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FULL PAPER

Adequacy of percutaneous non-targeted liver biopsy under real-time ultrasound guidance when comparing the Biopince™ and Achieve™ biopsy needle

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Objective: The purpose of this study was to compare the adequacy rates of percutaneous liver biopsies, in parenchymal liver disease, using the Biopince™ (Argon Medical, Texas, TX,) 16G and Achieve™ (Carefusion, Illinois, IL, USA) 18G biopsy needles in relation to the Royal College of Pathologists guidelines and to assess risk of complications.

Methods: Data for all percutaneous non-targeted “medical” liver biopsies using the Biopince 16G and Achieve 18G biopsy needles were collected retrospectively over a 2-year period. Total biopsy core length and number of portal tracts was recorded along with adequacy of biopsy as assessed according to Royal College of Pathologists criteria.

Results: In total, 194 percutaneous liver biopsies met the inclusion criteria; 53 using the Biopince needle and 141 using the Achieve needle. The mean total core length was 23 mm (SD 4.1) and 20 mm (SD 6.8) for the Biopince and Achieve needles, respectively ($p = 0.0005$). The

mean number of portal tracts was 11 (SD 4.2) and 7 (SD 3.4) for the Biopince and Achieve needles, respectively ($p < 0.0001$). An adequate biopsy was obtained in 15 (31.3%) and 1 (1.3%) case using the Biopince and Achieve needles, respectively ($p < 0.001$). Compromised biopsies were obtained in 32 (66.7%) and 39 (50.6%) cases using the Biopince and Achieve needles, respectively. Inadequate biopsies were obtained in 1 (2%) and 37 (48.1%) cases using the Biopince and Achieve needles, respectively.

Conclusion: The Biopince 16G needle, when compared with the Achieve 18G needle, acquires a significantly greater total core length and number of portal tracts with significantly improved adequacy rates. There were no major complications associated with its use.

Advances in knowledge: The Biopince 16G needle achieves significantly better specimen adequacy, when compared with the Achieve 18G needle and with no added major complications associated with its use.

INTRODUCTION

Liver biopsy remains a valuable tool for clinicians treating parenchymal liver disease and is commonly used to confirm clinical diagnosis, provide prognostic information, identify aetiology where clinical diagnosis is uncertain and to identify the major aetiology when multiple pathologies are suspected.

Despite advances in imaging techniques and the use of biochemistry, serology and virology liver biopsy is still regarded as a valuable tool for assessing liver disease. It not only has a diagnostic role but it also provides information regarding severity of disease and stage of fibrosis, which are important for prognostication, clinical management and clinical trials.

Advances in needle technology and image guidance have simplified the process of obtaining liver tissue. Commonly, the biopsy needle design involves a side-notch needle; however more recently an end-cut and full core needle device has been introduced allowing the whole length of the advanced needle to acquire the tissue. When used in oncological specimen sampling, this needle type has been shown to have low risks of complications and a high rate of a specific pathological diagnosis (99%).¹

An adequate liver biopsy, whilst minimizing the risk, is therefore important. Studies have demonstrated that assessment of disease severity and stage of fibrosis is compromised in liver biopsies shorter than 25 mm or containing less than 11 portal tracts.^{2,3}

Guidance published by The Royal College of Pathologists (RCPATH) have incorporated minimum adequacy requirements in relation to accurate analysis.⁴ However, there clearly needs to be a balance between clinical benefit of the biopsy and risks to the patient.

The risk of major complication for liver biopsy is low.^{5,6} The mortality rate for targeted lesions is very low^{7,8} comprising 1 per 10,000 biopsies and is even lower for biopsies undertaken for parenchymal disease.^{9,10}

In Royal Derby Hospital, the biopsy needle used varied between an end-cut full core (Biopince) and side-notch (Achieve) needle depending on the operator. Furthermore, there is clinical equipoise regarding the most appropriate minimum specimen size for accurate histological assessment. On the basis of oncological reports suggesting that the end-cut full core needle type may improve diagnostic accuracy and maintain a low risk of complication, we hypothesized that this finding may be replicated in non-oncological liver biopsies. The purpose of this study therefore, was to compare the adequacy rates of percutaneous liver biopsies using the Biopince 16G and Achieve 18G biopsy needles in relation to the RCPATH guidelines and to assess the risk of complications.

METHODS AND MATERIALS

All liver core biopsies reported in Royal Derby Hospital between November 2014 and October 2016 were identified using the histology database (iLab, CSC Global). Targeted liver lesions, transjugular liver biopsies and those cases where the pathology report did not include the total core length or number of portal tracts were excluded.

Liver biopsies were obtained using either the Biopince (16 gauge, 10 cm needle; Argon Medical, TX) or the Achieve (18 gauge, 15 cm needle; Carefusion, IL) under real-time ultrasound guidance.

The data collected included the type of biopsy needle used, total core length (mm), number of portal tracts, number of cores, sample fragmentation, rebiopsy within 3 months and final diagnosis.

Sample adequacy was assessed according to total length of core and number of portal tracts in accordance with the RCPATH guidelines⁴ and the biopsies categorized into three groups; “adequate”, “compromised” and “inadequate” (Table 1).

