Clinical application of radiofrequency ablation negative pressure automatic biopsy gun in liver space-occupying lesions patients

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Abstract: Objective: With the rapid developments in hepatic lesions detection technologies, the incidence rate of liver space-occupying lesions (SOLs) has accelerated dramatically. This investigation is aimed to evaluate the safety and clinical efficacy of radio frequency ablation negative pressure automatic biopsy gun (RFANPABG) for treatment in liver space-occupying lesions (SOLs) patients. Methods: A comparison study of puncture biopsy with 348 cases of diagnosed liver SOLs patients enrolled from January 2013 to August 2014. RFANPABG were performed on the average random distribution 174 patients, and radiofrequency ablation conventional puncture biopsy gun (RFACPBG) were regularly conducted on the other 174 patients to evaluate the technical success rate of puncture efficiency, the needle tract bleeding rate, the needle tract tumor growing rate and so on. Results: For the RFANPABG, the technical success rate of puncture efficiency was 97.70% (170/174), higher than that of RFACPBG with 85.06% (148/174) (P<0.05); the needle tract bleeding rate was 1.15% (2/174), lower than that of RFACPBG with 6.32% (148/174) (P<0.05); and the needle tract tumor growing rate was 0.58% (1/174), also lower than that of RFACPBG, which is 4.60% (8/174) (P<0.05). Conclusion: The higher puncture efficiency, lower needle tract bleeding rate and needle tract tumor growing rate of RFANPABG, in conjunction with the clinical data findings, make RFANPABG a promising useful diagnostic modality in SOLs.

Keywords: Hepatic space-occupying lesions, radiofrequency ablation negative pressure automatic biopsy gun, puncture efficiency, needle tract bleeding rate, needle tract tumor growing rate

Introduction

With the wide spreading infection of hepatovirus, especially the hepatitis C infection [1, 2], the global incidence of liver cancer is rising sharply year by year in worldwide, especially in China. For example, WHO estimate about 47,000 deaths caused by liver cancer per year in Europe [3]; while in China, the mortality rate was estimated about 26.26 per 100,000, taking about 19.33% of all sites of cancers [4]. Hepatic resection and liver transplantation are known as the curative treatment options for malignant liver tumor [5], however, just 10-54% malignant liver tumor patients are suitable to surgery [6]. In addition, with low respectability rate (20-37%) and shortage of the grafts, the majority of malignant liver tumor patients are not received surgical treatment [7, 8]. Different loco regional nonsurgical therapies, such as transarterial chemoembolization (TACE), percutaneous ethanol injection(PEI), cry therapy, interstitial laser therapy, microwave coagulation, radiofrequency ablation (RFA) and so on, have been developed for treatment of malignant liver tumor patients [5, 9]. Several local ablative techniques have been used for several decades [10], and the radiofrequency ablation (RFA), as the most popular local ablative technique with easily to operate and low morbidity, have been widely used in malignant liver tumor treatments [11-13]. The space-occupying lesions (SOLs) of liver mean a unique and distinct spectrum when compared with those normal livers. Although many pathological factors, such as hepatic hemangioma, hepatoblastoma, focal nodular hyperplasia, hepatic adenoma, hepatocellular carcinoma and so on may lead to the...
performance of liver SOLs [14-17], clinical presentations of liver SOLs have played an important role for malignant liver tumor judgment [18, 19]. As the radiofrequency ablation (RFA) have been widely applied in malignant liver tumor treatments [11-13], these techniques should also be applied in liver SOLs treatment.

Radiofrequency ablation, known as “radiofrequency thermal ablation”, is a recently developed thermo ablative technique, with combination of energy absorption, heating and conduction to generate areas of coagulative necrosis and tissue desiccation [20-22]. With low morbidity and mortality rates, effective tumor ablation, producing larger volume of coagulation necrosis and so on, RFA gained a tremendous enthusiasm in modern management of malignant liver tumors in recent years [11-13, 20]. However, the risks and probability of RFA operation failure should not be ignored, one of the most important, the use of RFA should be in the target lesions and be justified by critically appraising. In addition, the lesions should be accurately diagnosed as malignant liver tumors before received the RFA. As the main basis and means for clinical pathologic diagnosis, puncture pathology biopsy has been in clinical application for more than 50 years, and biopsy gun also has been applied for more than 10 years. However, some application flaws and complications has hindered the clinical application of biopsy gun to a certain extent, such as the puncture efficiency were 75 to 95%, the needle tract bleeding rate were 1.7 to 7.5%, and the needle tract tumor growing rate were 2.1 to 8.0%.

