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A randomised study on the efficacy and safety of an automated Tru-Cut needle for percutaneous liver biopsy

R.A. de Man[1*], H.R. van Buuren[1], W.C.J. Hop[2]

Departments of [1]Gastroenterology and Hepatology and [2]Epidemiology and Biostatistics, Erasmus University Medical Centre Rotterdam, the Netherlands, tel.: +31 (0)10-463 37 93, fax: +31 (0)10-436 59 16, e-mail: r.deman@erasmusmc.nl, [*]corresponding author

ABSTRACT

Background: We studied whether the theoretical advantages of a spring-loaded liver biopsy needle exist in clinical practice and if so if they are dependent upon the experience of the physician performing the biopsy.

Methods: In a stratified randomised study we enrolled 215 consecutive patients to compare the safety and efficacy of a new automatic biopsy gun (Acecut) with that of a standard Tru-Cut needle.

Results: A total of 464 biopsies were performed. The endpoints of the study were number of needle passes needed per patient, tissue yield of each needle pass and post-biopsy complications. The performance of the automatic needle was superior and more consistent with respect to tissue yield compared with the Tru-Cut needle (median yield 100% and 80%, respectively; p<0.001). The difference was most marked for inexperienced physicians. There was no difference between the two needles in the number of passes needed. More post-biopsy pain and post-biopsy use of analgesics were observed in the automatic needle group (p=0.04).

Conclusion: The automatic Tru-Cut needle offers an advantage, particularly for physicians with no or limited experience in liver biopsies. However more post-biopsy pain and post-biopsy use of analgesics were observed in the automatic needle group.

INTRODUCTION

Several new types of automatic spring-loaded Tru-Cut liver biopsy needles have recently been introduced. These devices are commonly referred to as 'biopsy guns'. The potential advantage of a biopsy gun is the shorter duration of the actual biopsy procedure which could reduce the number of complications. In addition, since the difficult Tru-Cut movement is automated, one would expect the tissue yield to be larger and needle performance more constant. However, whether these theoretical benefits are of importance in clinical practice may depend upon the experience of the physician performing the biopsy.

Aims of the study

We initiated a randomised study of the standard Tru-Cut liver biopsy needle and an automatic spring-loaded Tru-Cut device to compare tissue yield, the quality of the biopsy specimen obtained and post-biopsy complications. A secondary aim was to test the hypothesis that a possible advantage of the automated device would be most apparent among inexperienced operators.

MATERIALS AND METHODS

The study population consisted of a cohort of all consecutive patients referred for percutaneous liver biopsy to the Department of Hepatogastroenterology between October 1994 and October 1996. The unit is a tertiary referral centre for liver diseases and liver transplantation.

Randomisation procedure

A computer-generated randomisation procedure was followed. Patients were randomly allocated to one of two

groups using consecutively numbered sealed nonopaque envelopes. Patients were stratified according to the experience of the operator. A physician was considered inexperienced if he had performed less than 50 Tru-Cut liver biopsies.

Biopsy needles

For this study we used a 14 gauge x 11.4 cm Tru-Cut needle (Baxter Healthcare Corporation, Deerfield, Ill, USA) as standard needle. This needle has a biopsy specimen notch of 20 mm. This was compared with a needle biopsy gun (Acecut, TSK Laboratory, Japan) with a 14 gauge x 11.5 cm needle and a 15 mm biopsy specimen notch.

Biopsy procedure

Preparation for the biopsy was identical for the two groups. After informing the patient about the procedure, a mid-axillary biopsy site was selected and checked by ultrasonography. The actual biopsy procedure was performed without ultrasound guidance. If desired by the patient premedication, consisting of intravenous midazolam (Dormicum) in a bolus dosage of 5 mg, was given. Dosages of 1 to 2.5 mg were administered to patients over 65 years of age who had cardiopulmonary or other diseases considered to increase the risks associated with intravenous administration of benzodiazepines. Oxygen saturation and heart rate were monitored by pulse oximetry. After skin disinfection and liberal local anaesthesia with 1% lidocaine the randomisation envelope was opened by the endoscopy nurse and the appropriate biopsy needle was presented. Our standard procedure is to obtain two biopsy specimens; if the biopsy was less than 15 mm long, the biopsy pass could be repeated a maximum of four times.

After the biopsy procedure the wet biopsy specimen was placed on a plate of paraffin and the length was measured using a micrometer. All patients undergoing this procedure as outpatients were observed for three hours in the day-care facility with standard checks on post-biopsy pain, pulse rate and blood pressure. A patient with pain was evaluated by the operator who could prescribe a bolus of 50 or 100 µg intravenous fentanyl citrate (Fentanyl). Our policy is to administer fentanyl early in the event of post-biopsy pain. At the end of the three-hour observation period the occurrence of pain was scored by the physician as none, mild or severe. This was further documented by the prescription of fentanyl. At the end of the three-hour observation period the patient was again seen by the physician and either sent home or admitted for further observation. Any admission was scored as a complication. When an in-patient underwent the biopsy procedure, the occurrence of pain, use of fentanyl and complications were recorded by the attending ward physician the day after the procedure. All data were registered on standard forms.

