

Randomized clinical trial of splenic radiofrequency ablation *versus* splenectomy for severe hypersplenism

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Background: Radiofrequency ablation (RFA) is a relatively new treatment for hypersplenism. The results of a randomized clinical trial comparing RFA and splenectomy with 5 years of follow-up are reported.

Methods: Fifty-seven patients with hypersplenism due to liver cirrhosis were assigned randomly (in a 1 : 2 ratio) to splenectomy (19 patients) or RFA (38). The RFA group was subdivided according to the percentage of the spleen ablated: less than 50 per cent (9 patients), 50–70 per cent (18) or over 70 per cent (11). Routine blood tests were performed before and after operation, and total spleen volume and ablated volume were measured by contrast-enhanced computed tomography. The primary endpoint of the trial was recurrence of hypersplenism, assessed as platelet and white cell counts, at 5 years after surgery.

Results: White cell and platelet counts increased rapidly after intervention in both groups. By 36 months after operation peripheral platelet and white cell counts had decreased significantly in the RFA group compared with the splenectomy group, and declined to baseline levels by 48 months. Hypersplenism recurred after 6 months in patients with less than 50 per cent of the spleen ablated. Blood cell count in the splenectomy group and in patients with more than 50 per cent of the spleen ablated decreased with time after operation, but to levels that remained significantly higher than those before operation ($P < 0.050$). Spleen volume reached its nadir 12 months after RFA and then increased with time.

Conclusion: Splenic RFA represents an attractive alternative treatment for hypersplenism induced by liver cirrhosis, particularly when more than 50 per cent of the spleen is ablated.

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Introduction

Hypersplenism is a commonly associated with portal hypertension induced by liver cirrhosis. Portal hypertension is an important cause of splenomegaly and hypersplenism^{1,2}. There are many methods for treating hypersplenism secondary to portal hypertension, such as splenectomy coupled with devascularization, portosystemic shunt procedures and splenic artery embolization^{3–5}. For most patients such operations are effective in preventing haemorrhage from oesophageal varices and in correcting thrombocytopenia. However, these procedures have high morbidity and mortality rates^{6,7}. Safer and less invasive surgical approaches for the management hypersplenism and portal hypertension are still being developed.

The safety and effectiveness of splenic radiofrequency ablation (RFA) have been demonstrated in experimental studies⁸, and it has become another option for the

treatment of hypersplenism. Splenic RFA has been shown to have beneficial short-term effects in patients with hypersplenism^{9,10}. However, robust evidence of its efficacy and safety compared with the standard approach of splenectomy for hypersplenism is still lacking, and its long-term effectiveness remains to be proven.

The present article reports the results of a randomized clinical trial conducted to evaluate the safety and efficacy of splenic RFA *versus* splenectomy for severe hypersplenism with 5 years of follow-up.

Methods

Patients with severe hypersplenism were registered in this single-institution randomized clinical trial between March 2003 and July 2004. Patients were randomly assigned (in a 1 : 2 ratio) to undergo either splenectomy

or splenic RFA. Randomization was by the envelope method, using numbers generated by a computerized random number generator. Adult patients were eligible for inclusion if they had severe hypersplenism, defined as splenomegaly, leucopenia (leucocyte count below $3.0 \times 10^9/l$) or thrombocytopenia (platelet count less than $50 \times 10^9/l$), and portal hypertension and hypersplenism secondary to liver cirrhosis. Bone marrow biopsies taken from all patients indicated that the proliferation of nucleated cells in bone marrow was active, consistent with the diagnostic criteria for hypersplenism.

The study protocol conformed to requirements outlined by the Helsinki Declaration, and was approved by the ethics committee of Southwest Hospital, affiliated to the Third Military Medical University. All patients provided informed consent before the operation.

The diagnosis of liver cirrhosis and portal hypertension was based on clinical evaluation and biochemical and imaging examinations, including oesophageal barium swallow, oesophagogastrosocopy, ultrasonography and upper abdominal enhanced computed tomography (CT)¹¹. Liver biopsy was performed in some patients to verify the clinical diagnosis.

