Cases 1 and 2: postnatal thoracotomy and good long-term outcomes.
Baud D et al. (2013) Ultrasound Obstet Gynecol [32]	Prospective case series (n=3)	Pulmonary sequestration	Not reported	No	Laser ablation / radiofrequency / coil embolization	17–25	Case 1: laser 50 W. Case 2: radiofrequency 100 W. Case 3: thrombogenic coil embolization.	Case 1: term birth, healthy infant. Case 2: preterm birth and neonatal death after severe procedure-related complications. Case 3: intrauterine death after embolization.
Mallmann MR et al. (2014) Ultrasound Obstet Gynecol [33]	Retrospective cohort (n=5)	Pulmonary sequestration with severe pleural effusion	Not reported	No	Laser ablation of feeding artery	24–31	Nd:YAG laser through an 18-G needle; 50 W with repeat coagulation if residual flow persisted.	All five laser-treated fetuses showed regression and were delivered at term.
Kosinski P et al. (2017) Ultraschall Med [34]	Case report (n=2)	Pulmonary sequestration	Not reported	No	Laser ablation of feeding artery	22 and 27	Case 1: diode laser 35 W. Case 2: Nd:YAG laser 50 W with pleural drainage.	Case 1 and 2: term delivery with normal Apgar score.
Ichino M et al. (2020) Eur J Pediatr Surg Rep [35]	Case report (n=2)	Complicated extralobar pulmonary sequestration	Not reported	No	Laser ablation of feeding artery	26 and 31	Diode laser, 15–20 W, followed by postnatal MRI/CT surveillance and thoracoscopic resection.	Both neonates were born asymptomatic at 38 weeks; residual lesions were resected thoracoscopically.
Ruano R et al. (2020) Fetal Diagn Ther [37]	Case report (n=1)	Bronchopulmonary sequestration	2.8 in one case	Yes in one case	Laser ablation of feeding artery	27	YAG laser 25 W.	Term birth with normal Apgar score in the index case.
Grozdeva L et al. (2021) Fetal Diagn Ther [9]	Narrative review (n=1)	Bronchopulmonary sequestration with hydrops	Reported variably	Yes in selected cases	Vascular laser ablation	28–31	Diode laser 30 W under ultrasound guidance; associated amniodrainage/thoracentesis in selected cases.	Term birth with normal Apgar score.
Zanini A et al. (2022) Eur J Pediatr Surg [36]	Retrospective case series (n=5)	Bronchopulmonary sequestration	Not reported	No	Prenatal ultrasound-guided laser coagulation	24–31	Diode laser 15–20 W; thoracocentesis or shunt as adjunct when needed.	Cases 1–4: term birth with normal Apgar scores. Case 5: follow-up unavailable in the local series.

Abbreviations: CT: computed tomography, CVR: CPAM volume ratio, GA: gestational age, MRI: magnetic resonance imaging, Nd:YAG: neodymium-doped yttrium aluminum garnet.

Literature review findings

Among the included studies, minimally invasive treatment of predominantly solid CPAM was reported in 14 publications comprising 29 fetuses, whereas 12 publications described 29 fetuses with pulmonary sequestration (PS). Reporting quality was heterogeneous, particularly for CVR values and prior corticosteroid use; however, the available outcome data allowed comparison of therapeutic effectiveness.

In CPAM, outcomes varied and appeared to depend on both the technique and preintervention severity. Overall, favorable outcomes, such as survival with resolution of hydrops or clinical stabilization, were reported in approximately 60-65% of cases, whereas fetal or neonatal mortality occurred in approximately 30-35%. Laser ablation, used predominantly in earlier studies, was associated with higher mortality, including fetal demise and early neonatal death in multiple reports. In contrast, sclerotherapy with ethanolamine, polidocanol, or sodium tetradecyl sulfate demonstrated more consistent resolution of hydrops and term delivery, with favorable outcomes reported in most treated cases.

Nevertheless, procedure-related complications were clinically important and included intravascular injection, cardiovascular instability, and postnatal infectious complications, indicating that treatment safety remains operator dependent.

