



Clinical Research Paper

Safety and efficacy of ultrasound-guided percutaneous biopsy with FAL tract sealing for pediatric hypervascular malignant solid tumors: A retrospective cohort study



Chuankai Lv ^{a,1}, Tianwei Zhang ^{b,1}, Cheng Zhang ^a, Qinghua Ren ^b, Xin Wei ^a, Wuhua Li ^a, Jiatong Xu ^c, Shen Yang ^b, Saishuo Chang ^b, Haiyan Cheng ^b, Zhiyun Zhu ^b, Jianyu Han ^b, Yijin Huang ^b, Jie Yin ^d, Hong Qin ^b, Huanmin Wang ^{b,e}, Jun Feng ^{b,*}, Wei Yang ^{b,*}, Xiaoman Wang ^{a,*}

^a Department of Ultrasound, Beijing Children's Hospital, Capital Medical University, National Center for Children's Health, Beijing 100045, China

^b Department of Surgical Oncology, Beijing Children's Hospital, Capital Medical University, National Center for Children's Health, Beijing 100045, China

^c Department of Pathology, Beijing Children's Hospital, Capital Medical University, National Center for Children's Health, Beijing 100045, China

^d Department of Radiology, Beijing Children's Hospital, Capital Medical University, National Center for Children's Health, Beijing 100045, China

^e Key Laboratory of Major Diseases in Children, Ministry of Education, Beijing Pediatric Research Institute, Beijing Children's Hospital, Capital Medical University, National Center for Children's Health, Beijing 100045, China

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ABSTRACT

Objective: To evaluate the safety and efficacy of ultrasound (US)-guided percutaneous needle biopsy combined with FAL tissue adhesive needle tract sealing in pediatric hypervascular malignant solid tumors.

Methods: A retrospective analysis was conducted on 149 pediatric patients with Adler grade ≥ 2 malignant solid tumors who underwent US-guided percutaneous needle biopsy between January 2021 and October 2025. Based on the application of FAL sealing, patients were divided into the FAL group ($n = 57$) and control group ($n = 92$). Using 1:1 propensity score matching (PSM) for baseline covariates (e.g., age, tumor size, Adler grade, biopsy needle size, and hematological metrics), we generated 39 matched pairs. The number of needle passes, postoperative changes in laboratory values, complication rates, and follow-up outcomes were compared between the two cohorts.

Results: Before matching, the FAL group presented with larger tumors, lower preoperative hemoglobin levels, a different pathological distribution, and imbalance in biopsy needle size than the control group. After PSM, baseline characteristics were balanced between the two groups. Patients in the FAL group more frequently underwent ≥ 4 needle passes than those in the control group [84.6% (33/39) vs. 60.5% (23/38), $P = 0.034$]. Furthermore, there were no significant differences in postoperative laboratory changes, complication rates, or diagnostic accuracy among surgically validated cases between the two groups. No FAL-related adverse events or needle tract seeding were observed during a median follow-up of 140 days in the matched FAL group.

Conclusion: In pediatric hypervascular malignant solid tumors, US-guided PNB combined with FAL tract sealing was associated with a higher number of biopsy passes without an observed increase in procedure-related complications, while diagnostic accuracy remained comparable. Further prospective multicenter and large-sample studies are needed for validation.

Level of evidence: Level III (Retrospective comparative study).

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* Corresponding authors.

E-mail addresses: 164376327@qq.com (C. Lv), ztwgh@hotmail.com (T. Zhang), 15210514388@163.com (C. Zhang), 13263371301@163.com (Q. Ren), wx19932008@sina.com (X. Wei), liwuhuasyd@163.com (W. Li), 416711593@qq.com (J. Xu), nmgysangshen@126.com (S. Yang), changsaishuo@163.com (S. Chang), chenghysunny@163.com (H. Cheng), yun_52@163.com (Z. Zhu), terracottawarrior@126.com (J. Han), drhuangyijin@163.com (Y. Huang), yinjie1015@126.com (J. Yin), qinhong999999@163.com (H. Qin), wanghuanmin@bch.com.cn (H. Wang), fengjun1900@163.com (J. Feng), yangwei@bch.com.cn (W. Yang), pcchty@yeah.net (X. Wang).

¹ Chuankai Lv and Tianwei Zhang are co-first authors and contributed equally to this work.

H I G H L I G H T S

- FAL tract sealing showed comparable safety in pediatric hypervascular malignant solid tumors after PSM.
- Postoperative laboratory changes were comparable between the FAL and control groups.
- FAL tract sealing was associated with more biopsy passes without an observed increase in complications.

1. Introduction

Pediatric malignant solid tumors are highly heterogeneous. Precise histopathological diagnosis and molecular subtyping (e.g., next-generation sequencing, NGS) serve as the cornerstone for formulating chemotherapy, surgical, and immunotherapeutic regimens [1–3]. Due to its minimal invasiveness, operational convenience, and real-time controllability, ultrasound (US)-guided percutaneous needle biopsy (PNB) has emerged as the preferred biopsy modality in pediatric clinical practice [2,4,5]. However, the unique physiological and anatomical characteristics of the pediatric population render PNB significantly riskier than in adults [4,6]. Children possess smaller organs and narrower anatomical spaces; furthermore, pediatric malignant solid tumors grow rapidly and are often massive and hypervascular at the time of detection, predisposing patients to severe post-biopsy complications such as hemorrhage and tumor rupture [4,6–8]. Additionally, disease-related consumption in some pediatric patients leads to baseline anemia or coagulopathy, which further amplifies the bleeding risk [9,10]. Consequently, conventional PNB techniques exhibit pronounced limitations in pediatric hypervascular malignant solid tumors. Due to the high risk of post-biopsy hemorrhage and tumor rupture, clinicians may opt for open surgical biopsies, which ensure definitive hemostasis but inflict greater surgical trauma. Alternatively, operators might deliberately limit the number of needle passes to mitigate bleeding risks [6], frequently resulting in inadequate specimen yields that necessitate repeat biopsies, thereby exacerbating the suffering of patients and increasing the healthcare burden. Therefore, there is an urgent clinical need to explore a needle tract sealing strategy tailored to the pediatric anatomical and physiological characteristics—one that balances safety, biopsy sampling, and operational convenience—to enhance the safety and diagnostic yield of PNB.