Table 1. RCPATH guidelines on specimen adequacy

	Core length (mm)	Number of portal tracts
Adequate	≥25	≥11
Compromised	<25	6–10
Inadequate	<6	<6

RCPATH, The Royal College of Pathologists.

Only one radiologist, with over 10 years of experience as a consultant, used the Biopince needle, whilst several used the Achieve needle. Therefore, a separate analysis was performed to assess intraoperator variability.

Any major complications defined as haemorrhage, iatrogenic injury to surrounding viscera and death was documented. A separate prospective audit was undertaken over a 6-month period recording minor complications defined as pain or transient hypotension.

Continuous data was analysed using the Student's *t*-test and categorical data analysed using the Fisher exact test. A *p*-value of <0.05 was deemed to be significant.

RESULTS

In total, 194 percutaneous liver biopsies met the inclusion criteria; 53 using the Biopince needle and 141 using the Achieve needle. All were performed by experienced interventional consultant radiologists. A single radiologist used the Biopince needle system and performed 28 of the 141 Achieve needle biopsies. The remaining 113 Achieve needle biopsies were undertaken by three different radiologists. All of the liver biopsies were reported by two consultant histopathologists.

The mean core length for the entire cohort was 20.8 mm (range 8–30 mm). The mean number of portal tracts obtained in the specimen was 8 (range 2–28). The mean number of core samples taken was 1.5 (range 1–5). The median age (range) of patient having a biopsy was 47 years (21–75) and 43 (24–79) for the Biopince and Achieve needle, respectively (*p* = ns). The male/female split (%) between the two cohorts was 45.3/54.7 and 54.6/45.4 for the Biopince and Achieve needle, respectively (*p* = ns).

The mean total core length of biopsy was 23 mm (SD 4.1) and 20 mm (SD 6.8) for the Biopince and Achieve needle, respectively (*p* = 0.0005) (Table 2). The mean number of portal tracts was 11 (SD 4.2) and 7 (SD 3.4) for the Biopince and Achieve needle, respectively (*p* < 0.0001). The median number of core biopsies taken using both sampling needles was 1 (*p* = ns). A fragmented biopsy was obtained in 1.8 and 28.1% of cases for the Biopince and Achieve needle, respectively

Table 2. Comparison of needle types between a single consultant radiologist

	Biopince™	Achieve™	<i>p</i>
Mean core length, mm (SD)	23 (4.1)	21 (3.8)	<0.001
Mean number of portal tracts (SD)	11 (4.2)	7 (3.5)	<0.0001
Specimen quality (%)			
Adequate	31.3	0	<0.0001
Compromised	66.7	42.9	ns
Inadequate	2	57.1	<0.0001

($p = 0.0001$). Rebiopsy rate within 3 months was 0% for the Biopince and 2.83% ($n = 4$) Achieve.

Pathological diagnosis was suggested in 97.4% of liver biopsies and included non-alcoholic and alcoholic liver disease, viral hepatitis, autoimmune hepatitis, cholangiopathy and metabolic/genetic factors including haemochromatosis.

An adequate biopsy was obtained in 15 (31.3%) and 1 (1.3%) of cases for the Biopince and Achieve needle, respectively ($p < 0.001$). Compromised biopsies were obtained in 32 (66.7%) and 39 (50.6%) of cases for the Biopince and Achieve needle, respectively ($p = ns$). Inadequate biopsies were obtained in 1 (2%) and 37 (48.1%) of cases for the Biopince and Achieve needle, respectively ($p < 0.001$).

Analysis of the performance of the single consultant radiologist using both needle systems demonstrated that the mean core length obtained using the Biopince and Achieve needle system was 23 mm (SD 4.1) and 21 mm (SD 3.8), respectively ($p < 0.001$) (Table 3). The mean number of portal tracts in the specimen was 11 (SD 4.2) and 7 (SD 3.5) for the Biopince and Achieve needle, respectively ($p < 0.0001$). Adequate biopsies were obtained in 15 (31.3%) and 0 (0%) of cases for the Biopince and Achieve needle, respectively ($p < 0.0001$). Compromised biopsies were obtained in 32 (66.7%) and 12 (42.9%) of cases for the Biopince and Achieve needle, respectively ($p = ns$). Inadequate biopsies were obtained in 1 (2%) and 16 (57.1%) of cases for the Biopince and Achieve needle, respectively ($p < 0.0001$).

There were no major complications encountered during the study period with either biopsy needle. The prospective audit looking at minor complications totalled 41 patients of which 27 underwent liver biopsy using the Biopince needle and 14 the Achieve. No patients in either of the two groups experienced pain during the biopsy. However, within 2 hours following the procedure, pain was experienced in 48.2% ($n = 13$) and 42.9%

($n = 6$) patients using the Biopince and Achieve biopsy needle respectively ($p = ns$ significant). There were no cases of transient hypotension in either group.

