

Transcatheter Arterial Embolization with N-butyl-2 Cyanoacrylate Glubrans 2 for the Treatment of Acute Renal Hemorrhage Under Coagulopathic Condition

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Abstract

Background: The efficacy and safety of transcatheter arterial embolization (TAE) using the N-butyl-2 cyanoacrylate (NBCA) Glubran2 in the treatment of acute renal hemorrhage (RH) under coagulopathic conditions are still no consensus.

Methods: Between February 2014 and June 2019, 8 patients underwent TAE with the NBCA Glubran2 for acute RH under coagulopathic conditions. Coagulopathy was defined as abnormal values of prothrombin time and activated partial thromboplastin time and/or a reduced platelet count. Angiograms and medical records were retrospectively reviewed to determine technical/clinical success, complications and recurrent hemorrhage after TAE, and follow-up outcomes were assessed.

Results: Of note, one patient presented with severe coagulopathy, and three presented with severe RH and hemodynamic instability. The NBCA Glubran2 was employed as a sole embolic material in six patients. In the remaining two patients, it was employed for secondary embolization. Under coagulopathic conditions, due to the use of the NBCA Glubran2, both technical success and clinical success for acute RH were achieved in all patients. During a mean follow-up time of 30.1 months (range, 3-84 months), neither persistent nor recurrent active hemorrhage required repeat endovascular or surgical treatment for hemostasis. No Glubran2-related complications occurred mid-TAE procedure. In addition, renal function information was available for all patients, and there was no significant difference between the serum creatinine levels [(83.8 ± 15.5) vs (85.8 ± 32.2) µmol/L] before and one week after Glubran2 embolization ($p=0.89$; CI, -34.5 to 30.5).

Conclusions: The present findings suggest that TAE with the NBCA Glubran2 may be a safe alternative treatment for the management of RH under coagulopathic conditions. In particular, this method appears to be a potentially attractive alternative when conventional embolic materials fail in patients with ongoing hemodynamic instability or even under severe coagulopathic conditions.

Introduction

Renal hemorrhage (RH) is a relatively common condition, and the etiology varies and is usually attributed to traumatic, iatrogenic, spontaneous or protopathic causes.¹ RH commonly has an acute presentation, and various modalities of treatment have been used.^{1,2} In general, the goal of treatment is to cease hemorrhage, stabilize vital signs and preserve as much renal function as possible. Traditionally, the initial treatment of RH has involved conservative fluid resuscitation and blood transfusion, followed by surgery when the condition is intractable.¹ Gradually, with advances in studies, trans-catheter arterial embolization (TAE) has been widely accepted, with the advantages of minimal invasiveness and a high success rate, as one of the most effective treatment options for acute RH.³⁻⁵

In clinical settings, acute RH patients sometimes present with a coagulopathic condition, and a worse outcome has been proven in these patients than in those without coagulopathy.⁶ MacLeod et al.⁷

commented that coagulopathy is an independent predictor of mortality even in the presence of other risk factors. The potential causes of coagulopathy could be a direct effect of acute massive RH, an associated effect of injury severity, the use of anticoagulants/antiplatelet drugs, and so on.⁶ The aim of many embolic materials, including gelatin sponge particles, polyvinyl alcohols, and micro-coils, is to induce thrombus formation; therefore, the efficacy of these materials depends mainly on the coagulation status of patients.⁸ TAE with the use of these conventional embolic materials under coagulopathic conditions often fails to achieve hemostasis, and hemorrhage may recur after embolism.⁶ However, there is still no consensus on which embolic material is superior for RH under this condition.

Liquid embolic materials such as N-butyl-2 cyanoacrylate (NBCA) have gained efficacy for achieving hemostasis in the treatment of acute arterial hemorrhage in various organs.^{6, 9-12} In particular, NBCA appears to have the considerable advantage of acting independently of underlying coagulopathy, making it a potential alternative in RH.¹³ Nevertheless, TAE for acute RH under coagulopathic conditions with NBCA is rarely described in the literature, and consensus on the efficacy and safety of NBCA under this condition has not been reached. The purpose of the present study is to evaluate the outcome of TAE with the NBCA Glubran 2 for controlling acute RH under coagulopathic conditions in the clinical setting.