Radiofrequency ablation

Patients who had a normal prothrombin time and simple hypersplenism, and no history or serious risk of oesophageal variceal bleeding, underwent percutaneous RFA. Vital signs were closely monitored for evidence of intra-abdominal haemorrhage. Laparoscopic RFA was carried out in patients who had an abnormal prothrombin time (over 20 s). Patients with a history of bleeding and/or severe oesophageal varices (verified by oesophageal barium swallow or gastroscopy) had an open splenic RFA procedure before portosystemic devascularization, portosystemic shunt or combined surgery.

An LDRF-50CA RFA system (Lead Electron Corporation, Mianyang, China) was used in all patients. Before operation, contrast-enhanced CT was performed, and an automated volumetric system¹² (Volume Calculating Software, Somatom Plus 4; Siemens Medical Systems, Munich, Germany) was used to measure splenic volume. Before surgery, the number and position of RFA needles were determined according to the shape and volume of the spleen. At most, three needles were used simultaneously. To avoid thermal injury to surrounding organs and decrease postoperative complications (particularly left pleural effusion), the middle and lower parts of the spleen were selected for ablation. In patients who underwent open RFA, the splenic artery was occluded to reduce the ablation

time. RFA needles were inserted under ultrasound guidance perpendicularly 3–5 cm into the spleen, away from the capsule and hilar vessels. Power was set initially at 50 W, increased by 10 W every 2 min to a maximum of 95 W, and then maintained until the impedance reached a maximum value. Energy deposition was terminated automatically, completing the ablation cycle. The electrodes were withdrawn by 1–2 cm for the next session. Because steam produced in this procedure interfered with observation, the needles were placed in different positions in the spleen. After treatment, electrode needles were withdrawn slowly with the radiofrequency generator set at 95 W to cauterize the needle route and decrease postoperative bleeding. Antibiotic prophylaxis was administered for 3–5 days after the procedure.

Postoperative monitoring

Peripheral platelet and white blood cell counts were determined before, and 1, 3, 5, 7 and 10 days after the procedure, 1, 3, 6 and 12 months later, and every 6 months thereafter. The portal system was checked routinely for portal vein thrombosis using Doppler ultrasonography at various times after surgery. Follow-up was continued until 31 July 2009.

Splenic volumes were measured by contrast-enhanced CT before and 1, 3, 6 and 12 months after the intervention, and once every 6 months thereafter as described previously¹². The percentage ablation volume was determined as ablation volume/total spleen volume. To assess the correlation between ablated volume and therapeutic effect, patients in the RFA group were subdivided according to the extent of spleen ablation: less than 50, 50–70 or more than 70 per cent.

Statistical analysis

The primary endpoint of the trial was recurrence of hypersplenism assessed as the number of white blood cells and platelets at 5 years after surgery. Using Pass 2002 (NCSS, Kaysville, Utah, USA) statistical software to calculate the sample size, the α error was set at 0.05, and the power at $1 - \beta = 0.90$. The sample distribution ratio was $R = 2$. Based on an assumed difference of 20 per cent in white blood cell count between the two groups 5 years after splenectomy, a total of 48 patients was deemed necessary: 16 in the splenectomy group and 32 in the splenic RFA group.

Data were expressed as mean(s.d.), unless indicated otherwise. Student's *t* test, one-way ANOVA, χ^2 analysis and linear regression analysis were used for statistical analysis, as appropriate. $P < 0.050$ was considered statistically significant. Statistical analysis was performed using

SPSS® version 13.0 statistical software (SPSS, Chicago, Illinois, USA).

Results

Of 116 patients with severe hypersplenism assessed for the study, 32 (27.6 per cent) were ineligible and another 27 (23.3 per cent) did not accept the randomization (*Fig. 1*). Fifty-seven patients fulfilled the eligibility criteria and were randomized. Fifty-one of these patients had posthepatic

cirrhosis (41 positive for hepatitis B surface antigen, 6 positive for hepatitis C antibody, 3 positive for both hepatitis B surface antigen and hepatitis C antibody, and 1 super-infected with hepatitis B and D virus), four had alcoholic liver cirrhosis and two had biliary cirrhosis. To verify the clinical diagnosis, liver biopsy was performed in 26 patients. The mean follow-up time was 65 (range 49–76) months. Nineteen patients were randomized to undergo splenectomy and 38 to splenic RFA. There were no differences in clinical indices between the two groups (*Table 1*).