Needle tract sealing techniques, also referred to as tract sealing, tract embolization, or tract plugging in the interventional radiology literature, have been reported to reduce the risks of complications such as bleeding and pneumothorax in adult solid organ biopsies [1,11,12]. In this study, FAL [13,14] tract sealing refers to the injection of FAL tissue adhesive through the coaxial sheath during needle withdrawal to physically seal the biopsy tract. Currently, commonly used clinical sealing materials include Gelfoam, fibrin sealant, and N-butyl-2-cyanoacrylate (NBCA) [1,9,15–18]. However, these well-established adult protocols are difficult to directly extrapolate to the pediatric population. Compared with liquid adhesives, Gelfoam-based techniques may require additional preparation, such as cutting, crushing, or suspension, and delivery through slender coaxial systems may be less convenient in small pediatric patients [15,19–22]. Dual-component biological agents, such as fibrin sealants, provide favorable sealing efficacy but may require preparation and mixing before administration and carry potential biologic-product-related concerns, including allergic reactions [20]. NBCA possesses advantages such as high fluidity, rapid polymerization, and potent hemostatic efficacy, and is widely utilized in biopsies of hypervascular tumors in adults [17,18,23]. Nevertheless, the polymerization of NBCA is exothermic and may be associated with localized pain or irritation. In addition, the polymerized film formed by

NBCA on organ capsules or the peritoneum may be relatively rigid [13]. FAL tissue adhesive is composed of 80% N-octyl-cyanoacrylate (NOCA) and 20% N-butyl-cyanoacrylate (NBCA). NOCA features a lower heat of polymerization and superior flexibility of the polymerized film [13,24]. Meanwhile, its moderately prolonged curing time (2–6 s) facilitates clinical handling. Despite these advantages, the application of this mixed formulation in pediatric practice lacks systematic validation, particularly for high-risk hypervascular and massive malignant solid tumors.

We hypothesized that FAL tract sealing would help reduce biopsy-related complications, such as hemorrhage and tumor rupture, while providing more opportunities for tissue acquisition when clinically required in pediatric hypervascular malignant solid tumors. Therefore, this retrospective matched cohort study aimed to evaluate the safety and biopsy outcomes of US-guided percutaneous needle biopsy combined with FAL needle tract sealing in this high-risk pediatric population.

2. Materials and methods

2.1. Study design and participants

This was a single-center, retrospective cohort study. We consecutively screened pediatric patients who underwent ultrasound (US)-guided percutaneous needle biopsy (PNB) for solid tumors at the Department of Surgical Oncology, Beijing Children's Hospital, between January 2021 and October 2025. Patients were eligible if they underwent US-guided coaxial PNB, had postoperative histopathological confirmation of malignant solid tumors, had hypervascular tumors, defined in this study as tumors with increased vascularity corresponding to Adler grade ≥ 2 on color Doppler imaging [25], and had available baseline, procedural, and post-biopsy outcome data. Patients were excluded if they had benign tumors or non-solid lesions, Adler grade 0–1 tumors, underwent biopsy using approaches other than US-guided PNB, had less than 30 days of follow-up, or had missing key variables required for group allocation, propensity-score matching, or outcome assessment; patients with minor missing data that did not affect these analyses were retained. The primary outcomes were defined as hemorrhage, tumor rupture, and the number of needle passes. Hemorrhage and tumor rupture were assessed together with postoperative laboratory changes. The number of needle passes was analyzed as a procedural sampling variable. A higher number of needle passes may provide more opportunities for tissue acquisition, but sampling adequacy should be determined by histopathological assessment of the acquired specimens. Safety outcomes included allergic reaction, non-target embolization, adhesive-related extensive tissue adhesion, infection, and tumor rupture with hemorrhage. This retrospective study was approved by the Medical Ethics Committee of the Beijing Children's Hospital ([2026]-E-026-R).

2.2. Indications for FAL tract sealing

FAL tract sealing was introduced at our center in August 2024 as an adjunctive hemostatic strategy for hypervascular malignant solid tumors. Patients treated before August 2024 underwent

standard US-guided coaxial PNB without tract sealing and served as historical controls. After August 2024, FAL tract sealing was applied to all patients with moderate-to-rich tumor vascularity on color Doppler imaging, defined as Adler grade ≥ 2 . No alternative tract-sealing or tract-embolization materials were routinely used during the study period. Patients were assigned to the FAL group or control group according to whether FAL tract sealing was performed.

2.3. Instruments and materials

All US guidance and evaluations were performed using a DIT-DD70 color Doppler US diagnostic system (DIT, Wuhan, China). Depending on the patient's body habitus and lesion depth, target lesions were comprehensively evaluated using two-dimensional grayscale and color Doppler flow imaging (CDFI) with a 3.5–5.0 MHz convex array transducer, or a 5–12 MHz (L12-5) or 3–7 MHz (L7-3) linear array transducer. Biopsy procedures were performed using a coaxial core biopsy system (Bard®, C.R. Bard, Inc., USA). Needle size was recorded according to the gauge of the core biopsy needle: 16G and 18G core biopsy needles were used through corresponding 15G and 17G coaxial introducer sheaths/cannulas, respectively. For patients in the FAL group, FAL medical tissue adhesive (FuAiLe, Beijing, China) was utilized for needle tract sealing. This composite formulation consists of 80% N-octyl-cyanoacrylate (NOCA) and 20% N-butyl-cyanoacrylate (NBCA) [13,14]. Detailed product information and cost information for FAL are provided in the Supplementary Material.