In PS, outcomes were more consistently favorable across studies. Reported overall survival exceeded 85-90%, with most fetuses achieving resolution of hydrops or substantial clinical improvement after intervention. Laser coagulation or ablation of the feeding artery was the predominant technique and demonstrated high efficacy in reversing hydrothorax and hydrops, particularly when complete interruption of vascular flow was achieved. Several series reported near-complete survival with term delivery, especially in more recent cohorts using standardized techniques.

However, treatment of PS is not without risk. Isolated reports described procedure-related mortality, including intrauterine and neonatal deaths following severe hemodynamic instability or technical failure. In addition, a substantial proportion of cases required postnatal surgical resection of residual lesions even after apparent prenatal success, indicating that fetal therapy should be considered primarily lifesaving rather than definitive.

When the two conditions are compared, PS appears more amenable to minimally invasive fetal therapy than CPAM. This difference is likely related to the presence of a well-defined systemic feeding vessel, which allows targeted vascular intervention. In contrast, predominantly solid CPAM lesions often lack a single dominant vascular target, resulting in more heterogeneous responses and higher complication rates.

From a clinical perspective, these findings suggest that minimally invasive intervention should be strongly considered in fetuses with hydrops secondary to PS, for which the likelihood of reversal and survival is high. In CPAM, however, treatment decisions should be individualized by balancing potential benefits against a higher risk of mortality and procedural complications, particularly in cases with a very high CVR or advanced hydrops. The detailed characteristics and outcomes of the included studies are summarized in Tables 1 and 2.

Discussion

CPAM and PS share the capacity to produce a life-threatening intrathoracic mass effect during fetal life, but they are not interchangeable entities [1-4]. This distinction is clinically important because lesion morphology and vascular anatomy determine which minimally invasive option is most appropriate. Macrocystic CPAM may respond to decompressive procedures such as thoracocentesis or thoracoamniotic shunting, whereas PS is more suited to interruption of the feeding vessel. The greatest therapeutic challenge remains a predominantly solid lesion associated with hydrops, especially when corticosteroids fail [5, 8, 9, 11, 12].

In this setting, open fetal surgery has historically been used as salvage treatment, but its maternal and fetal risks are considerable [6, 7]. The literature reviewed here supports the current movement toward less invasive alternatives. In PS, laser ablation of the feeding artery has produced the most consistent results because it directly targets the lesion's vascular dependence [9, 28-37]. In contrast, outcomes in solid CPAM have been less predictable with laser-based destruction of parenchyma, and this technique has been reported mainly in earlier series [13-17, 21].

A clearer comparison among sclerosants is clinically more useful than repetition of individual study details. Ethanolamine was the most frequently reported sclerosant for solid CPAM and was associated with resolution of hydrops and term delivery in most treated fetuses [18, 20, 24]. Ethanolamine is an organic amine sclerosant that induces a local inflammatory reaction, leading to endothelial injury, fibrosis, and subsequent vascular occlusion at the injection site. Its main practical advantages are broad availability, low cost, and technical similarity to other ultrasound-guided needle procedures familiar to fetal therapy teams. The principal safety concern is inadvertent intravascular injection, which may cause catastrophic fetal cardiovascular injury; this risk underscores the need for continuous Doppler guidance and careful needle positioning [18, 20, 24].

Polidocanol was reported less often and generally with favorable fetal outcomes, but the evidence base is smaller and published descriptions are less complete regarding lesion evolution, CVR response, and the long-term neonatal course [18, 22]. Polidocanol is a nonionic surfactant derived from lauryl alcohol and ethylene oxide and exerts its sclerosing effect through endothelial disruption and thrombosis at the application site. In PS, intravascular use in the feeding vessel appears conceptually attractive, although the number of reported cases remains very limited [27].

Sodium tetradecyl sulfate has been described only in isolated CPAM cases, with encouraging short-term results but insufficient data for meaningful comparative conclusions [25]. It is an anionic sclerosing surfactant that causes endothelial injury, platelet aggregation, and thrombotic occlusion of targeted vessels.