Materials And Methods

Study Population

This retrospective study was approved by both our institutional review board and by the written consent of patients. In this clinical setting, abnormal values of prothrombin time (PT) and activated partial thromboplastin time (APTT) and/or a reduced platelet count ($< 50 \times 10^9/L$) were defined as a coagulopathic condition. Under this condition, all institutional registers of consecutive patients who experienced acute RH and subsequently underwent TAE with the NBCA Glubran 2 as the primary embolic material between February 2014 and June 2019 were included. In addition, patients who received both another embolic material and the NBCA Glubran 2 during the same procedure were also included. All patients were confirmed to have renal active hemorrhage via CT before treatment, identifying the number and location of bleeding arteries, and to determine, if possible, the underlying cause of acute RH.

N-butyl Cyanoacrylate Embolization Procedure

The embolization material employed in the present study was Glubran 2® (N-butyl-2 cyanoacrylate; Braun, Melun, France), a modified NBCA. The benefits and potential risks of TAE with Glubran 2 were explained to the patients and/or their relatives, and detailed informed consent was obtained from all patients.

To identify and localize the bleeding site, under local anesthesia, an accurate over-view angiogram was initially performed using a 5-French selective Simon catheter (Radifocus Angiographic Catheter; Terumo, Leuven, Belgium) through a 5-French introducer (Radifocus Introducer II Introducer Sheath; Terumo,

Leuven, Belgium) into the right femoral artery. Following the identification of the bleeding site, a compatible 2.4-French microcatheter (Progreat; Terumo, Leuven, Belgium) was then coaxially positioned, ensuring that the microcatheter tip was as close as possible to the target bleeding site. The dead space of the microcatheter was initially loaded with a 5% dextrose solution to prevent the early polymerization of Glubran 2 into the lumen of the microcatheter. To improve presentation, Glubran 2 was thoroughly mixed with eth-iodized oil (Ethiodized Poppyseed Oil injection; Hengrui Medicine, Jiangsu, China) (concentration ratio ranged from 1:2 – 1:7, depending on the distance from the micro-catheter tip to the bleeding site and arterial flow speed). Under fluoroscopy control, the mixture was injected as slowly as possible using thumb pressure and was adjusted according to Glubran 2 propagation in the bleeding artery and target arterial flow speed. Glubran 2 injection was continued until the bleeding artery was completely occluded to ensure that undesired embolization of normal arterial branches was avoided, reducing infarcted renal parenchyma loss as much as possible. At the end of Glubran 2 embolization, the microcatheter was removed rapidly, and a final renal angiogram through the 5-French Simon catheter was performed to obtain vessel occlusion. One week after treatment, renal function was retested and compared with the function before embolization.

Definitions of efficacy, safety and Follow-up

The efficacy of TAE with Glubran 2 included both technical and clinical evaluations.¹⁴ Technical success was defined as the complete occlusion of target bleeding vessels on the final renal angiogram. Clinical success was defined as the absence of rehemorrhage needed for repeat endovascular treatment or surgery after Glubran 2 embolization. The safety of TAE with Glubran 2 was evaluated, including complications that occurred mid-TAE, especially clinical or technical adverse events mid-Glubran 2 injection and after, and renal function was assessed via serum creatinine levels after one week. During the follow-up, CT and/or color Doppler ultrasound and clinical evaluations were performed on an outpatient basis for all patients on the 1st, 3rd, and 6th months and at 6-month intervals thereafter or sooner when clinically indicated. Any instances of recurrent bleeding or post-TAE complications were recorded.

Statistical Analyses

The *SPSS* statistical software package (version 23.0; *SPSS* statistical software, Chicago, Illinois, USA) was used for all statistical analyses in this study. Continuous variables were expressed as the means±standard deviation. Qualitative variables were presented as a percentage. When assessing the correlation between preprocedural and postprocedural variables, a paired *t* test was used. Findings with a *P* value less than 0.05 were deemed statistically significant.

