MANUSCRIPT CATEGORY – ORIGINAL ARTICLE

Title:
Targeted ultrasound of the liver: impact on scanning time of a new approach in chronic liver disease.

Running title:
TUSL for chronic liver disease

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Abstract and Keywords:

Introduction:
Targeted ultrasound of the liver (TUSL) has been proposed as a new approach in chronic liver disease to meet the increasing demands on ultrasound services in this patient population. This study analyses the impact of TUSL on examination time.

Methods:
Retrospective cohort analysis of time taken to perform liver ultrasound on consecutive chronic liver disease patients pre- (n=230) and post- (n=147) introduction of TUSL. Within each cohort patients were subdivided into three categories based on the clinical indication: Group 1. hepatocellular carcinoma (HCC) surveillance; Group 2. detection of cirrhosis, fibrosis or fatty liver; Group 3. detection of portal hypertension.

The primary outcome was difference in examination time in the pre and post intervention groups.

Results:
Introduction of TUSL led to 49% reduction in examination time (median (Q1-Q3) 23.7 (16.7-36.2) min in pre TUSL period vs 12.1 (6.4-19.5) min in post, p<0.001) and it was consistent across all three clinical indication groups (gr1: median 23.1 minutes vs 8.1 minutes [p<0.001], gr2: 23.0 minutes vs 14.3 minutes [p<0.001], gr3: 32.2 minutes vs 15.3 minutes [p = 0.006]). After the adjustment for clinical indication and sonographer’s experience impact of TUSL on time reduction remained significant with a 66.6% time reduction. (95%CI 53.6 to 79.5).

Conclusion:
TUSL improves efficiency of chronic liver disease ultrasound with halving of examination times and consequently has the potential to greatly improve resource utilization.

Keywords: liver, chronic liver disease, ultrasound, cirrhosis, hepatocellular carcinoma

Introduction:
Chronic liver disease prevalence is increasing in Australia as in other parts of the world. Liver disease currently affects more than six million Australians with an annual cost burden that now exceeds that of diabetes and chronic kidney disease combined. Furthermore, hepatocellular carcinoma (HCC), a fatal complication of chronic liver disease has become the fastest growing cause of cancer death in the country. It is well established that ultrasound is the modality of choice to screen for chronic liver disease. The change in prevalence of chronic liver disease has resulted in
increasing demands on ultrasound services for both diagnosis and surveillance for complications. Much of the referral base for these patients is from specialists, typically gastroenterologists, hepatologists and infectious diseases physicians, and specific clinical questions are usually asked of the ultrasound examination. Against this background an approach has been proposed for targeted ultrasound of the liver (TUSL). In this approach a matrix has been devised which guides the sonographers on what to examine dependent on the clinical question. The aim is to improve efficiency by focusing on answering the specific clinical questions rather than performing complete upper abdominal ultrasound studies, which has been the usual abdominal ultrasound scanning model in Australia.

This TUSL approach was introduced at our institution in 2012 and anecdotally appeared to have improved resource utilization. To our knowledge no one has analysed the impact of TUSL on examination time. The aim of this study was to assess the impact of this approach on efficiency by comparing the ultrasound scanning times before and after its introduction.

**Methodology:**

**Study design:**

This was a retrospective cohort analysis of time taken to perform liver ultrasounds on consecutive chronic liver disease patients prior to the introduction of the TUSL protocol and following the introduction of the protocol.

The TUSL protocol is based on the matrix shown in Table 1. This matrix guides the sonographer on what to examine based on the clinical question. Column 1 represents the request questions or indications for examination in the form they are usually asked. There is overlap and duplication in some of the request categories in keeping with the real life variation in clinical questions asked. Columns 2-5 describe what parts of the ultrasound examination the sonographer should perform in order to answer the clinical question. The primary purpose of column 2 ‘survey liver for focal lesions’ is to carefully examine the entire liver for any focal lesion that may require further work up as possible HCC, and to assess the liver for fatty infiltration. Column 3 ‘cirrhosis images’ requires assessment of the liver for evidence of cirrhosis by reviewing the liver and hepatic vein surfaces for nodularity, and internal liver parenchyma for nodularity.
Column 4 ‘Ligamentum Teres’ is utilized in patient groups where the likelihood of portal hypertension is low but its detection may help clarify the sonographic diagnosis of cirrhosis in more equivocal cases. It requires the sonographer to assess for the presence of a patent paraumbilical vein as a sign of portal hypertension. This is indicated by widening (>2.5 mm) of a hypoechoic channel within the ligamentum teres or hepatofugal venous flow within it, either being a specific sign of portal hypertension (PHT). The final column, column 5 ‘Portal and hepatic veins, ligamentum teres, and spleen for PHT’ includes a formal portal and hepatic vein Doppler assessment and spleen size measurement to assess for portal hypertension. Spleen size is measured using craniocaudal length in coronal plane with 13 cm taken as upper limit of normal.