Taken together, the available literature suggests that ethanolamine currently has the strongest practical support among sclerosants, whereas polidocanol and sodium tetradecyl sulfate remain promising but less well documented options.

Our case is consistent with that interpretation. After failure of maternal betamethasone, a single ultrasound-guided injection of 5% monoethanolamine oleate (Ethamolin®; 50

mg/mL) was followed by a marked decrease in CVR and complete resolution of hydrops, allowing the pregnancy to continue to term. The prenatal imaging appearance initially suggested a hybrid lesion, but postnatal pathology confirmed PS. This diagnostic transition is relevant because prenatal management must often proceed under imaging-based uncertainty, with definitive classification becoming possible only after resection. From a pragmatic perspective, this case also reinforces that ethanolamine can be considered when a severe solid thoracic lesion is progressing and advanced fetoscopic technology is unavailable or impractical.

Conclusion

Minimally invasive fetal intervention should be considered for severe thoracic lesions associated with hydrops when conservative management fails. In selected solid-appearing lesions, ultrasound-guided sclerotherapy offers a less invasive alternative to open fetal surgery, with potential maternal and fetal advantages. Based on the present case and reviewed literature, 5% monoethanolamine oleate appears to be a feasible, low-cost option, particularly in resource-limited settings, provided that meticulous Doppler-guided technique is used to minimize the risk of intravascular complications.

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Supplementary material 1. Search strategy

1) MEDLINE via PubMed: (("Congenital Pulmonary Airway Malformation"[MeSH] OR "Congenital Cystic Adenomatoid Malformation"[MeSH] OR CCAM[tiab] OR CPAM[tiab] OR "Pulmonary Sequestration"[MeSH] OR sequestration[tiab]) AND ("Fetal Therapy"[MeSH] OR "Prenatal Intervention"[MeSH] OR "Intrauterine Treatment"[tiab] OR "Minimally Invasive"[tiab] OR "Laser Ablation"[tiab] OR "Sclerotherapy"[tiab] OR "Radiofrequency"[tiab] OR "Percutaneous"[tiab]) AND (case[tiab] OR "case report"[Publication Type] OR "case series"[tiab]) NOT (animal[MeSH] OR placenta[tiab] OR newborn[tiab] OR postnatal[tiab]))

2) Embase: ('congenital pulmonary airway malformation'/exp OR 'congenital cystic adenomatoid malformation',ab OR CCAM,ab OR CPAM,ab OR 'lung sequestration'/exp OR 'pulmonary sequestration',ab OR sequestration,ab) AND ('fetal therapy'/exp OR 'fetal therapy',ab OR 'prenatal intervention',ab OR 'intrauterine treatment',ab OR 'minimally invasive',ab OR 'laser ablation',ab OR sclerotherapy,ab OR radiofrequency,ab OR

percutaneous,ab) AND (case,ab OR 'case report'/exp OR 'case report',ab OR 'case series',ab) NOT ('animal'/exp OR placenta,ab OR newborn,ab OR postnatal,ab)

3) LILACS via BVS: (("Congenital Pulmonary Airway Malformation" OR "Congenital Cystic Adenomatoid Malformation" OR "Malformação Congênita das Vias Aéreas Pulmonares" OR "Malformação Adenomatoide Cística Congênita" OR CCAM OR CPAM OR "Pulmonary Sequestration" OR "Sequestro Pulmonar" OR sequestration) AND ("Fetal Therapy" OR "Terapia Fetal" OR "Prenatal Intervention" OR "Intervenção Pré-Natal" OR "Intrauterine Treatment" OR "Tratamento Intrauterino" OR "Minimally Invasive" OR "Minimamente Invasivo" OR "Laser Ablation" OR "Ablação a Laser" OR Sclerotherapy OR Escleroterapia OR Radiofrequency OR Radiofrequência OR Percutaneous OR Percutâneo) AND (case OR "case report" OR "relato de caso" OR "case series" OR "série de casos")) NOT (animal OR animals OR placenta OR newborn OR "recém-nascido" OR postnatal OR "pós-natal")