Results

Demographics and Coagulopathic Conditions

During the study period, TAE with the NBCA Glubran 2 was employed in 8 consecutive acute RH patients under coagulopathic conditions with a total of 8 hemorrhaged vessels. The mean patient age was 53.5 ± 14.6 years, and 5 male patients (62.5%) were included. All patients presented with back muscle aches and active renal hemorrhage on CT before treatment. Of the included patients, one presented with traumatic acute RH, three presented with iatrogenic acute RH, and four presented with spontaneous RH resulting from renal arterial aneurysm rupture, vascular malformation or angiomyolipoma. Under this setting of coagulopathic conditions, the mean PT, APTT, platelet counts and INR values were 18.5 ± 3.4 s, 47.5 ± 22.1 s, $(48.4 \pm 8.9) \times 10^9/L$, and 1.88 ± 0.44 , respectively. Three patients with vein thrombosis were under the influence of anticoagulants around the time of RH. One patient (No. 4) who presented with severe coagulopathy had underlying heparin-induced thrombocytopenia. Three patients had coagulopathy associated with liver cirrhosis: one with superimposed hypersplenism and two with cancer. Among the 8 patients, three presented with severe RH and hemodynamic instability, and the mean patient hemoglobin level was 61 ± 7 g/L.

Procedure of NBCA Glubran 2 embolization and Efficacy

In six patients, Glubran 2 was employed as the sole embolic material (Fig. 1). In the remaining two patients, Glubran 2 was added during the same procedure for persistent hemorrhage after TAE with microcoils in one patient, and secondary embolization was achieved in another patient as a rescue procedure for rehemorrhage two days after initial TAE with gelatin sponge particles and polyvinyl alcohols. The mean volume of Glubran 2 injected was 1.36 ± 0.43 mL (range, 0.8-2.0 mL); in two patients, less than 1.0 mL was used, and the mean treatment time was 15.3 ± 4.0 min (range, 9–21 min). Technical success of TAE with Glubran 2 for acute RH was achieved in all patients. Final renal angiograms revealed complete occlusion of all targeted bleeding vessels. The clinical success rate of Glubran 2 embolization for acute RH was 100%. During a mean follow-up time of 30.1 months (range, 3–84 months), neither persistent nor recurrent active hemorrhage requiring repeat endovascular or surgical treatment to achieve hemostasis after TAE with Glubran 2 was observed in our series. Of the two patients who received Glubran 2 as a second-line rescue embolic material, there was also no recurrent hemorrhage after embolization. One patient died during the follow-up 3 months after embolization as a result of primary disease deterioration (hepatic failure due to hepato-cellular carcinoma).

Safety of Glubran 2 embolization

No Glubran 2 related complications occurred mid-TAE procedure. Two patients experienced aggravation of their back muscle aches, which were spontaneously relieved within half a month without any specific treatment. One patient with severe coagulopathy developed subarachnoid hemorrhage, was treated conservatively and recovered without permanent sequelae. Renal function information was available for all patients, and the mean serum creatinine levels before and one week after Glubran 2 embolization were 83.8 ± 15.5 $\mu\text{mol/L}$ and 85.8 ± 32.2 $\mu\text{mol/L}$, respectively. There was no significant difference between the serum creatinine levels before and one week after Glubran 2 embolization ($p = 0.89$; CI, -34.5 to 30.5).

Unfortunately, only two patients underwent renal glomerular filtration rate examination; thus, it was difficult to evaluate this measurement before and after Glubran 2 embolization.