Hence, we performed a radiofrequency ablation negative pressure automatic biopsy gun (RFANPABG) for treatment the liver space-occupying lesions (SOLs) patients. This study was aim to evaluate the safety and clinical efficacy of using RFANPABG for liver SOLs treatment, and also to investigate the possible clinical application prospect.

Materials and methods

General data

All the 348 patients (general data were shown in Table 1) were consecutive studied and average random distributed from Chinese diagnosed and/or treated with liver SOLs in our hospital, during January 2013 to August 2014. This study was conducted in accordance with the declaration of Helsinki. This study was approved by the local ethics committee, and the written informed consent form was obtained by each subject. All participants’ general data were obtained from questionnaires, including living environment conditions, occupation, ages and so on. All patients were diagnosed with liver SOLs and the corresponding diseases by B ultrasound, CT, and pathological examination, and they accepted treatment by RFANPABG or RFACPBG with the recommend operational procedures.

Establishment the 3D-CT image of target liver SOLs

The 3D-CT image of target liver SOLs was obtained by using INNOVA4100 IQ angiography machine with 3D-CT navigation function. The puncture point and route to the target lesions were determined avoiding ribs. In addition, the puncture angle and probe insertion depth were determined under bull’s-eye view.

Local negative pressure biopsy and radiofrequency ablation

The puncture of target lesions with negative pressure biopsy gun needle and RFA needle were conducted under bull’s-eye view. When reached the proper position, operate the nega-
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Table 2. Puncture efficiency, needle tract bleeding rate and needle tract tumor growing rate between the RFANPABG treatment group and the RFACPBG treatment group

<table>
<thead>
<tr>
<th>Index</th>
<th>RFANPABG treatment</th>
<th>RFACPBG treatment</th>
<th>$\chi^2$ and $P$-value</th>
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</thead>
<tbody>
<tr>
<td>Puncture efficiency</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Success</td>
<td>170 (97.7%)</td>
<td>148 (85.1%)</td>
<td>$\chi^2 = 17.655$</td>
</tr>
<tr>
<td>Fail</td>
<td>4 (2.3%)</td>
<td>26 (14.9%)</td>
<td>$P&lt;0.001$</td>
</tr>
<tr>
<td>Needle tract bleeding rate</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bleeding</td>
<td>2 (1.1%)</td>
<td>11 (6.3%)</td>
<td>$\chi^2 = 6.473$</td>
</tr>
<tr>
<td>No bleeding</td>
<td>172 (98.9%)</td>
<td>163 (93.7%)</td>
<td>$P = 0.011$</td>
</tr>
<tr>
<td>Needle tract tumor growing</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Growing</td>
<td>1 (0.6%)</td>
<td>8 (4.6%)</td>
<td>$\chi^2 = 5.589$</td>
</tr>
<tr>
<td>No growing</td>
<td>173 (99.4%)</td>
<td>166 (97.4%)</td>
<td>$P = 0.018$</td>
</tr>
</tbody>
</table>

Table 2. Puncture efficiency, needle tract bleeding rate and needle tract tumor growing rate between the RFANPABG treatment group and the RFACPBG treatment group

All statistical analyses were performed by using the Statistical Package for Social Sciences software (SPSS, Windows version release 17.0; SPSS Inc.; Chicago, IL, USA). The chi-squared ($\chi^2$) test was utilized to evaluate the Hardy-Weinberg equilibrium in treatment efficacy. A level of $P<0.05$ was considered statistically significant.

Results

Patient characteristics

The demographic and clinical characteristics of the studied diagnosed liver SOLs patients in the RFANPABG treatment group and the RFACPBG treatment group are summarized in Table 1. There are no significant statistical different of age and gender between the RFANPABG treatment group and the RFACPBG treatment group. In addition, there are also no significant statistical different of patients number between the RFANPABG treatment group and the RFACPBG treatment group, whether been statisticated by lesion site, lesion maximum diameter distribution or lesion number.

