

ORIGINAL ARTICLE

PAIN ASSOCIATED WITH LIVER BIOPSIES THROUGH PERCUTANEOUS APPROACH UNDER SONO-GRAPHIC GUIDANCE-A CROSS SECTIONAL PILOT STUDY IN A TERTIARY CARE HOSPITAL

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Background: Pain is one of the most common and feared complication of percutaneous liver biopsy under local anaesthesia using sonographic guidance. This observational study was set to judge the intensity of pain felt by adult patients presenting for percutaneous liver biopsy with known/suspected underlying hepatic pathology. **Methods:** This observational cross sectional study which was piloted on 10% of the original sample size was conducted at Aga Khan University Hospital, Karachi. Study population was the adult patients coming for percutaneous liver biopsy at the Department of Radiology. Descriptive statistics were run, data was checked for normality. Means and Standard deviations were done for continuous variables and where data was skewed, median with inter quartile range was computed. Later data was clumped in categories, frequency and percentages were reported for categorical variables. Graphical representation of data was done. **Results:** A total of 50 patients were recruited. Minimum pain reported on visual analogue scale (VAS) was 0 and maximum as 4. 30% of patients rated 3 and similarly 30% of the people rated 4 on the VAS. Mean pain experienced was 2.7 ± 1.11 and a median of 3 on VAS. This indicates that a minority of patients in our survey had a complaint of mild pain during the procedure. **Conclusions:** Percutaneous liver biopsy is a very safe procedure and minimal pain was felt by a minority of patients whereas the rest showed satisfaction from the procedure with no post procedural complaints.

Keywords: Pain, Visual Analogue scale, percutaneous liver biopsy

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INTRODUCTION

The World Health Organization (WHO) estimates that there are 350 million people with chronic HBV infection and 170 million people with chronic HCV infection worldwide.^{1,2} Pakistan is afflicted with a very high prevalence of Hepatitis B and C, chronic hepatitis and hepatocellular carcinoma.³

Percutaneous liver biopsy is considered as a very important intervention for the evaluation of various liver diseases. It is still a gold standard for assessing liver diseases though its role is evolving over time.⁴⁻⁷ Most biopsies are currently performed to assess for the degree of liver damage for parenchymal disease or to monitor the response to therapy.⁸ In addition, biopsies are often done to help in guiding the management of hepatitis C and non-alcoholic steato-hepatitis and to assess the response to therapy.^{5,6} Liver biopsy procedures have been improved over time in various medical centres around the globe and are now performed under ultrasound guidance rather than the previously blinded method.⁹

Among the vast majority of Pakistani population who are affected by chronic hepatitis, there is a recognized fear of this procedure because it is regarded as invasive and painful with the possible risk of grave complications. In one study done on 484 percutaneous biopsy patients, the total complication

rate was 6.4%, of which 4.5% were due to major bleeding; the death rate was 1.6%.¹⁰

The aim of this study was to assess the demographic factors and the pain score of patients undergoing sonographic percutaneous liver biopsy in our hospital.

MATERIAL AND METHODS

An observational pilot was carried out. This was a cross-sectional study which was conducted at the Department of Radiology, Aga Khan University Hospital (AKUH) Karachi, Pakistan. Study duration was one month (November of 2010). Convenient non-probability sampling was done. Those that were part of the eligibility criteria and were not on the in the exclusion criteria were the study population. Only those particular patients were enrolled in the study that fulfilled the following eligibility criteria: had an established or suspected liver pathology due to which they were referred for the procedure, had normal coagulation profile, and were above the age of 18 years. Those who did not give consent were excluded.

The principals of the Declaration of Helsinki (1964, modified 2008)¹¹ were followed. Informed consent was taken from each patient prior to participation in the study. If a patient could not give consent, then informed consent was taken from

guardian/next to kin. Confidentiality of the patient was maintained all the names and personal information regarding any individual was not disclosed and all the names present in the forms were coded.

A 10 centimetre blank visual analogue scale (VAS)¹² was used for assessing the intensity of the pain felt by the patient. Subjects were explained beforehand and were asked to mark the intensity of their pain on this scale in which '0' indicated no pain and '10' indicated severe pain. 10 millilitres of 2% Xylocaine (local anaesthesia) mixed with adrenaline was infiltrated at the biopsy site. The procedure was conducted under ultrasound guidance utilizing an 18/16-gauge disposable Tru-cut needle, along with an automatic gun for extracting the liver biopsy sample. After the procedure finished, the patients were carefully instructed to lie down on their right side in order to put pressure at the bandaged biopsy site for allowing haemostasis for a duration lasting approximately 30 minutes and to remain in bed for the next 2.5 hours. Subjects were requested to grade the intensity of their pain on the visual analogue scale at the end of the procedure (after needle removal) and after 30 minutes duration. Any complications noted during or after the procedure were documented.