Discussion

The outcomes of TAE with NBCA for acute arterial bleeding (only one RH patient was included) and postpartum hemorrhage under coagulopathic conditions have been described previously.^{6, 12} The efficacy of TAE with the NBCA Glubran 2 has been evaluated mainly in acute RH caused by trauma and arteriovenous malformation^{6,9,15-17}; however, patients with RH under coagulopathic conditions have rarely been reported in the literature. This might partly be due to the ambiguity of defining “coagulopathic condition” in this setting. Yemenites T et al.⁶ defined abnormal values of platelet count ($< 5 \times 10^4/\mu\text{L}$ and/or INR < 1.5) as a condition of coagulopathy because these values require correction by the infusion of platelets or fresh frozen plasma. Moreover, Kane-matsu M et al.¹⁸ determined the condition of coagulopathy in patients with postpartum hemorrhage with a disseminated intravascular coagulation scoring system. PT and APTT are considered predictive factors in initial coagulopathy profile-related mortality.^{7,19} In the present study, the selection criteria for coagulopathic conditions mainly depended on the indicators of PT, INR, APTT and platelet count, and eight patients with coagulopathy and acute RH who suffered from anticoagulant drugs or liver cirrhosis were included.

Under coagulopathic conditions, it has been reported that the achievement of hemostasis with absorbable gelatin sponge particles is not satisfactory, and this condition is frequently associated with the mechanism of poorly enhanced hemostatic capacity and prohibited thrombus formation.^{6,8,13,20} TAE with microcoils is more feasible and effective than with gelatin sponge particles, especially in terms of hemostasis and the prevention of recurrent hemorrhage in patients under coagulopathic conditions.⁶ However, in two of the eight patients in the present study, adequate hemostasis was not achieved after TAE with gelatin sponge particles, polyvinyl alcohols or microcoils; then, the patients were successfully treated with repeat complement Glubran 2 embolization, which was similar to the treatment for arterial bleeding reported by Yemenites T et al.^{6,21} This rescue success was mainly attributed to the physicochemical property of Glubran 2, which works independently of its hemostatic capacity. Polymerization can occur immediately upon contact with blood, leading to instant and complete vessel occlusion. This material appears to be an appropriate and promising alternative for coagulopathy when complete hemostasis is difficult to achieve with gelatin sponge particles, polyvinyl alcohols and/or microcoils.

The NBCA Glubran 2 is commonly mixed with lipiodol at concentration ratios from 1:1 to 1:10^{6, 11}, depending on the distance from the microcatheter tip to the bleeding site as well as the arterial flow speed. Dilution of Glubran 2 prolongs the polymerization time and thereby enables the mixture to travel a greater distance. It has been noted that NBCA provides quick, stable thrombus and that the treatment time for TAE with NBCA is significantly shorter than that for TAE with gelatin sponge particles and/or microcoils, even in severe coagulopathy.^{13,18} Interestingly, one patient in our study with severe

coagulopathy was successfully treated; the concentration ratio was 1:2, and the treatment time was 14 min; the concentration ratio used was higher and the treatment time was similar to those used for mild coagulopathy. Therefore, employing Glubran 2 may have great potential as a primary alternative tool in the presence of RH with severe coagulopathy; in particular, conventional materials inevitably require prolonged time periods and patients with ongoing extravasation. Further studies are needed to confirm this conclusion, and considerable experience is required to achieve optimal results with Glubran 2, particularly in coagulopathy.

The results of this study further enhance the suggestions demonstrating that NBCA is a potent embolic material under various conditions. In the present study of patients with acute RH in the setting of coagulopathic conditions, both technical and clinical success were achieved in all patients; it seemed that Glubran 2 was effective in terms of ceasing acute RH, even under the condition of coagulopathy. Alina et al.²² commented that patients under coagulopathic conditions after TAE were more likely to experience recurrent hemorrhage than patients without these conditions in gastro-intestinal hemorrhage. Regarding the hemostasis of RH, no recurrence was observed in patients after TAE with Glubran 2, and the use of NBCA in the setting of coagulopathy seemed to contribute to a reduction in the rescue of recurrent hemorrhage. In terms of the safety of TAE with Glubran 2 for RH, no complications occurred mid-TAE procedure related to embolization. Two patients experienced aggravation of their back muscle aches after TAE, but they spontaneously resolved within one month without any specific treatment. One patient with severe coagulopathy developed subarachnoid hemorrhage, which was caused by severe coagulation disorder, was treated conservatively and recovered without permanent sequelae. Preserving renal function is a crucial factor in renal embolization. In the current study, renal function was not affected, achieving the aim of preserving as much renal function as possible. Therefore, we consider that TAE with Glubran 2 does not add to the risk of complications for patients with RH under coagulopathic conditions.