DISCUSSION

Despite advances in non-invasive techniques, the liver biopsy remains an important tool in the investigation of parenchymal liver disease. Its role is much more than to just provide a diagnosis. The biopsy provides prognostic information regarding severity of disease and stage of fibrosis which influences clinical management and clinical trials. Where there are suspected multiple pathologies the liver biopsy helps to identify the dominant factor.

There has been much debate as to what constitutes an adequate liver biopsy¹¹ with suggestions of biopsy core length of anywhere from 10 to 25 mm being considered sufficient for both diagnosis and staging.¹²⁻¹⁴ As to what constitutes an adequate number of portal tracts this ranges from no minimum number specified to more than 11.^{2,3,15} Bedossa et al³ and Colloredo et al² have attempted to study the issue of adequacy using scientific approaches. Bedossa et al³ with the use of image analysis, concluded that the variability of the relative amount of fibrosis decreased as specimen length increased. Colloredo et al² by deliberately gradually reducing the area of liver biopsy for pathological assessment, noted that the smaller the amount of tissue studied significantly reduced the scores for necroinflammation and fibrosis. This was attributed to fewer numbers of portal tracts and would lead to an underestimation of disease severity and stage of fibrosis. The general consensus from these studies is that the smaller the liver biopsy size the less accurate the pathological interpretation. RCPATH has attempted to standardize the criteria for adequacy (Table 1).

This study has demonstrated that the use of the Biopince 16G needle system results in significantly longer and intact liver core biopsy with increased numbers of portal tracts and significantly improved adequacy rates when compared with the Achieve 18G needle.

Liver biopsy is associated with a low rate of major complications 0.22–0.75%.^{5,6} Most complications that arise are related to patient's clinical condition, the operator's expertise, type of needle and number of passes.¹⁶ In this study, there were no major complications with the use of either needle and the minor complication rate, pain being the most frequently encountered, was similar.

The use of either needle system is technically similar and the cost is also comparable (unit price of the Biopince vs the Achieve needle is £11.50 vs £16.50, respectively). The Biopince needle results in the harvest of a full cylindrical specimen, whilst the Achieve has side notch technology (D-shaped) that will reduce the volume of harvested tissue¹⁷ and may explain our studies findings.

Other researchers have also demonstrated improved specimen acquisition using a full core needle when compared with the

Table 3. Results between the Biopince and Achieve biopsy needles

	Biopince	Achieve	<i>p</i>
Mean core length, mm (SD)	23 (4.1)	20 (6.8)	0.0005
Number of portal tracts (SD)	11 (4.2)	7 (3.4)	<0.0001
Median number of cores (SD)	1	1	ns
Fragmented sample obtained (%)	1.8	28.1	0.0001
Rebiopsy rate within 3 months (%)	0	2.83	–
Specimen quality (%)			
Adequate	31.3	1.3	<0.001
Compromised	66.7	50.6	ns
Inadequate	2	48.1	<0.001

side-notch needle. Constantin et al¹⁷ compared the side-notch needle to the full core needle in renal biopsies. They concluded that the 16G end-cut needle (Biopince) provided a better sample (glomerular yield), required fewer cores and resulted in fewer complications than the 14G Tru-cut needle. A further study (published as an abstract) compared the 16G Biopince with the 16G Tru-Cut Tenmo Evolution in liver biopsies.¹⁸ They also found that the needle resulted in more cores meeting the RCPATH criteria but did not investigate for differences in complication rates.

Longer intact biopsy biopsies are easier to handle than smaller fragmented biopsies. Therefore, it would be anticipated that there would be a reduction in the length of time taken at various steps within the laboratory process leading to improved efficiency.

The assessment of severity of disease and stage of fibrosis in a longer intact biopsy can be stated with a greater degree of confidence and less caution than that associated with smaller fragmented biopsies. This improves the discussions between pathologist and hepatologist at multidisciplinary team meetings.

The 3-month repeat biopsy rate with Biopince was 0% and for Achieve was 2.83%. It is acknowledged that whilst small biopsies are difficult to interpret they may contain diagnostic findings and sufficient tissue for an attempt at grading and staging of disease but there is a risk of under scoring severity of disease and stage of fibrosis.

This study demonstrates that the use of the Biopince 16G needle when compared with the Achieve 18G leads to significantly longer core length of biopsy, with more portal tracts and less fragmentation. There were no major complications with the use of either needle. The benefits of a bigger biopsy include increased accuracy of pathological assessment of disease severity and stage of fibrosis which, in turn improves the level of accuracy for both patient management and clinical trials. This imparts a real clinical benefit to the patient with no additional risk.

The limitations of the presented study are its relatively small numbers. All the Biopince needle samples were taken by a single consultant radiologist, which may have led to some operator bias and the results could be influenced by the operators experience and comfort with either needle system. We did, however, attempted to correct for interobserver variability by performing an analysis of a single consultant radiologists outcomes using both biopsy needles, albeit with small numbers.

CONCLUSION

The study has demonstrated that the Biopince 16G biopsy needle performed significantly better than the Achieve 18G biopsy needle with a significant improvement of adequate liver biopsies and a significant reduction of inadequate biopsies, as per RCPATH criteria. There were no major complications and no difference in the rate of minor complications.

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