Study endpoints

The study endpoints were:

- the number of passes performed and total biopsy length/number passes;
- the cumulative length of the liver tissue obtained and the quality of the material obtained (fragmented *vs* a coherent biopsy specimen);
- the number of passes with insufficient material defined as less than 10 mm (insufficient pass), no tissue yield (failed passes) or no tissue yield at all (failed procedure);
- post-biopsy complications.

Statistical evaluation

The aim was to include at least 50 patients in each physician stratum. Power calculations were not performed since no data were available on the performance of the automatic needle. We assumed that in a study of 100 patients no clinically significant differences would be missed. Since recruitment in the inexperienced physician group was slower than expected, a total of 215 patients were enrolled. Equality of the medians was tested by the two-sample Wilcoxon rank-sum test. The relationship between the type of physician who took the biopsy, needle type and tissue yield was evaluated using multiple regression analysis. Whether the differences between needle types depended on the physician was tested using appropriate interaction terms. Dichotomous parameters were tested by Fisher's exact test.

RESULTS

Patients

In total, 215 patients were randomised. Five patients were excluded from the study because the physician decided to change the biopsy procedure to either an ultrasound-guided biopsy (of the left liver lobe) (n=2) or a laparoscopic biopsy (n=3). In one case the data sheets were lost. In total 209 patients could be evaluated. The groups were well matched for demographic, clinical and laboratory variables (*table 1*).

Physicians

Four experienced and three inexperienced physicians participated in this study. In 159 cases the biopsy procedure was performed by an experienced physician (78 automatic needle and 81 Tru-Cut). In 50 cases the biopsy procedure was performed by an inexperienced physician (24 automatic needle and 26 Tru-Cut).

Biopsy length

No differences were found in either the number of passes needed for each needle type or the number of insufficient or failed passes. There were no failed procedures.
To correct for the maximum tissue yield possible, all data

Table 1
Patient characteristics and features at entry

	AUTOMATIC NEEDLE	HAND-OPERATED NEEDLE
Number of patients	102	107
Age	41 (19-72)	45 (17-68)
Sex (female/male)	39/63	38/69
Aetiology of the liver disease		
Hepatitis B	47	52
Hepatitis C	24	20
Primary biliary cirrhosis	4	5
Primary sclerosing cholangitis	4	1
Autoimmune hepatitis	2	2
Alcoholic liver disease	2	3
Post-transplantation	4	8
Cryptogenic	15	16
Evaluation of haemostasis		
Number of patients with prolonged prothrombin time	1	3
APTT (normal 25-40 seconds)	29 (20-40)	28 (23-46)
Platelets (normal 140-360.10^9/l)	202 (58-660)	202 (41-381)
Bleeding time (normal <240 seconds)	170 (60-355)	142 (60-420)

Continuous data are presented as median plus ranges.

were analysed as percentage of the specimen notch used per biopsy pass. This percentage was significantly higher for the automatic needle compared with the Tru-Cut needle (100 *vs* 80%; p<0.001) (*table 2*).
The difference in mean use of the needle notch did not differ between individual physicians in one group. A clear trend (p=0.109) was found towards an increased benefit of the automatic biopsy device among inexperienced physicians compared with the experienced ones (*table 3*).

Complications
Three patients (all randomised to the automatic needle group) suffered complications in this study. Two patients were admitted because of pain and discharged the next day without complaints. One patient with documented intraperitoneal bleeding received two units of red blood cells. The difference between the two groups was not statistically significant.

After a biopsy procedure the pain experienced by the patient as interpreted by the physician was more severe in the automatic needle group (p=0.012). This paralleled the increased prescription of fentanyl in the automatic needle group (p=0.04). The difference in post-biopsy pain was independent of the experience of the physician (p=0.08 and p=0.05 for the experienced and inexperienced groups, respectively) (*table 4*).
The overall incidence of major complications in this series was 0.6% (3/464). The incidence of minor complications (pain with administration of analgesics) was 13.5% (63/464).