Data collection tool employed was a questionnaire. Forms were checked for completeness and consistency. For data entry, a database and entry screen was developed. The data was single entered by a data entry operator. Descriptive statistics were run including frequencies and measures of central tendency and dispersion on continuous variables. Data was checked for normality. Means and standard deviations were reported and where data was skewed median with inter quartile range was reported. Later data was clumped into categories and for categorical variables frequencies and percentages were computed by assessing proportions. Graphical representation of data was done. For association between categorical variables Chi Square was used and when the expected cell count was less than 5 then Fisher's exact test was computer. For association between categorical variable and continuous variable Students *t*-test was done. The data was analysed on SPSS software version 17.

RESULTS

A total of 50 patients were recruited in the pilot study. Out of a total of 50 patients, 35 (70%) were male and 15 (30%) were females, 15 patients (30%) were between 18–25 years of age, 25 patients (50%) were 26–40 years old and 10 patients (20%) were above the age of 40 years.

A total of 30% of patients had rated the visual analogue scale at 3, 30% at 4 and 40% at a

combined 1 and 2 (Table-1). Mean pain experienced was 2.7 ± 1.11 and a median of 3 on the visual analogue scale This indicated that a minority of patients in our survey had the complaint of mild pain (3,4) during the procedure. No patient complained of any pain 30 minutes after the procedure. There were no complications and majority of the patients (70%) were satisfied with the entire procedure.

Table-1: Rating on the VAS

VAS score	Number of participants
1	10
2	10
3	15
4	15

There was an association between younger age (<40years) and reporting mild pain (mean 3.14 ± 0.79) on the visual analogue scale. People more than 40 years of age tolerated pain better (mean 1 ± 0.1) as compared to those younger than 40 years of age using Student test (p -value<0.001).

Similarly the female sex tolerated pain better (mean pain VAS 1.67 ± 0.49) as compared to males who marked mild pain (mean 3.14 ± 1.00) (p -value <0.001).

DISCUSSION

Despite the prevalence and intensity of hepatic diseases, little has been done to understand and evaluate the pain associated with liver biopsy. Usually local anaesthesia is used for the procedure. The right-shoulder pain noted after liver biopsy procedure is a well-known symptom to clinicians that perform these procedures and is likely to be of viscerosomatic origin, instead of suggesting a severe complication like intra-abdominal bleeding. High anxiety levels have been observed to exacerbate the acute postoperative pain on the basis of which the anxiety level can be assessed prior to the procedure.¹³ For stressed patients, the dose of anxiolytic medication should be adjusted, the biopsy site should be infiltrated with longer acting local anaesthetics, and adequate analgesia should be maintained as per requirement.

In another study by Eisenberg *et al*¹⁴ which used 5mg of diazepam orally 1 hour before the procedure and local infiltration with 10 mL of 2% lidocaine just before needle insertion had forty-seven (84%) of the 54 respondents reporting pain 30 min after the biopsy (visual analogue scale, 4.2 ± 0.5) and this corresponds with our findings; 60% who had mild pain immediately after the procedure. Women in the Eisenberg study reported higher pain intensities than men throughout the entire follow-up period, although the difference between sexes was statistically significant ($p < 0.02$) only at the 24-hour time point, whereas in our study men experienced

more pain than women which was statistically significant at 30 minutes. This difference is noteworthy. Higher pain levels in women after liver biopsy were reported in another study also⁸, whereas severe pain was noted in 6 of 30 patients, all men, in another.¹⁵ The cause for the sex differences in pain perception is unknown.

A recent randomized controlled trial used equimolar mixture of oxygen and nitrous oxide (EMONO) inhalation as analgesia before percutaneous liver biopsy in France.¹⁶ Analgesics control was significantly better in the EMONO group than in the placebo group ($p=.045$) The number of patients who agreed to undergo another liver biopsy under the same conditions was significantly higher in the EMONO group than the placebo group (92.0% vs 75.5%, $p=.026$). There were no side-effects from the administration of an EMONO. In another comparative study¹⁷ thirty minutes after the procedure, pain levels were significantly lower in the group given sublingual tramadol HCl (50 mg) flash tabs with oral lorazepam (1.8 ± 0.3) as compared to the group using oral diazepam (5 mg) (3.1 ± 0.3 , $p<0.005$).

The strength of the study was the validated method used for data collection that is, the Visual Analogue Scale which is well recognized & reliable. A limitation of the study was a problem of interviewer/investigator bias could have been introduced in the study and led to information bias but this was taken care of by providing both interviewers with proper training, and a structured questionnaire to reduce interviewer bias.

CONCLUSIONS

Although this was a pilot study, it clearly showed that some patients feel mild intensity of pain during percutaneous liver biopsy procedures. A better understanding of pain related to the procedure can be performed with larger scale studies. However, there is always room for improvement and patient comfort should always be borne in mind for successful outcomes and in providing a satisfactory interventional experience. Future studies can be designed to evaluate the analgesic efficacy and safety of newer techniques of pain management like an equimolar mixture of oxygen and nitrous oxide (EMONO) inhalation.¹⁸

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