Technical success rate of puncture efficiency and post procedure complications

All patients could tolerate the combined treatment, and both the RFANPABG needles and the RFACPBG needles are successfully entered the target lesions for each puncture. After the puncture by negative pressure automatic biopsy gun or conventional puncture biopsy gun, each patient successfully received RFA treatment. The success of puncture is defined as obtaining the right expected tissue samples, and the location of lesions are desiccated and coagulative necrosis under medical examination; the needle tract bleeding is assessed by serum hemoglobin level, prothrombin time, platelet count and the treatment response by a CT scan of the liver from 3-5 days after RFA; and the needle tract tumor growing is assessed with reexamination once for every 2 to 3 months by CT or B ultrasound, and blood, liver and renal function detection. There are significant statistical differences of the puncture efficiency, the needle tract bleeding rate and the needle tract tumor growing rate between the RFANPABG treatment group and the RFACPBG treatment group. As shown in Table 2, the technical success rate of puncture efficiency in the RFANPABG treatment group is 97.7%, about 1.15 fold than that (85.1%) in the RFACPBG treatment group ($\chi^2 = 17.655$, $P<0.001$). At the same time, the needle tract bleeding rate in the RFANPABG treatment group is 1.1%, while 6.3% in the RFACPBG treatment group, which is significant much lower with treated by RFANPABG ($\chi^2 = 6.473$, $P = 0.011$). After treatment by RFANPABG or RFACPBG, the post procedure complications of all patients are been studied by follow-up surveys, and the corresponding needle tract bleeding rates are been statistically analyzed. 173 patients are free of needle tract tumor growing after received the RFANPABG treatment, and only 166 patients are free of needle tract tumor growing after received the RFACPBG treatment.
the needle tract tumor growing rate is significantly lower in the RFANPABG treatment group ($\chi^2 = 5.589, P = 0.018$).

**Discussion**

With the increasing incidence rates of malignant liver tumor, more and more alternative treatments to control or potentially cure liver disease have been develop [23-25]. As a new multidisciplinary technique with many key advantages including low morbidity and mortality rates, effective tumor ablation [11-13, 20], radiofrequency ablation (RFA) technique has been used as one effective loco regional nonsurgical treatment modality in modern management of malignant liver tumors in recent years [11, 12, 26]. However, many factors should be taken into consideration before received the RFA, for example, the lesions should be accurately diagnosed before RFA treatment. Accordingly, many techniques for clinical pathologic diagnosis also get remarkable progress [23, 24, 27].

As the liver SOLs work as the very possible symptoms for malignant liver tumors, such as hepatocellular carcinoma, hepatic adenoma and hepatoblastoma, accurate diagnosis of the liver SOLs may show very important role in timely diagnosis and treatment for malignant liver tumors [18, 19]. Liver SOLs have unique and distinct spectrums different from normal liver, many classic and modern techniques have been developed for these diagnose, for example, B ultrasound, CT and fine needle aspiration biopsy [17]. Puncture pathology biopsy works as the main basis and means for lesions diagnose in clinical application for a long history, and the biopsy gun also has been used in clinical diagnose for 10 years. Although the puncture efficiency could up to 95%, the needle tract bleeding rate could be minimized to 1.7%, and the needle tract tumor growing rate also could be minimized to 2.1%, these deficiencies still have hindered the clinical application of biopsy gun in some extent.

In this study, we invented the radiofrequency ablation negative pressure automatic biopsy gun (RFANPABG), then preliminary applied in diagnosis and treatment of liver SOLs, and the corresponding puncture efficiency, needle tract bleeding rate and needle tract tumor growing rate were also compared with treatment the ablation conventional puncture biopsy gun (RFACPBG). Results showed a very higher puncture efficiency, lower needle tract bleeding rate and needle tract tumor growing rate of treatment by RFANPABG, which realized the fast in situ diagnosis and treatment of SOLs, moreover, applying this technique may significantly reduce the risk of possible complications. With these innovations and advantages, the RFANPABG may become into a promising useful clinical diagnostic modality in liver SOLs in the future.

**Disclosure of conflict of interest**

None.

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