2.4. Procedures

To reduce operator-related variability, all procedures were performed by physicians from the same specialized team, each possessing over 5 years of experience in US-guided biopsy.

Anesthesia and needle selection: Local infiltration anesthesia or general anesthesia was administered on an individualized basis, factoring in the patient's age, compliance, and tumor location. Following satisfactory anesthesia, percutaneous needle biopsy (PNB) was executed using a coaxial biopsy needle [22]. For cases expected to require additional tissue for histopathological evaluation or molecular testing, a 16-gauge (16G) large-core needle was prioritized. For high-risk cases, an 18G core biopsy needle with a smaller outer diameter was selected to minimize iatrogenic tract injury. The instruments utilized are illustrated in Figures 1A and B.

US-guided targeted sampling: The entire procedure was conducted under real-time US guidance with dynamic monitoring of the needle tip position (Fig. 1C). The needle trajectory was adjusted according to the macroscopic quality of the acquired specimens, and a multi-angle, multi-depth, and multi-planar approach was employed to obtain adequate tumor tissue specimens.

Tract flushing and sealing: After sampling, the outer sheath of the coaxial needle was retained within the tumor, and the inner stylet was removed. A three-way multidirectional stopcock was connected, and sealing was performed as follows: (1) Isolation flushing: 1–2 mL of 5% glucose injection was infused through the stopcock to flush the outer sheath lumen, preventing premature polymerization and luminal occlusion caused by contact between the FAL adhesive and blood. (2) Precise sealing: 0.5–1 mL of FAL adhesive was drawn and injected through the outer sheath (ensuring 0.3–0.5 mL entered the tissue). Under real-time US monitoring (Fig. 1D), the needle was withdrawn slowly at a constant speed while the outflow of the hyperechoic adhesive was observed, allowing the FAL adhesive to be uniformly distributed along the needle tract from deep to superficial until the needle tip entirely exited the subcutaneous tissue. (3) Complete tract sealing and needle removal: The stopcock was disconnected, and the trace amount of FAL adhesive remaining in the outer sheath was allowed

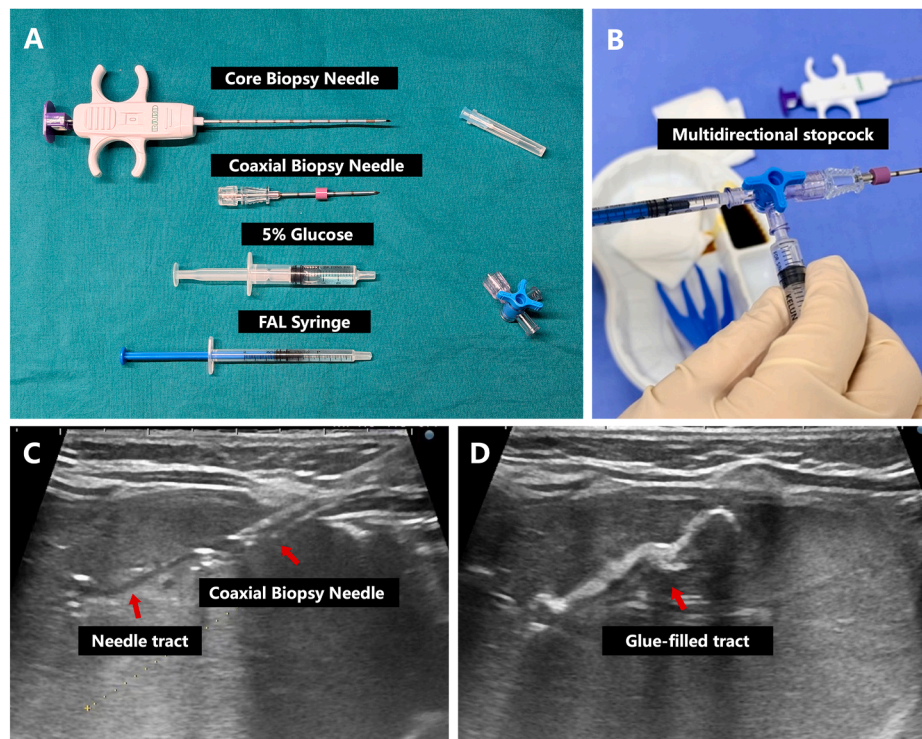


Fig. 1. Equipment and real-time ultrasound monitoring of FAL Tract Sealing biopsy in a hepatoblastoma patient. (A, B) Surgical instruments utilized for the FAL tract sealing procedure. (C) The residual cavity of the needle tract is visualized as a linear hypoechoic defect (arrow). (D) The FAL-filled tract is visualized as a linear hyperechoic strip (arrow).

to naturally infiltrate the capsule and subcutaneous tissue to achieve complete sealing of the entire biopsy tract. Finally, the coaxial outer sheath was slowly withdrawn.

Postoperative observation: Local compression was applied for hemostasis, and vital signs were monitored. Patients were observed for signs of active bleeding, such as abdominal pain or pallor. Postoperative US was performed to evaluate the needle tract and surrounding tissues for hematoma formation.