DISCUSSION

When performing a liver biopsy the first decision to be made is the choice between the cutting needle (Tru-Cut system) and the aspiration needle (Menghini type). With both needle types adequate tissue samples can be obtained while there is an advantage for Tru-Cut needles in diagnosing cirrhosis.[1] In an experimental animal model using direct comparison the Tru-Cut needle performed better compared with aspiration needles with regard to tissue yield and specimen quality.[2] Although the overall incidence of post-biopsy bleeding in nonmalignant liver disease is low (0.4 per 1000 for fatal bleeding and 1.6 per 1000 for nonfatal bleeding), the incidence of severe post-biopsy bleeding is higher for cutting needles compared with aspiration needles.[3,4] In the experimental model as well as in autopsy studies it has been shown that an automatic biopsy device produces adequate tissue samples.[5] The aim of our study was to compare in everyday clinical practice the performance of an automatic with a hand-operated Tru-Cut needle. Our hypothesis was that the impact of an automatic biopsy device would be the greatest among inexperienced physicians whereas no clear advantage would found for experienced physicians. This study shows that the use of an automatic Tru-Cut needle device is superior to a standard Tru-Cut needle as far as tissue yield is concerned. Lindor demonstrated that this is also true when only experienced operators participate.[6]
Are these differences clinically relevant? Obviously adequate tissue specimens can be obtained with both needles. The tissue yield of the automatic needle seems to be more con-

Table 2
Results of biopsy procedures

	AUTOMATIC NEEDLE	HAND-OPERATED NEEDLE
Needle passes	2 (1-4)	2 (1-4)
Number of patients (n)		
Needle passes (%)		
1 pass	5 (4.9)	2 (1.9)
2 passes	77 (75.5)	78 (72.9)
3 passes	17 (16.7)	24 (22.4)
4 passes	3 (2.9)	3 (2.8)
Number of failed needle passes (n)		
First biopsy	3	8
Second biopsy	4	7
Third biopsy	0	5
Fourth biopsy	0	0
Number of failed procedures (no material obtained)	0	0
Biopsy length (mm)		
Cumulative biopsy length as percentage of biopsy notch (%)	100 (25-140)	80 (21-138)
Cumulative biopsy length	30 (15-56)	35 (17-73)
Median biopsy length per pass	15 (5-20)	16 (6-24.5)
Biopsy quality if biopsy obtained		
Good-quality first biopsy (%)	94.8	94.8
Good-quality second biopsy (%)	92.3	86.4
Good-quality third biopsy (%)	94.7	85.7
Good-quality fourth biopsy (%)	100	100

Continuous data are presented as median plus ranges. Quality data relate to the percentage of biopsies yielding good quality tissue.

Table 3
Liver tissue yield expressed as percentage of the biopsy notch in relation to the experience of the operator

	AUTOMATIC NEEDLE	HAND-OPERATED NEEDLE
Inexperienced operator	100% (36-123)	69% (30-137)
Experienced operator	100% (25-140)	85% (21-122)

Data are presented as median plus ranges.

Table 4
Complications and post-biopsy sequelae

NEEDLE TYPE	AUTOMATIC NEEDLE	HAND-OPERATED NEEDLE
Patients on midazolam pre-medication (%)	82	84
Post-biopsy pain (n (%))		
None	45 (47.4)	70 (68.6)
Mild	33 (34.7)	20 (19.6)
Severe	17 (17.9)	12 (11.8)
Post-biopsy fentanyl (n)		
None	56	78
50 µg	35	17
100 µg	4	6
Admissions (n)	3	0

sistent which is particularly beneficial for operators who perform liver biopsies sporadically. Our data support a recommendation that those who will not be performing frequent liver biopsies in the future should learn to use an automatic device while the type of needle is of less relevance for those working in specialised liver units.
We started using ultrasound routinely for all patients in 1983. This approach has since been shown to reduce the incidence of post-biopsy complications.[6] However the occurrence of post-biopsy pain and use of analgesics were higher in the automatic needle group. Although it seems logical to attribute more blunt tissue trauma and more pain to the spring-loaded device, the study design with regard to the occurrence of pain should be interpreted with caution: the scoring of post-biopsy pain and the decision to use fentanyl were left to the physician in charge and not to more patient-related measurements. In the combined Mayo Clinic – Barcelona study 207 patients were biopsied with an automatic Tru-Cut needle under ultrasound guidance and 216 hand-held Tru-Cut biopsies under ultrasound guidance were performed.[6] The occurrence of post-biopsy pain was 40.6% for the automatic group and 34.3% for the hand-operated group. The data seem to support the idea that post-biopsy pain increases with the use of a spring-loaded biopsy needle. Since compliance with repeated liver biopsies is essential for the treatment and follow-up of patients with chronic liver disease, this is an important aspect which should not be disregarded easily. We can only speculate on the exact cause of post-biopsy pain with a spring-loaded biopsy needle. One explanation may be that because some operators keep close contact with the upper side of the rib during the procedure, the spring-loaded device causes more blunt trauma to the periostium.

Our data support the recommendation that physicians who perform liver biopsies infrequently should learn to use an automatic Tru-Cut biopsy device. A follow-up study with a 20 mm specimen Tru-Cut biopsy device would be worthwhile, especially to address the issue of an increase in post-biopsy pain following the use of a spring-loaded biopsy gun.

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