

PERFORMANCE OF MANUAL VERSUS AUTOMATED DEVICE ASSISTED LIVER BIOPSY

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ABSTRACT

OBJECTIVE: To assess the performance of manual and automated biopsy device (Bard Magnum) –assisted biopsy methods in terms of specimen adequacy, procedure time, number of passes and complications. **METHODS:** The study was conducted at the Sarwar Zuberi Liver Centre and the Department of Radiology of Civil Hospital and Dow university of Health Sciences, Karachi from September 2007 to September 2010. All adult patients undergoing liver biopsy under ultrasound guidance with standard technique were included. 18-G cutting edge needles were for both the manual biopsy as well as the automated biopsy device. Studied variables were sample adequacy, procedural time, number of passes per procedure, complications and need for post procedural analgesia. Chi square and t-test were used for comparing the proportions and mean values respectively between the two groups, with significance at $p < 0.05$. **RESULTS:** A total of 405 biopsies were performed: 174 manually and 285 with automated device- assistance. Adequate sample was obtained in 98.2% by the former and 100% in the latter. Majority specimen was obtained in single pass by either method. Sample size was adequate in both but fragmentation was significantly more common with manual biopsy. Assisted device was complicated by hypotension in one case only. Two cases of hypotension and one case each of hematoma formation and vaso vagal syncope was observed in manual method. Procedure time was significantly shorter on using device (3.6 vs. 8.40 minutes, $p < 0.05$). Need for post procedural analgesia was not markedly different. **CONCLUSION:** There was no significant difference between the performances of the two techniques except for shorter time in automated device- assisted method and more fragmentation of sample by manual biopsy.

Key words: Liver biopsy, manual biopsy, ultrasound guidance, automated biopsy device

Introduction

Liver biopsy is considered the gold standard for evaluation of liver disease.¹⁻³ Its main aim is three fold: evaluation of current status of a diseased liver; identification of the stage of fibrosis and steatosis and identification of complications such as hepatocellular carcinoma and cirrhosis.^{4,5} In chronic antibody positive non viremic, Hepatitis C patient with normal enzymes, liver biopsy usually shows an abnormal histology.⁶ The biopsy itself is said to have multiple potential

drawbacks such as discomfort, biopsy site infection, or hematoma, internal bleeding or biliary leakage and sampling error.^{2,4,5} The technique of the procedure- whether blind or ultrasound guided or assisted, manual or automated device assisted – is also controversial.^{1,7} Ultrasound guidance is now the preferred method,^{1,8} but there is still relatively sparse data regarding the performance of manual or automated device- assisted procedure, particularly in the local resource constrained settings. The aim of this study was to assess the performance of manual and automated biopsy device (Bard Magnum) – assisted biopsy methods in terms of specimen adequacy, procedure time, number of passes and complications

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Methods

The study was conducted at the Sarwar Zuberi Liver Centre and the Department of Radiology of Civil Hospital and Dow University of Health Sciences, Karachi from September 2007 to September 2010. All adult patients undergoing liver biopsy under ultrasound guidance with standard technique were included by consecutive purposive sampling technique. Pediatric patients and those with mass lesions were excluded. 18-G cutting edge needles were for both the manual biopsy as well as the automated biopsy device. Till November 2009, manual biopsy was performed by the physicians and radiologist in nearly the same number under ultrasound guidance. From November 2009 onwards, exclusively device assisted biopsy was performed by the radiologist. Studied variables were sample adequacy, procedural time, number of passes per procedure, complications and need for post procedural analgesia (injectable diclofenac). Sample adequacy was determined as acceptance for histological examination, length of sample in mm and fragmentation of sample. Procedure time was defined as time in minutes from skin incision to sample retrieval. Standard technique of pre procedural exclusion of coagulopathy and ascites, peri-procedural asepsis and post procedural observation of vital signs following pressure packing of the biopsy site was practiced. Post procedural ultrasound of liver was also carried out to rule internal hematoma or biliary leakage. Patients were advised to take bath after 24 hours, remove the skin pack then and contact immediately in case of redness, fever or pain at the site of biopsy. Data was entered and analyzed using Statistical Package of Social Sciences (SPSS) program version 15.0. Chi square and t- test were used for comparing the proportions and mean values respectively between the two groups, with significance at $p < 0.05$.

Results

The average age of the patients was 35.6 ± 16.24 years ranging from 17- 52 years. Most patients ($n=305$) were suffering from hepatitis C not responding to conventional ribavirin therapy.