2.5. Data collection and definitions

Baseline data of all patients were collected, including age, sex, tumor type, tumor location, maximum tumor diameter, Adler grade, and preoperative laboratory parameters. The biopsy modality, number of needle passes, postoperative complications, and outcomes were recorded. Definition of Adler grade [25]: Tumor internal blood flow signals were evaluated using color Doppler flow imaging (CDFI). The specific grading criteria were as follows: Grade 0, no obvious flow signal; Grade I, 1 or 2 small vessels with a diameter <1 mm detected; Grade II, 3 or 4 small vessels detected; Grade III, >4 vessels detected, or vessels interwoven into a network. The Adler grading was assessed collaboratively by an Ultrasound physician and a clinician; in case of discrepancy, a consensus was reached through discussion. Postoperative evaluation: Bleeding and coagulation changes were objectively evaluated by calculating the differences between laboratory results within 72 h postoperatively and preoperative baseline values (e.g., $\Delta\text{Hb} = \text{Pre Hb} - \text{Post Hb}$). Diagnostic accuracy was assessed only in patients who subsequently underwent surgical pathological validation. A biopsy diagnosis was considered correct when it was concordant with the final surgical pathological diagnosis; patients without surgical pathological validation were not included in the denominator. Complication assessment: Postoperative complications included allergic reaction, non-target embolization, adhesive-related extensive tissue adhesion along the biopsy tract, infection, and tumor rupture with hemorrhage. Adhesive-related extensive tissue adhesion referred to clinically significant broad adhesion involving adjacent tissues, identified on follow-up imaging or during subsequent surgery. Non-target embolization referred to unintended deposition of FAL adhesive outside the biopsy tract, including adjacent vessels, bile ducts, or bronchi.

2.6. Statistical analysis

Statistical analyses were performed using SPSS version 31.0 (IBM Corp., Armonk, NY, USA) and Python version 3.12 (Python Software Foundation, Wilmington, DE, USA). Continuous variables in this study exhibited a non-normal distribution and were expressed as medians (interquartile ranges, IQRs). Intergroup comparisons were conducted using the Mann–Whitney U test (asymptotic method without continuity correction). Categorical data were expressed as percentages [% (n/N)], and intergroup differences were evaluated using the Pearson χ^2 test; the Fisher exact test was applied when more than 20% of the cells had an expected frequency of less than 5. For subgroup analyses involving multiple comparisons, P-values were adjusted using the post hoc Bonferroni correction. To minimize selection bias, propensity score matching (PSM) was utilized to balance baseline characteristics between the two groups. Covariates incorporated into the matching model included potential confounders and prognostic indicators: age, sex, tumor size, Adler grade, tumor location, pathological diagnosis, biopsy needle size, preoperative hemoglobin, platelet count, fibrinogen, and activated partial thromboplastin time. The number of needle passes was considered a biopsy-related outcome and was therefore excluded from matching. Covariate balance was assessed using standardized

mean differences (SMDs), with SMDs <0.2 considered acceptable. The matching algorithm employed a 1:1 nearest-neighbor matching method without replacement, with a caliper width set to 0.2 times the standard deviation of the logit of the propensity score. In the PSM-matched cohort, an exploratory ROC analysis was performed to identify the biopsy-pass cutoff that best distinguished the FAL and control groups using the maximum Youden index (Supplementary Fig. S1). All statistical tests were two-sided, and a P-value <0.05 was considered statistically significant.

3. Results

A total of 149 pediatric patients with Adler grade ≥ 2 malignant solid tumors who underwent US-guided percutaneous needle biopsy were ultimately included in this study, comprising 92 patients in the control group and 57 patients in the FAL group. The demographic characteristics, tumor-related parameters, biopsy needle size and preoperative laboratory results of the two groups are summarized in Table 1 (Before PSM). Biopsy sites were categorized according to the anatomical region of the main target lesion, including abdominal, limb/superficial soft-tissue, pelvic, thoracic, and head-and-neck sites. Abdominal lesions were the most common, accounting for 76.5% (114/149), including retroperitoneal lesions (n = 62), liver lesions (n = 31), renal lesions (n = 6), adrenal lesions (n = 6), mesenteric/omental lesions (n = 7), and pancreatic lesions (n = 2). Limb/superficial soft-tissue lesions accounted for 8.7% (13/149), including extremity intramuscular soft-tissue lesions (n = 10) and superficial gluteal/truncal lesions (n = 3). Pelvic lesions also accounted for 8.7% (13/149), including pelvic masses (n = 11) and bladder lesions (n = 2). Thoracic lesions accounted for 2.7% (4/149), including mediastinal lesions (n = 2), pulmonary/intrathoracic lesions (n = 1), and chest-wall lesion (n = 1). Head-and-neck lesions accounted for 3.4% (5/149), including cervical lesions (n = 3) and scalp/postauricular lesions (n = 2). Significant differences were observed between the two groups in maximum tumor diameter, preoperative hemoglobin level, and pathological diagnosis, and imbalance in Adler grade and biopsy needle size was observed based on SMD, as shown in Table 1. To control for intergroup confounding biases, 1:1 propensity score matching (PSM) was employed. Among patients with complete data for the matching covariates, the matching procedure generated 39 matched pairs. In the matched cohort (n = 78), all baseline covariates achieved acceptable balance, with all SMDs below 0.2 (Table 1, After PSM). Table 2 presents the clinical outcomes before and after PSM. Before PSM, the distribution of the number of needle passes was significantly higher in the FAL group than in the control group and the proportion of patients undergoing ≥ 4 needle passes was significantly higher in the FAL group ($P < 0.001$). After PSM, the distribution of the number of needle passes was significantly higher in the FAL group than in the control group [4 (IQR, 4–5; range, 3–7) vs. 4 (IQR, 3–4; range, 3–6), $P = 0.008$]. Regarding postoperative coagulation profiles and various laboratory parameters, no statistically significant differences were observed between the two groups. Among patients who underwent subsequent surgical pathological validation, diagnostic accuracy did not differ significantly between the two cohorts either before PSM [97.7% (42/43) vs. 86.4% (19/22), $P = 0.109$] or after PSM [100.0% (18/18) vs. 85.7% (12/14), $P = 0.183$], although it remained numerically higher in the control group than in the FAL group.