The present study has a number of limitations. First, TAE with Glubran 2 for acute RH under coagulopathic conditions has the common limitations of NBCA^{8,15-18}, including microcatheter lumen instant occlusion, difficulty controlling precisely occluded sites, and NBCA/lipiodol mixture composition, which seems to require a long learning curve and is restricted to the knowledge and experience of clinicians with NBCA. Second, our cohort was relatively small and retrospective, and with all its inherent limitations, a multi-institutional prospective study may be required to determine the indications for coagulopathic conditions and the medical costs of TAE with Glubran 2. Third, the aim of the present study mainly focused on evaluating the preliminary outcomes of TAE with Glubran 2 for RH under coagulopathic conditions. No comparison was conducted between Glubran 2 and conventional embolic materials or between coagulopathic and non-coagulopathic conditions, which may need to be shown subsequently. Nevertheless, to the best of our knowledge, the present study may be by far the sole study and the largest case series regarding TAE with the use of Glubran 2 as the embolic material for RH under coagulopathic conditions.

Conclusions

Coagulopathic conditions and the necessity of treatment for acute RH make TAE with the NBCA Glubran 2 a reasonable, safe and effective therapeutic technique. In particular, this technique appears to be a potentially attractive alternative when conventional embolic materials fail, in patients with ongoing hemodynamic instability, or even under severe coagulopathic conditions. Further studies are warranted to confirm the findings.

Declarations

Ethical approval

The study protocol was reviewed and approved by the institutional review board (IRB) of the Nanjing First Hospital, Nanjing Medical University (Nanjing, China)(approval no.: NJFH-2013-110). In addition, the study was performed in accordance with the Declaration of Helsinki and the Ethical Guidelines for Clinical Studies.

Consent for publication

Not applicable.

Data available statement

The datasets generated and analyzed during the current study are not publicly available as the experimental data are related to other experiments that are progressing, but are available from the corresponding author on reasonable request.

Competing interests

The authors of this manuscript declare no relationships with any companies whose products or services may be related to the subject matter of the article. The content of the manuscript is original, and it has not been published or accepted for publication.

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Authors' contributions

MFG contributed to data collection, manuscript writing/editing. XH and BXZ contributed to project development, data collection, data analysis. JK contributed to project development, data collection, data analysis, manuscript editing. TW contributed data analysis. JPG contributed to project development. HBS contributed to project development.