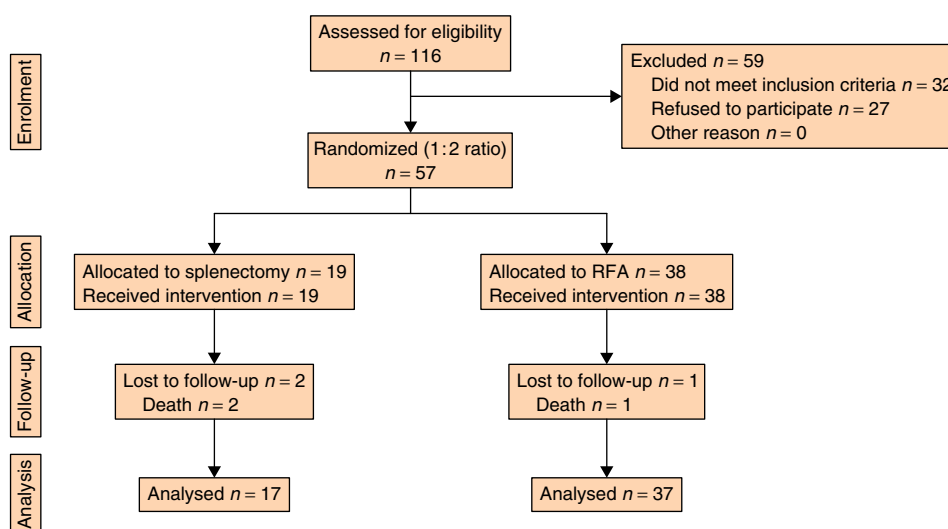


Fig. 1 CONSORT diagram for the study. RFA, radiofrequency ablation

Table 1 Clinical indices of treatment groups

	Splenectomy (n = 19)	Radiofrequency ablation (n = 38)	P*
Age (years)			
Mean(s.d.)	46(10)	45(8)	0.735†
Median (range)	48 (18–57)	46 (30–58)	
Sex ratio (M : F)	14 : 5	23 : 15	0.326
Child–Pugh–Turcotte classification			0.853
A	7	12	
B	9	21	
C	3	5	
Leucocyte count ($\times 10^9/l$)			
Mean(s.d.)	2.2(0.3)	2.3(0.4)	0.275†
Median (range)	2.2 (1.7–2.7)	2.4 (1.6–3.1)	
Platelet count ($\times 10^9/l$)			
Mean(s.d.)	34.0(8.9)	33.1(6.7)	0.631†
Median (range)	33.9 (19.7–50.2)	33.6 (21.7–47.2)	
History of bleeding oesophageal varices	4	12	0.404
Splenomegaly grade			0.655
Mild	2	6	
Moderate	12	27	
Severe	5	5	

* χ^2 test, except †Student's *t* test.

Operative procedures

In the splenectomy group, four patients had splenectomy alone for simple hypersplenism. Fifteen patients in addition underwent portosystemic shunt (4), portosystemic devascularization (7) or combined surgery (4) because of a history of bleeding and/or severe oesophageal varices.

In the RFA group, five patients underwent percutaneous RFA, 13 had a laparoscopic procedure and 20 underwent open splenic RFA before portosystemic devascularization (8), portosystemic shunt (5) or combined surgery (7). The amount of spleen ablated was less than 50 per cent in nine patients, 50–70 per cent in 18 and over 70 per cent in the remaining 11 patients.

Complications

In the splenectomy group there was one postoperative death from multiple organ failure. Another patient died from primary liver cancer 57 months after surgery. Other severe complications in this group included intra-abdominal haemorrhage and an abscess in the splenic recess, treated surgically.