In terms of safety, postoperative complications did not differ significantly between the two groups before PSM [1.8% (1/57) vs. 0.0% (0/92), $P = 0.383$] and after PSM [2.6% (1/39) vs. 0.0% (0/39), $P = 1.000$]. One severe event occurred in the overall eligible cohort: a patient with pediatric hepatocellular carcinoma in the FAL group, who developed tumor rupture and hemorrhage 50 h

Table 1

Demographics and baseline characteristics of the 149 patients in the study cohort before and after propensity score matching (PSM).

Parameters	Before PSM				After PSM			
	Control group (n = 92)	FAL group (n = 57)	P-value ^a	SMD	Control group (n = 39)	FAL group (n = 39)	P-value ^a	SMD
Age (months)	48.50 (21.00, 79.50)	52.00 (22.00, 106.00)	0.983	0.027	51.00 (26.50, 77.00)	42.00 (23.50, 109.00)	0.576	0.048
Gender			0.901				0.818	
Male	55.4% (51/92)	57.9% (33/57)		0.050	56.4% (22/39)	61.5% (24/39)		0.104
Female	44.6% (41/92)	42.1% (24/57)		0.050	43.6% (17/39)	38.5% (15/39)		0.104
Tumor size (cm)	9.40 (7.47, 11.70)	10.60 (8.20, 13.50)	0.041	0.328	10.20 (7.85, 13.35)	10.30 (7.80, 12.30)	0.799	0.051
Adler grade			0.051				1.000	
Grade 2 (moderate vascularity)	31.5% (29/92)	15.8% (9/57)		0.377	15.4% (6/39)	17.9% (7/39)		0.069
Grade 3 (rich vascularity)	68.5% (63/92)	84.2% (48/57)		0.377	84.6% (33/39)	82.1% (32/39)		0.069
Needle size ^b			0.059				1.000	
16G	43.2% (32/74)	61.4% (35/57)		0.370	56.4% (22/39)	56.4% (22/39)		0.000
18G	56.8% (42/74)	38.6% (22/57)		0.370	43.6% (17/39)	43.6% (17/39)		0.000
Tumor position ^c			0.600				0.950	
Abdomen	72.8% (67/92)	82.5% (47/57)	1.000	0.233	76.9% (30/39)	79.5% (31/39)	1.000	0.062
Extremities and other sites	14.1% (13/92)	8.8% (5/57)	1.000	0.169	7.7% (3/39)	7.7% (3/39)	1.000	0.000
Thorax	3.3% (3/92)	1.8% (1/57)	1.000	0.096	5.1% (2/39)	2.6% (1/39)	1.000	0.134
Pelvis	9.8% (9/92)	7.0% (4/57)	1.000	0.100	10.3% (4/39)	10.3% (4/39)	1.000	0.000
Pathology ^c			0.005				0.869	
NB	53.3% (49/92)	36.8% (21/57)	0.298	0.335	46.2% (18/39)	43.6% (17/39)	1.000	0.052
STS	28.3% (26/92)	19.3% (11/57)	1.000	0.212	20.5% (8/39)	25.6% (10/39)	1.000	0.122
Liver tumor	9.8% (9/92)	31.6% (18/57)	0.007	0.559	17.9% (7/39)	20.5% (8/39)	1.000	0.065
Others ^d	8.7% (8/92)	12.3% (7/57)	1.000	0.117	15.4% (6/39)	10.3% (4/39)	1.000	0.154
Preoperative labs								
Hb (g/L)	119.00 (104.25, 131.00)	108.00 (95.00, 123.00)	0.010	0.316	112.00 (96.00, 127.00)	110.00 (96.00, 122.50)	0.776	0.032
PLT (× 10 ⁹ /L)	324.50 (282.25, 399.75)	341.00 (280.00, 476.00)	0.489	0.134	353.00 (277.00, 455.50)	329.00 (278.00, 425.50)	0.845	0.001
FIB (g/L)	2.79 (2.28, 3.59)	2.89 (2.02, 4.03)	0.903	0.053	3.25 (2.38, 4.15)	2.91 (2.11, 3.92)	0.427	0.167
APTT (s)	34.20 (31.80, 36.65)	34.10 (31.20, 38.90)	0.866	0.111	34.20 (32.35, 37.20)	34.50 (31.40, 38.95)	0.834	0.025

PSM, propensity-score matching; SMD, standardized mean difference; NB, neuroblastoma; STS, soft tissue sarcoma; Liver tumor, hepatic malignant tumors; Hb, hemoglobin; PLT, platelet count; FIB, fibrinogen; APTT, activated partial thromboplastin time.

^a Differences between groups were analyzed using the Mann–Whitney U test for continuous variables and Pearson's χ^2 test or Fisher's exact test for categorical variables, as appropriate.

^b Variables with missing data are reported using the available denominator shown in each cell.

^c Main-row P-values represent overall group comparisons, whereas subcategory P-values are Bonferroni-adjusted post hoc P-values.