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Figures

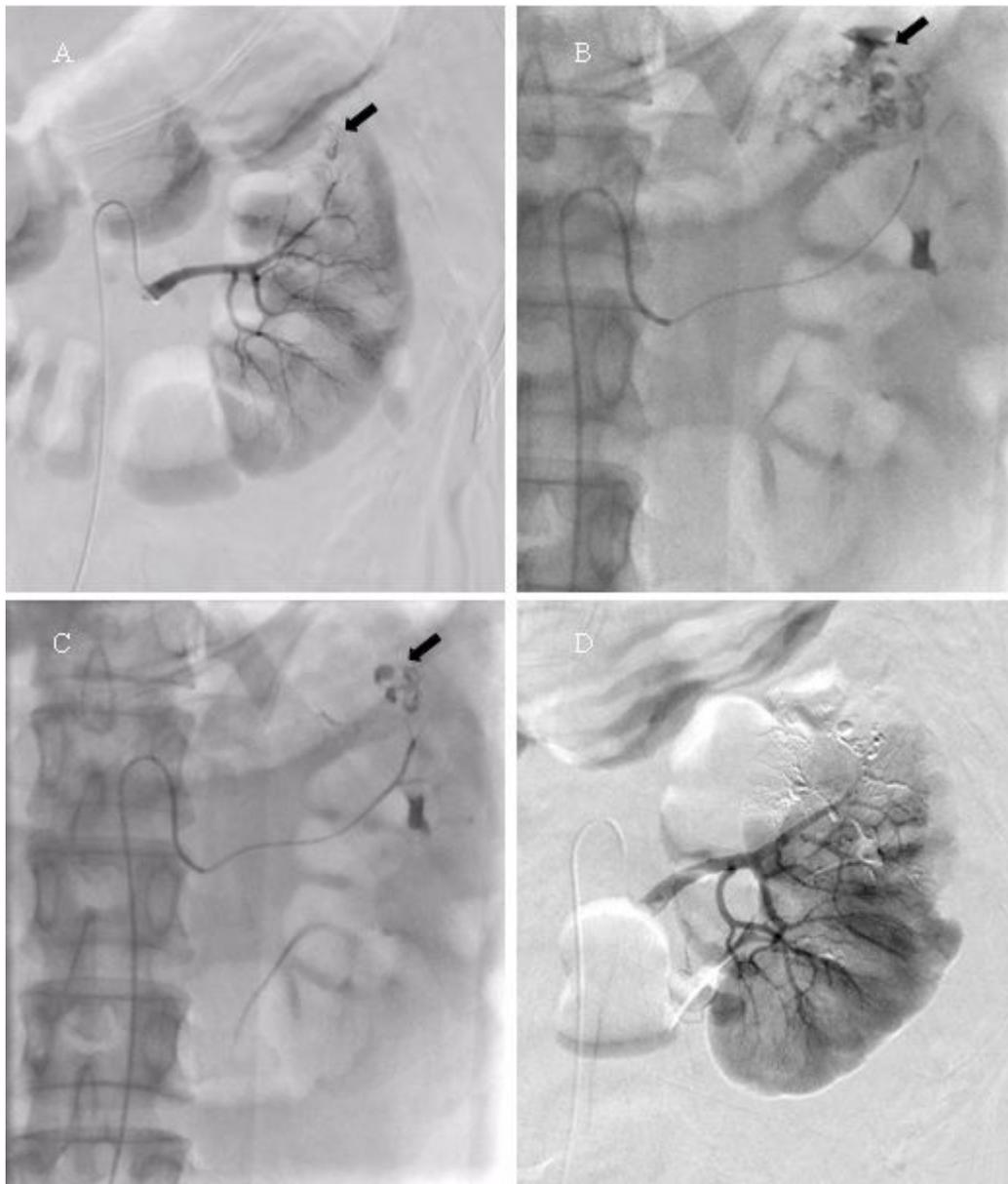


Figure 1

Images from a 37-year-old female with renal hemorrhage due to angiomyolipoma (AML) rupture during anticoagulant treatment who underwent transcatheter arterial embolization (TAE) using the N-butyl-2 cyanoacrylate (NBCA) Glubran2. A) The left renal overview angiogram was initially performed using a Simon catheter, revealing a dysplastic and aneurysmal vessel (black arrow). B) Thumb pressure angiogram through the tip of the microcatheter, which was as close as possible to the target bleeding site, demonstrating rupture of the renal parenchyma and spillage of the contrast agent (black arrow). C) Mixture of Glubran2 and ethiodized oil (concentration ratio 1:7) was injected as slowly as possible into the bleeding target arterial, cast filling dysplastic and aneurysmal arteries (black arrow). D) Completion angiogram after TAE with the NBCA Glubran2 demonstrating AML devascularization and maximum preservation of the normal renal parenchyma.