In the RFA group, one patient died from upper gastrointestinal haemorrhage 49 months after operation. Two patients who underwent percutaneous RFA exhibited intra-abdominal haemorrhage and shock after the procedure; in one patient the bleeding was stopped during emergency laparoscopy and the other required splenectomy after an ineffective laparoscopic attempt to achieve haemostasis.

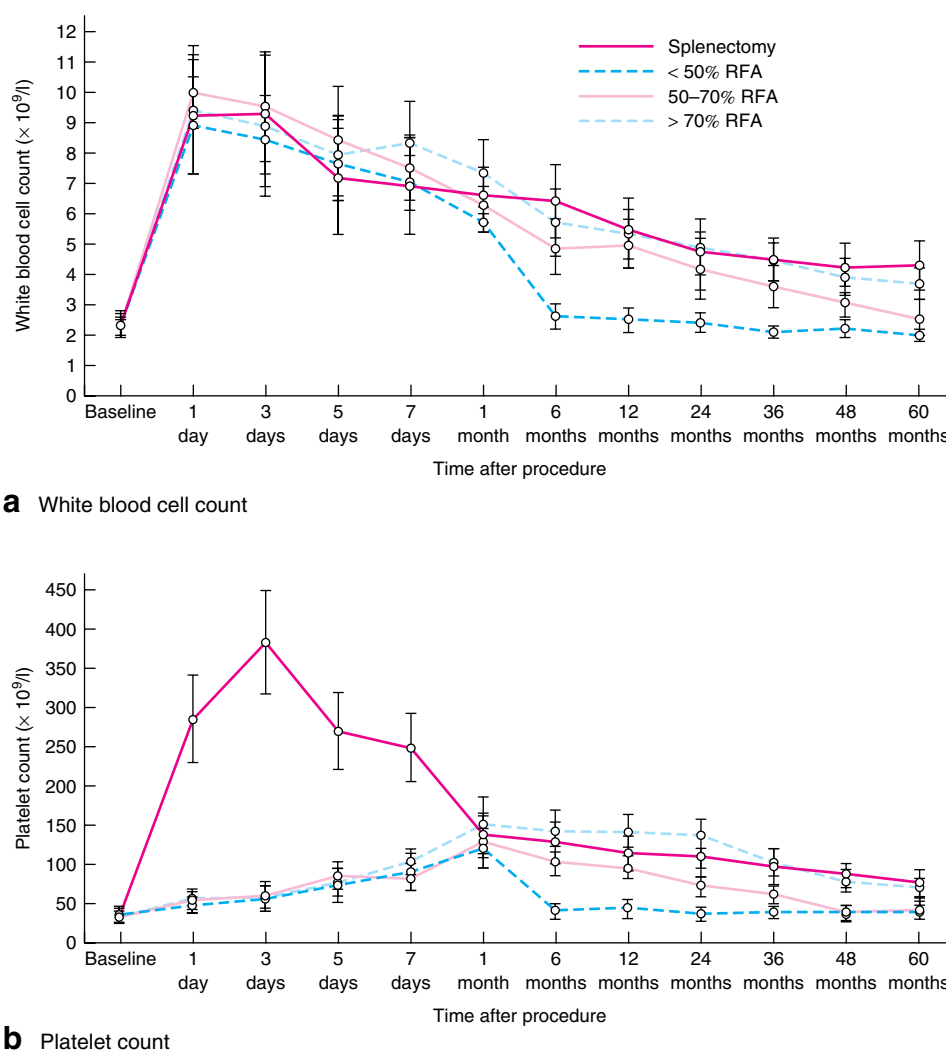


Fig. 2 Mean(s.d.) **a** white blood cell and **b** platelet counts after splenectomy or splenic radiofrequency ablation (RFA) in 57 patients with cirrhotic hypersplenism