^d Others included Wilms tumor, yolk sac tumor, inflammatory myofibroblastic tumor, pancreatic solid pseudopapillary neoplasm, malignant peripheral nerve sheath tumor, mucinous adenocarcinoma, renal cell carcinoma, pancreatoblastoma, gastrointestinal stromal tumor, and pulmonary blastoma.

Table 2

Outcomes of the 149 patients in the study cohort before and after propensity score matching (PSM).

Parameters	Before PSM			After PSM		
	Control group (n = 92)	FAL group (n = 57)	P-value ^a	Control group (n = 39)	FAL group (n = 39)	P-value ^a
Number of biopsy passes ^{b,c}	4 (3, 4)	4 (4, 5)	<0.001	4 (3, 4)	4 (4, 5)	0.008
<4 passes	47.7% (42/88)	15.8% (9/57)	<0.001	39.5% (15/38)	15.4% (6/39)	0.034
≥4 passes	52.3% (46/88)	84.2% (48/57)		60.5% (23/38)	84.6% (33/39)	
Postoperative complication ^d	0.0% (0/92)	1.8% (1/57)	0.383	0.0% (0/39)	2.6% (1/39)	1.000
Changes in laboratory values (Δ) ^e						
Δ Hb (g/L)	8.00 (3.00, 15.00)	5.50 (−2.00, 12.50)	0.164	10.50 (4.75, 16.25)	6.50 (−1.00, 12.50)	0.149
Δ PLT (× 10 ⁹ /L)	11.00 (−44.00, 57.00)	27.00 (−40.50, 62.75)	0.515	29.00 (4.25, 55.50)	30.00 (−35.75, 61.25)	0.885
Δ APTT (s)	0.50 (−1.25, 4.85)	4.15 (0.30, 7.90)	0.085	3.10 (−0.10, 4.85)	4.50 (0.92, 7.58)	0.268
Δ FIB (g/L)	0.27 (−0.05, 0.91)	0.10 (−0.53, 0.51)	0.119	0.59 (0.12, 1.16)	0.17 (−0.42, 0.57)	0.068
Diagnostic accuracy ^f	97.7% (42/43)	86.4% (19/22)	0.109	100.0% (18/18)	85.7% (12/14)	0.183

^a P-values were calculated using the Mann–Whitney U test for continuous variables and Pearson's χ^2 test or Fisher's exact test for categorical variables, as appropriate.

^b Variables with missing data are reported using the available denominator shown in each cell. Biopsy-pass data were available for 88 of 92 control patients before PSM and 38 of 39 control patients after PSM; all FAL patients had available biopsy-pass data.

^c The cutoff value for the number of biopsy passes was determined by exploratory ROC analysis. Biopsy-pass number was further categorized as <4 and ≥ 4 passes according to this cutoff (Supplementary Fig. S1).

^d Postoperative complications included allergic reaction, non-target embolization, extensive tissue adhesion, infection, and tumor rupture with hemorrhage.

^e Changes in laboratory values (Δ) were calculated as the preoperative value minus the postoperative value.

^f Diagnostic accuracy was calculated only among patients with subsequent surgical pathological validation.

postoperatively. Emergency US and intraoperative exploration confirmed that the polymerized film formed by the FAL sealing at the biopsy tract in the right hepatic lobe remained completely intact (Figures 2A and B). The hemorrhage resulted from spontaneous rupture of the left hepatic tumor, independent of the biopsy or tract sealing. Unfortunately, the patient succumbed to

disseminated intravascular coagulation (DIC) driven by massive hemorrhage. No FAL-related allergic reaction, non-target embolization, adhesive-related extensive tissue adhesion, infection, or needle tract seeding was observed.

After PSM, local anesthesia was used in 89.7% (35/39) of control patients and 59.0% (23/39) of FAL patients, whereas general

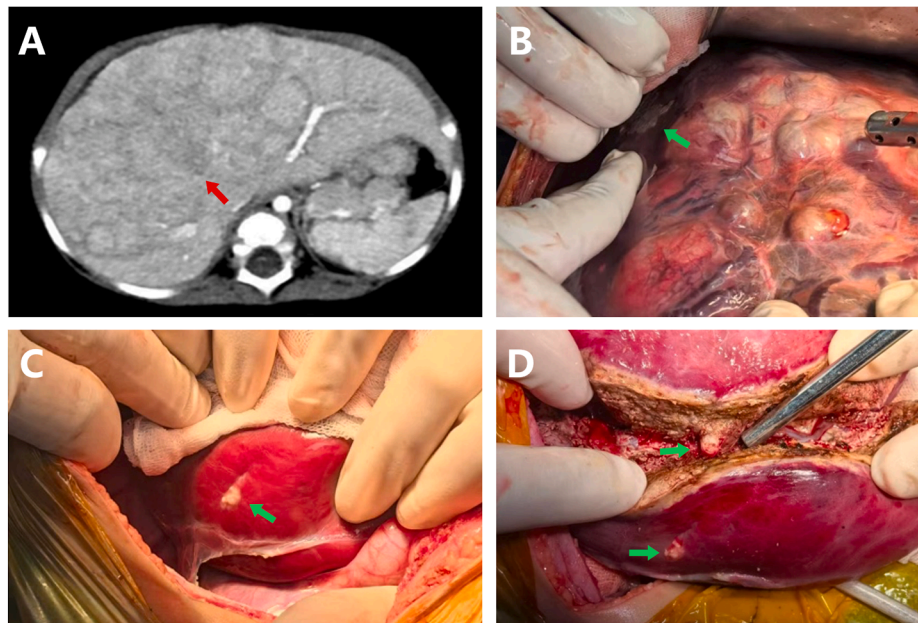


Fig. 2. Radiological and intraoperative images of the FAL sealing effect. (A) Preoperative computed tomography (CT) scan of a patient with hepatocellular carcinoma (HCC). (B) Intraoperative view of the intact FAL sealing structure at the biopsy site. (C) Intraoperative visualization of the sealed surface in a patient with hepatoblastoma (HB). (D) Cross-section showing the solidified adhesive within the needle tract (upper arrow) and the sealed tract entry point on the liver capsule (lower arrow).

anesthesia was used in 10.3% (4/39) and 41.0% (16/39), respectively ($P = 0.004$). Regarding postoperative tolerance, a retrospective review of medical records revealed no instances of severe pain necessitating an escalation in analgesic therapy. During clinical observation, a few patients occasionally experienced mild, transient abdominal pain; however, these episodes were self-limiting, could be alleviated by routine oral analgesics or observation alone, and did not prolong the hospital stay.