A total of 405 were performed: 174 manually and 285 with automated device- assistance. Adequate sample was obtained in 98.2% by the former and 100% in the latter. Majority specimen was obtained in single pass

by either method. Sample size was adequate in both but fragmentation was significantly more common with manual biopsy. Assisted device was complicated by hypotension in one case only. Two cases of hypotension and one case each of hematoma formation and vaso vagal syncope was observed in manual method. No indent of biliary leakage or biopsy site infection was observed in either group. Procedure time was significantly shorter on using device (3.6 vs. 8.40 minutes, $p < 0.05$). Need for post procedural analgesia was not markedly different. These details are given in (Tab. 1).

	Manual biopsy N=174	Automated device assisted N=285
Sample adequacy	171 (98.2%)	285 (100%)
Average sample length (mm)	15.4	20.3
Fragmentation	62 (8.68%)	3(1.05%)*
Average number of passes	1.8	1.0
Average procedural time (minutes)	10.40	3.6*
Complications		
- Hematoma	- 01	- nil
- Vasovagal syncope	- 01	- nil
- Hypotension	- 02	- 01
- Infection	- Nil	- nil
- Biliary leakage	- Nil	- nil
Post procedural analgesia	107(61.49%)	173 (60.70%)

Table 1: Comparison of performance of manual and automated device-assisted liver biopsy.

Discussion

Liver biopsy is an essential evaluation tool for chronic hepatitis patients. Sequential 3-5 yearly liver biopsies tend to detect progressive liver disease particularly in the untreated patients.^{6,9,10}

Controversy tends to surround majority of its technical aspects as to who should do it and how? This is apart from the cost particularly when using ultrasound guidance and automated devices.^{7,11} Traditionally, trained physicians used to perform it as a bed side procedure,¹ using palpation and percussion as their guides to the optimal biopsy site. Today, it is mostly radiologists and occasionally gastroenterologists who are performing it under ultrasound guidance.^{1,11} In this study, all the procedures were carried out under ultrasound guidance and all the device- assisted biopsies were performed by the radiologists.

Sampling error is also considered an important issue as only a tiny (less than 1/50000th) tissue sample of the liver is available for analysis.^{2,5} Even that may not

be adequate for histological examination due to fragmentation and small size.^{8,12} In this study remarkable adequacy of specimen was found with both techniques- device assisted being marginally better. However the sample size length obtained by the latter was significantly greater than the manual method. It may be due to the make of the needle or greater maneuvering required in the manual method. The average sample length was 15.4- 20.3 mm in this study (Tab. 1). Ideally a specimen length of 25 mm is required,¹³ which is rarely obtained in practice.¹⁴ Due to this limitation, a satisfactory sample varies from 1-4 cm and a sample which is 1.5 cm in length \pm containing⁴⁻⁶ portal tracts is considered acceptable.^{15,16} Conversely, some even consider a short sample as a positive feature for prognosis.¹⁷ The number of passes were also not very many likely to be due to ultrasound guidance.

The procedure time was significantly shorter in the device- assisted procedure. This is due to the longer time required for introduction of the manual core biopsy needle first with a closed cutting edge and then for stabilization, slow advancement, then opening up the cutting edge to take the sample and finally closing the edge and withdrawing the needle in a closed safe position. In the device- assisted technique all this is pre-arranged by loading and locking the device so that once the device is introduced, specimen is obtained at a click. This considerably reduces the procedure time and helps allay patient's anxiety. This may indirectly be responsible for the lower frequency of hypotension and absence of vaso vagal syncope in the device- assisted technique.

The absence of major complications is comparable to that by Chiraviroli et al.⁸ The absence of hematoma and biliary leakage is most certainly due to adequate selection site under ultrasound guidance. Pressure packing also prevented local hematoma except for one case in manual biopsy where three passes had to be made for obtaining the right sample. Meticulous attention to the asepsis also prevented infection despite the lack of antibiotic coverage.

Ultrasound guided device- assisted liver biopsy is valuable but not available in many local centers. It is therefore a positive aspect of this study that the relative safety and adequacy of the manual method was reaffirmed.

Conclusion

There was no significant difference between the


performances of the two techniques except for shorter time in automated device- assisted method and more fragmentation of sample by manual biopsy.

Disclosure

The automated biopsy device and biopsy kit contents from October 2009 onwards were procured from HEC Research grant number 1121.

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