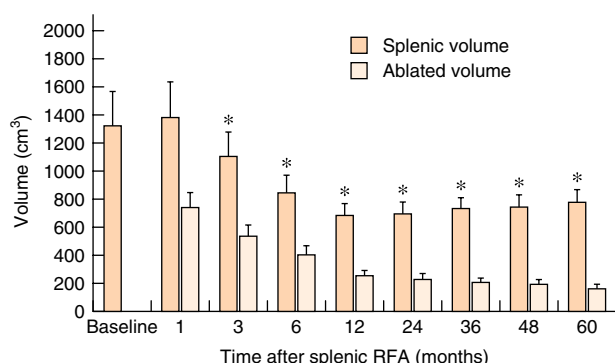


Fig. 3 Changes in **a** total splenic volume and **b** ablated volume after splenic radiofrequency ablation (RFA) in 38 patients. The volume ratio of ablated lesions to whole spleen decreased from 47.8 per cent 1 month after operation to 21.4 per cent at the end of follow-up. * $P < 0.050$ versus baseline (paired-samples t test)

There were no other major severe complications in this group. Most patients (22 of 38) reported mild left upper abdominal pain, which resolved within 5 days without special treatment. Nine patients had pleural effusion, usually following more than 50 per cent ablation; two required single thoracentesis. Half of the patients in the RFA group had intermittent mild fever (up to 38.5°C) for 5–21 days. White blood cell counts were normal or increased slightly during the period of fever, and temperature normalized rapidly after treatment with drugs or cooling. There was a positive correlation between the duration of fever and ablation volume ($r = 0.893$, $P < 0.001$). Seven patients in the splenectomy group developed portal vein thrombosis compared with one in the RFA group ($P = 0.002$).

Efficacy

Peripheral platelet and leucocyte counts increased rapidly shortly after RFA as well as after splenectomy. Leucocyte counts remained higher than baseline for the first 6 months. White cell counts in the RFA group were lower than those in the splenectomy group by 36 months after operation ($3.5(0.5)$ versus $4.5(0.7) \times 10^9/l$; $P = 0.008$), and decreased to baseline levels by 48 months ($2.6(0.4) \times 10^9/l$ versus $2.3(0.4) \times 10^9/l$ before operation; $P = 0.163$). As with leucocyte counts, platelet counts in the RFA group decreased gradually over time. Platelet counts in the RFA group were decreased significantly at 36 months compared with those in the splenectomy group ($67.8(13.1)$ versus $97.4(24.7) \times 10^9/l$; $P = 0.021$) and decreased to baseline levels by 48 months ($40.7(10.3) \times 10^9/l$ versus $33.1(6.7) \times 10^9/l$ before operation; $P = 0.073$).

The mean leucocyte count in all RFA subgroups increased rapidly after operation and reached levels higher than baseline within 6 months (Fig. 2). Leucocyte counts in the group with less than 50 per cent ablation of the spleen decreased to baseline level by 6 months after the operation ($P = 0.063$), indicating recurrent hypersplenism. White cell counts in the subgroups with more than 50 per cent splenic ablation decreased to below the normal level at 36 and 48 months after RFA respectively, but were still higher than preoperative counts (both $P < 0.001$). By 60 months after treatment, leucocyte counts in the group with more than 70 per cent splenic ablation were significantly lower than those in the splenectomy group ($P = 0.031$), but remained higher than baseline levels.

The change in platelet counts in splenectomized patients was different from that in the RFA groups (Fig. 2). The mean platelet count in the splenectomy group increased rapidly and peaked 3 days after surgery ($P < 0.001$). Differences between the splenectomy and RFA subgroups were significant at 3 days (all $P < 0.001$). Platelet counts in all three RFA subgroups increased slowly; by the end of the first week, levels were twice those seen before the procedure and similar to those in splenectomized patients at the end of the first month ($P = 0.167$). Platelet counts decreased to baseline by 6 months after surgery in patients with less than 50 per cent splenic ablation ($P = 0.065$) and by 48 months in those with 50–70 per cent ablation ($P = 0.178$). As with white cell counts, platelet counts in all groups decreased gradually over time, but by 5 years after operation were still almost twice as high as before surgery in splenectomized patients and those with greater than 70 per cent splenic ablation.