In the PSM-matched cohort, the median follow-up time was 916 days (804, 1492), with a range of 516–1622 days in the control group, and 140 days (96, 256), with a range of 30–439 days in the FAL group. During the follow-up period, continuous monitoring via imaging modalities such as US, CT, or MRI revealed no evidence of needle tract tumor seeding in any of the cases.

4. Discussion

Through a retrospective cohort analysis combined with propensity score matching (PSM), this study provides a pediatric validation study regarding the safety and biopsy outcomes of ultrasound (US)-guided percutaneous needle biopsy (PNB) combined with the FAL needle tract sealing technique in a relatively large cohort of pediatric patients with malignant solid tumors with increased vascularity. Previous studies on tract sealing have predominantly focused on adult solid organs [1,9,11,12,15,16,18], while sealing strategies tailored to pediatric malignant solid tumors with increased vascularity remain under-investigated [21]. Our findings help fill this void in pediatric oncology. After PSM, the results showed that the FAL group underwent more biopsy passes than the control group, while postoperative laboratory changes, complication rates, and diagnostic accuracy among surgically validated cases remained comparable between the two groups. As a preliminary finding, FAL tract sealing may provide additional hemostatic protection during multiple biopsy passes, and the higher number of biopsy passes in the FAL group should be interpreted as a procedural finding that may provide more opportunities for tissue acquisition when clinically required. The unique anatomical and physiological characteristics of pediatric

solid tumors impose stringent demands on the selection of biopsy instruments and sealing materials. In addition to the routine 16-gauge (16G) core biopsy needle, this study utilized a thinner 18G core biopsy needle for high-risk cases to minimize the extent of tissue injury. Because biopsy needle size may influence bleeding risk, it was included as an additional covariate in the revised PSM model. Therefore, we interpreted safety outcomes cautiously and stated that the potential influence of needle size should be considered when interpreting the results. We also noted that future prospective studies with standardized needle-selection protocols are needed. Moreover, previous studies have reported that the coaxial core biopsy system itself may reduce biopsy-related bleeding risk [26]. Thus, the observed safety profile should be interpreted in the context of both the coaxial biopsy technique and FAL tract sealing.

An ideal sealing material for pediatric biopsy should be convenient to deliver through a coaxial system and should allow controlled tract sealing under imaging guidance. Unlike Gelfoam-based tract plugging techniques, which may require preparation before delivery, or biological sealants that require preparation and mixing, FAL is a liquid tissue adhesive that can be injected through the coaxial sheath and visualized in real time as a hyperechoic tract under US monitoring. The FAL tissue adhesive utilized in this study has a moderately longer curing time (2–6 s) compared to conventional NBCA [13,14]. Combined with flushing the outer sheath lumen with 5% glucose injection, this helped reduce premature polymerization and luminal occlusion caused by early contact between the FAL adhesive and blood [18]. Real-time US-monitored injection of FAL may facilitate controlled physical sealing along the biopsy tract, supporting the clinical imperatives of procedural simplicity and delivery efficiency. In addition, tract cauterization using microwave ablation, which requires access to microwave ablation equipment, has recently been reported as another strategy for biopsy tract sealing in pediatric intra-abdominal tumors, further highlighting the clinical interest in pediatric tract-sealing approaches [27].

Benefiting from the reliable sealing strategy described above, this study achieved a higher number of biopsy passes in the FAL group without an observed increase in hemorrhage or tumor

rupture. In the modern diagnostic and therapeutic system for pediatric malignant solid tumors, acquiring adequate and high-quality tumor tissue is a core prerequisite for performing next-generation sequencing (NGS), formulating targeted and immunotherapeutic regimens, and evaluating prognosis [1,3]. However, previous studies have indicated that an increased number of needle passes is an independent risk factor for postoperative hemorrhage [8,28]. Therefore, under conventional biopsy modalities, operators may limit the number of needle passes when confronted with tumors with increased vascularity or large tumor size due to concerns over bleeding risks [6]. Based on the propensity-score-matched data, the FAL group underwent more biopsy passes than the control group. This finding suggests that FAL tract sealing may support more opportunities for tissue acquisition when additional biopsy passes are clinically needed. Furthermore, this increased number of biopsy passes did not lead to increased blood loss, and real-time intraoperative US monitoring showed that Doppler flow signals within the needle tract decreased or disappeared after the injection of FAL in selected cases. The clinical benefits of the tract sealing technique lie not only in simple hemostasis but also in supporting tissue acquisition when multiple biopsy passes are required. However, diagnostic accuracy among surgically validated cases remained comparable between groups; therefore, the increased number of biopsy passes should be interpreted as greater procedural sampling intensity rather than evidence of histopathological sampling adequacy or superior diagnostic accuracy.