The TUSL protocol not only includes the targeted ultrasound examination as described but also involves provision of a targeted report. The targeted report includes the indication for examination, the sonographic findings and a statement explaining that only a focused limited examination was performed to answer the specific clinical question.

It should be stressed that there is the option to extend the TUSL examination and the report should an unexpected or significant finding be discovered during the examination.

**Study setting and population:**

Cases were identified using the institutions Radiology Information System. Cases included in the pre-TUSL cohort included any upper abdominal ultrasound referred by Gastroenterology or Infectious Diseases units, between May and August 2011 inclusive, with the clinical question being HCC, cirrhosis, fibrosis, Hepatitis B or C initial screening study, fatty liver disease, non-alcoholic fatty liver disease, non-alcoholic hepatic steatosis or portal hypertension. Cases included in the post TUSL cohort were any upper abdominal ultrasound reported as a targeted ultrasound of the liver between May and August 2012 inclusive. The TUSL protocol was introduced into our institution in March 2012. The time period chosen to assess the intervention commenced in May 2012 which provided a two-month period for the protocol to have become routinely used. Data collection finished at end of August 2012. The dates chosen for pre-TUSL protocol cohort included the same time period of the year, one the year prior to the introduction of the TUSL protocol.
**Data collection and analysis:**

Information collected on both groups included i) date of ultrasound study, ii) clinical indication, iii) indication for study correlated to first column of the TUSL matrix, iv) start and finish time of ultrasound examination, defined as time of first and last image taken, respectively, v) Sonographer(s) who completed the study. Of note the sonographer information was recorded using a binary system, (1 = single trained sonographer, 2 = trainee sonographer followed by trained sonographer). The purpose of this was to have a method of identifying when a trainee sonographer was involved which then necessitated a secondary scan by a trained sonographer. Ultrasound examinations completed by multiple sonographers therefore reflected these studies.

After the information was collected the clinical indications of the studies were correlated to the TUSL matrix with three main indication categories being further devised to reflect the three main types of clinical questions asked (see Table 2):

Category 1: those indications querying HCC, Category 2: those indications querying cirrhosis, fibrosis or fatty liver, and Category 3: those indications querying portal hypertension.

All data analyses were performed using Stata 12 (StataCorp, TX, USA) and $p<0.05$ was considered statistically significant.

Kruskall-Wallis test was used to determine the difference in examination time based on the time of the assessment (pre or post the introduction of TUSL), sonographer experience (trained versus trainee) and indication category (1: ?HCC, 2: ?Cirrhosis, fibrosis or fatty liver, and 3: ?portal hypertension).

Associations between sonographer experience and indication category and examination time were performed within and between groups (pre and post introduction of TUSL). Multivariate gamma regression analysis was undertaken to determine the impact of TUSL introduction on the examination time while adjusting for sonographers’ experience and indication category.

**Results:**

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There were 230 cases in the pre-TUSL period and 147 in the post-TUSL period (Table 3). Both cohorts were similar in terms of clinical indication and sonographer experience.

In both cohorts just over 60% of cases were in the category 1, approximately 30% of cases were in category 2, and less than 10% in category 3. A single sonographer performed the vast majority of examinations in both cohorts.

Univariate analysis demonstrated a 49% decrease in the scanning time in the post-TUSL cohort compared to the pre-TUSL cohort with median scanning time in the post-TUSL cohort being 12.1 minutes, versus 23.7 minutes in the pre-TUSL group (p<0.001) (Figure 1).

A breakdown of ultrasound examination times by indication for the pre and post TUSL cohorts (Figure 2) revealed a statistically significant reduction in examination time for all three clinical indication categories after introduction of TUSL protocol. Category 1 examination times reduced from 23.1 to 8.1 minutes (p<0.001), category 2 reduced from 23.0 minutes to 14.3 minutes (p<0.001), and category 3 reduced from 32.2 to 15.3 minutes (p=0.006).

Multivariate regression analysis revealed an overall 66.6% (95%CI 53.6 to 79.5) reduction in time secondary to the TUSL intervention when adjusted for indication of study and sonographer experience.