Ablation volume

Previous experimental studies showed that it was difficult to quantify the ablated area precisely immediately after RFA because of the 'bystander effect', caused by congestion and bleeding surrounding ablation lesions⁸. The best time to measure the ablated volume accurately was 4–6 weeks after RFA. Total splenic volume in the RFA group decreased by 3 months ($P < 0.001$) (Fig. 3), with a maximum reduction at 12 months after the procedure. After this the volume increased, but remained smaller than before RFA ($P < 0.050$). The ablation volume decreased gradually after RFA (Fig. 4), and the ratio of ablated tissue to entire splenic tissue decreased from 47.8 per cent 1 month after the operation to 21.4 per cent at the end of follow-up.

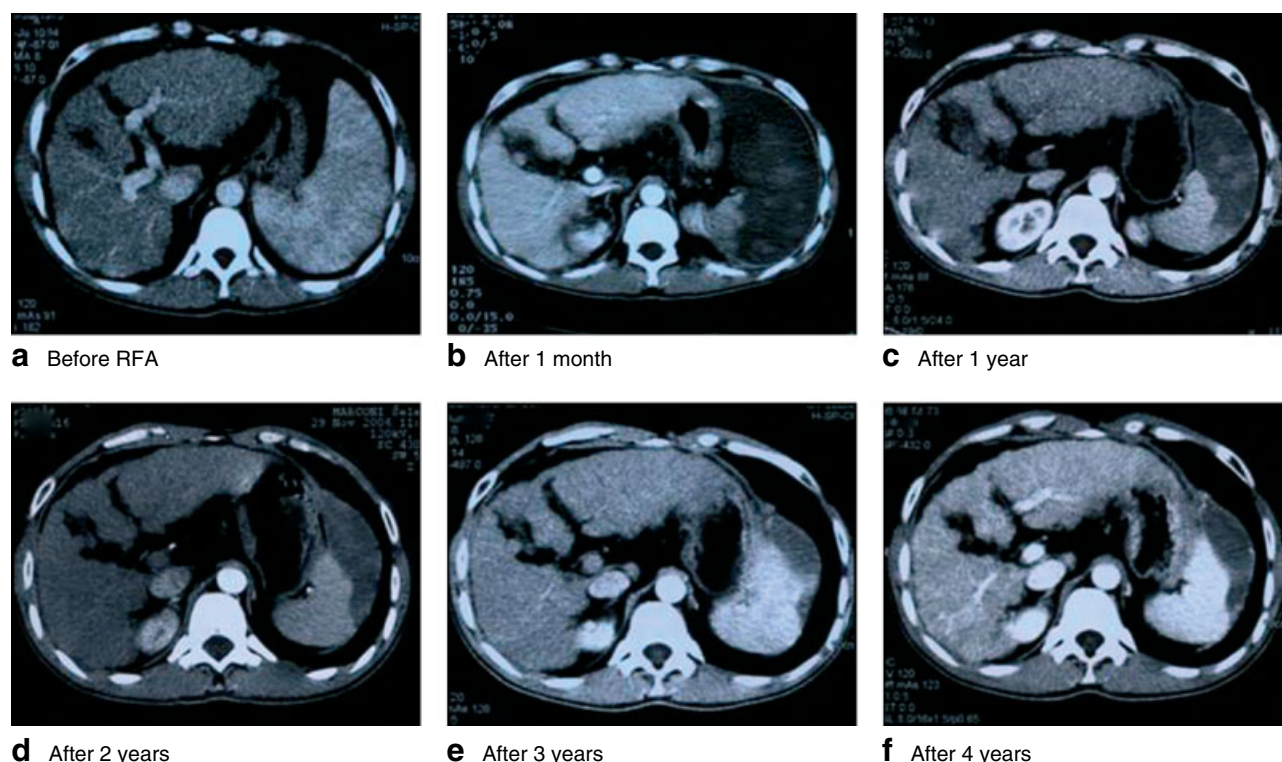


Fig. 4 Contrast-enhanced computed tomograms image of a patient in the radiofrequency ablation (RFA) group. **a** Before splenic RFA; total spleen volume is 1864.2 cm³. **b** One month after RFA; total spleen volume is 2088.1 cm³ and ablated volume 1524.4 cm³ (73.0 per cent ablated). **c** One year after RFA; total spleen volume is 824.8 cm³ and ablated volume 476.2 cm³ (57.7 per cent ablated). **d** Two years after RFA; total spleen volume is 861.2 cm³ and ablated volume 336.7 cm³ (39.1 per cent ablated). **e** Three years after RFA; total spleen volume is 893.6 cm³ and ablated volume 257.4 cm³ (28.8 per cent ablated). **f** Four years after RFA; total spleen volume is 917.5 cm³ and ablated volume 233.6 cm³ (25.5 per cent ablated)