In the current matched cohort, diagnostic accuracy was numerically higher in the control group than in the FAL group. Diagnostic accuracy was assessed only in patients who subsequently underwent surgical pathological validation. Because the FAL implementation period was limited, the FAL group had a shorter follow-up period and fewer opportunities to obtain subsequent surgical pathological validation. In contrast, the historical control group had a longer follow-up period and more surgically validated cases. Future prospective studies with longer follow-up are needed to further evaluate diagnostic accuracy.

While supporting more extensive biopsy sampling, the FAL sealing technique also showed a comparable safety profile in the matched cohort. Although one delayed tumor rupture with hemorrhage occurred in the FAL group after PSM, the FAL-sealed biopsy tract remained intact, and no rupture occurred at the biopsy site. No adverse events directly attributed to FAL sealing were recorded. Although the NOCA component of FAL may reduce concerns related to heat generation and film rigidity compared with NBCA alone, liquid tissue adhesives theoretically still carry risks such as localized pain or irritation, non-target embolization, and inflammatory tissue reactions. These risks require strict control during pediatric biopsy procedures [18,29]. In this study, FAL was injected under real-time US monitoring, with the dosage strictly controlled at 0.3–0.5 mL according to the diameter and depth of the needle tract and the operator's intra-procedural assessment. Because FAL was not mixed with radiopaque material, intravascular permeation could not be assessed fluoroscopically. Therefore, monitoring in this study mainly relied on real-time ultrasound. After entering the tissue, FAL reacts rapidly within approximately 1–2 s and appears as a hyperechoic adhesive tract on ultrasound, which allows it to be distinguished from surrounding tissues and vessels. No clinical or imaging evidence of non-target embolization involving blood vessels, bile ducts, or bronchi was observed in this study. In our cohort, FAL-related local inflammation or aggravated pain was not observed as a clinically significant complication. A small fraction of patients experienced transient abdominal pain within 24 h postoperatively, which may have been related to mild peritoneal irritation along the needle tract. Such symptoms were

self-limiting, could be alleviated by routine oral analgesics or observation alone, and did not prolong the hospital stay. Therefore, careful control of the injection dosage and speed under real-time US monitoring remains important to minimize unnecessary peritoneal stimulation.

We retrospectively analyzed the only case of delayed tumor rupture and hemorrhage in the full cohort to elucidate its underlying mechanism. The patient's preoperative imaging (Fig. 2A) revealed multiple intrahepatic metastases, and the patient underwent percutaneous hepatic artery embolization concurrently with the liver tumor biopsy under general anesthesia. Intraoperative exploration confirmed that the polymerized FAL film at the right hepatic puncture site remained structurally intact (Fig. 2B) with no signs of bleeding. The active hemorrhage was in the left lateral hepatic lobe, originating from a spontaneous tumor rupture. Further analysis suggested that embolization of the right hepatic artery may have led to redistribution of arterial blood flow, potentially causing increased perfusion pressure within the left hepatic tumor. Coupled with the extremely friable texture of this massive tumor, such hemodynamic fluctuations may have contributed to the delayed rupture of the left hepatic tumor, which was considered unlikely to be directly related to the biopsy or the needle tract sealing procedure.

Finally, direct intraoperative visualization during a subsequent tumor resection in one patient provided additional visual evidence of the in vivo distribution. The puncture site on the right liver was clearly visible, and the polymerized film adhered well to the liver capsule (Fig. 2C). During the dissection of the tumor from the normal hepatic parenchyma, the solidified adhesive could be clearly observed distributed along the needle tract (Fig. 2D), suggesting the continuous physical sealing from the deep tumor to the liver surface. These anatomical findings were consistent with the clinical observations and support the feasibility of FAL tract sealing in selected pediatric biopsy cases.

There are several limitations to the present study. First, FAL tract sealing was introduced at our center in August 2024; therefore, temporal bias related to the historical-control design cannot be fully avoided. In addition, as a National Center for Children's Health, our hospital may receive a relatively high proportion of large or hypervascular tumor cases. To reduce bias related to differences in tumor vascularity, we excluded Adler grade 0–1 tumors in the revised analysis; however, because this remains a single-center cohort, further prospective multicenter studies are still needed to validate these findings. Second, although tumor location, pathological diagnosis, and biopsy needle size were included in the PSM model, the sample size was limited, and analyses could only be performed according to broad anatomical and pathological categories rather than detailed pathological subtypes. This issue should be addressed in future prospective studies with larger sample sizes. Third, although all procedures were performed by physicians from the same specialized team with more than 5 years of experience, FAL use and procedural strategy may still have been influenced by operator judgment and experience. In future work, we hope to further validate these findings through enhanced training, establishment of SOP, regular experience review, and prospective multicenter studies.

5. Conclusion

In pediatric hypervascular malignant solid tumors, US-guided PNB combined with FAL tract sealing was associated with a higher number of biopsy passes without an observed increase in procedure-related complications, while diagnostic accuracy remained comparable. Further prospective multicenter and large-sample studies are needed for validation.

Ethical approval and consent to participate

The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. This retrospective study was approved by the Medical Ethics Committee of the Beijing Children's Hospital ([2026]-E-026-R).

Consent for publication

Not applicable.

Availability of data and materials

The datasets generated during and/or analyzed during the current study are available from the corresponding author on reasonable request.

Declaration of generative AI and AI-assisted technologies in the writing process

During the preparation of this manuscript, the authors used AI-assisted language tools only for language translation, English editing, and grammar correction. All scientific content, data analysis, interpretation of results, and conclusions were independently generated and verified by the authors. The authors reviewed all AI-assisted language edits and take full responsibility for the final manuscript.

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Conflicts of interest

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at <https://doi.org/10.1016/j.jpedsurg.2026.163326>.

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