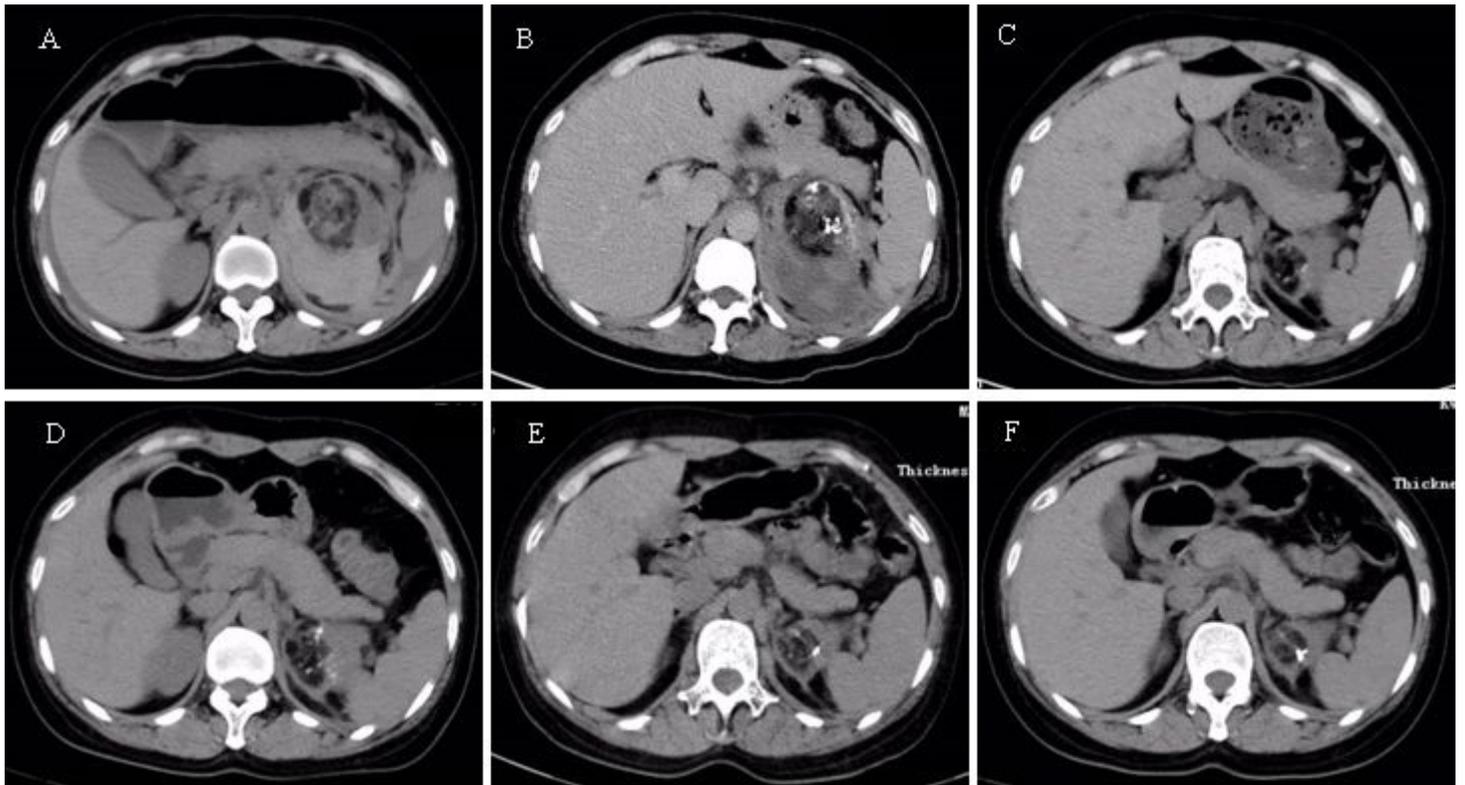


Figure 2

Axial CT findings before and after transcatheter arterial embolization (TAE) using the N-butyl-2 cyanoacrylate (NBCA) Glubran2 (the same patient as in figure1.). A) Axial CT image obtained before TAE with the NBCA Glubran2. An inhomogeneous endophytic renal mass with low-attenuating areas of intratumoral fat and high-attenuating hemorrhagic areas around the kidney. B) Nonenhanced CT control images were obtained one week after TAE. A strong cast of the NBCA Glubran2 was observed. C & D & E & F) CT at the 3-, 6-, 9-, and 12-month follow-ups. A stable cast of the NBCA Glubran2 was demonstrated, and a significant reduction in AML size was depicted.