Discussion

RFA has received increasing attention as a tissue-sparing approach for treating malignant neoplasms. Indications are expanding rapidly to include tumours in the liver, kidney, lung, bone, breast and adrenal gland^{13–15}. Recent advances in RFA equipment have extended its use to partial splenectomy and hepatectomy^{16,17}. RFA represents a novel option for treating hypersplenism in patients with cirrhosis awaiting a liver transplant. The safety and efficacy of splenic RFA have been verified in this and previous studies^{8–10}.

In the present study, one patient in the splenectomy group died from intra-abdominal bleeding, ascites and infection. Intra-abdominal bleeding and haemorrhagic shock represented severe complications in the RFA group, but there were no deaths, nor were there complications such as hyperpyrexia, splenic abscess or splenic rupture (seen frequently after partial splenic embolization)^{6,7}. The

severity of complications (duration of fever, pleural effusion) increased with the volume of ablation. Laparoscopic RFA is probably preferable to the percutaneous approach because bleeding from puncture wounds during percutaneous procedures in patients with abnormal coagulation may not be noted quickly.

In agreement with previous studies, splenic RFA yielded good short-term effects. To study the dose–effect relationship, RFA data were analysed according to the percentage of splenic volume ablated. Short-term effectiveness was good in all groups, but hypersplenism recurred by 6 months in patients with less than 50 per cent splenic ablation. Hypersplenism in patients with more than 50 per cent of the spleen ablated was well controlled, particularly if the ablation volume was greater than 70 per cent. Balancing risks and benefits, the ideal ablation volume should probably be between 50 and 70 per cent.

There are many operative methods for treating upper gastrointestinal haemorrhage and cirrhotic hypersplenism,

but they are all palliative with the exception of liver transplantation. Portal vein thrombosis is not a contraindication to liver transplantation, but greatly increases the difficulty of the procedure. Liver transplantation in patients with portal vein thrombosis is associated with increased operating time, more frequent transfusions, rethrombosis and lower survival rates^{18,19}. The incidence of portal vein thrombosis ranges from 1.6 to 11 per cent after splenectomy^{20,21}. Splenomegaly (over 1 kg) increases the risk of portal vein thrombosis greatly. A possible explanation for this is the sudden reduction in splenic vein flow, initiating a thrombus that migrates proximally towards the portal vein. Another possible factor is the increase in platelet count, proportional to the volume of spleen excised^{22–24}. In the present study, the incidence of portal vein thrombosis was considerably higher after splenectomy than in the RFA group. Therefore, splenic RFA leaves patients in good condition for future liver transplants.

The ablated part of the spleen shrank significantly in the first year after RFA but, because portal hypertension was not resolved, the volume of the residual spleen increased. The volume of spleen ablated led to different surgical results; for example, hypersplenism recurred if less than 50 per cent of the spleen was ablated, whereas recurrence of hypersplenism was uncommon in patients with a larger ablation volume.

RFA and partial splenic embolization have similar therapeutic principles. However, RFA produces a more confined lesion, reducing the frequency and severity of complications. Splenic RFA rarely leads to abscess formation which may be related to the fact that it produces coagulation necrosis, as opposed to the liquefaction after embolization. RFA is convenient to perform, and requires less expensive equipment. In addition, splenic RFA preserves the immune function of the body, because a portion of the spleen is retained.

As with any new technology, the advantages and disadvantages of RFA need to be verified by more evidence-based studies. Because surgeons have limited experience with this treatment, there is no reference for issues such as how to control the ablation volume more precisely or how to assess the dose–response effect of splenic RFA; these require further investigation. However, based on this study, it is likely that RFA will provide a new safe treatment choice for patients with cirrhosis, with long-term results comparable to those of splenectomy.

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