**Discussion:**

Liver disease affects over a quarter of Australia’s population and is responsible for one quarter of all organ transplants\(^1\). The prevalence of common causes of chronic liver disease including hepatitis B and C, and NAFLD is increasing with NAFLD, for example, affecting 5.5 million Australians\(^1\).

Historically ultrasound referrals to assess for the presence and the complications of chronic liver disease have come from subspecialists typically gastroenterologists, hepatologists and infectious diseases physicians\(^7\). However, given the increasing and sizeable prevalence of liver disease these subspecialists are now recommending General Practitioners directly refer for ultrasonic liver screening\(^6,12\).
This combination of an increasing prevalence of chronic liver disease and its associated complications, and a broadening referral base, has resulted in a growing demand on already busy ultrasound services, a growth which will undoubtedly continue. This makes the use of an efficient approach important in terms of resource utilization.

The major benefit of the TUSL protocol is efficiency. This study demonstrated that the introduction of the TUSL protocol approximately halved overall scanning times, regardless of the indication for the examination and the experience of the sonographer completing the scan. Statistically significant time reduction was seen for all examination indications included in the study with the greatest reduction in examination time seen in patients with the clinical indication of HCC screening. In this group examination times decreased to approximately one third (median time 23.1 vs 8.1 minutes).

A potential but unproven secondary benefit to introduction of the TUSL protocol may be improvement in the accuracy of the examination. Accuracy of the TUSL examination was not addressed by this study and would be difficult to assess. It is conceivable, however, that the accuracy of the examination may be improved given that sonographers can focus on the clinical question and not be potentially distracted by completing an unnecessary comprehensive upper abdominal examination.

The concept of focused examinations is not new to medicine in general or even ultrasound imaging, for example cardiologists typically examine only the cardiovascular system during consultations, and ultrasound is commonly restricted to just the renal tract when assessing renal pathology. Nevertheless, the common model for ultrasound examination of the liver in Australia at least, is to complete a comprehensive upper abdominal ultrasound examination including assessment of the biliary system, pancreas, kidneys and spleen regardless of the specificity of the clinical question. TUSL appears to be the first protocol of its kind in directing a limited upper abdominal ultrasound in patients with chronic liver disease tailored to the clinical question being asked.
An issue that may be raised by some is the potential for TUSL to overlook incidental abdominal findings in the abdomen. In reality the focused approach is no different from that used in many other ultrasound areas. For example, a Doppler ultrasound of the aorta and iliac arteries does not routinely evaluate the liver. The clinical question is what should dictate the focus of the study regardless of whether or not the examination is the first ultrasound performed. If it were argued that the examination should be a comprehensive abdominal study at the first examination, for example, it could be argued that scans thereafter should be comprehensive as pathology may have developed in the interim. TUSL is intended to be used in a specific patient population with specific clinical questions. The guidelines developed for TUSL do however stress the need to use clinical judgment and depending on what may be seen in the focused study to extend the examination appropriately.

This study does have some limitations. Firstly, the time measurements used in analysis represented the actual ultrasound scanning time, that is, between the first image and the last image acquisition time, rather than the total sonographer time. However, the scanning time was the most objective measure available with this study design and represents a substantial component of the total sonographer and ultrasound room time for each examination.

The applicability of these findings to other practices would depend mainly on the referral population and the specificity of the clinical questions being asked. It is most likely that the nature of the clinical questions will be essentially the same in centres referring this patient population for ultrasound so it could be predicted that similar time savings would be observed.

In some of this patient population ultrasound elastography would also be appropriate. This could easily be built into the TUSL matrix in centres providing ultrasound elastography using conventional ultrasound imaging machines (as distinct from mechanical transient elastography). Whilst elastography will add time to the examination, the time savings described in this report would still apply to the remainder of the examination.

**Conclusion:**
TUSL uses a matrix to match the focus of the ultrasound examination to the clinical question. This study demonstrates that TUSL improves efficiency of chronic liver disease ultrasound with approximately 50% reduction in scanning time. In patients where the clinical question is purely HCC surveillance the scanning time is reduced to one third. Given the results of this study we feel TUSL has the potential to greatly improve ultrasound utilization in an era of increasing demands and should be used in the appropriate clinical settings. It may also improve accuracy as a result of the focused nature of the examination although this is as yet unproven.

References:


Figure 1: Box plot of overall ultrasound time by TUSL intervention. The central bar is equal to the median ultrasound examination time, the boxes the interquartile range, the bars three standard deviations and the dots the outliers. Significant examination time reduction of almost 50% was seen after the introduction of the TUSL intervention with overall examination times reducing from 23.7 to 12.1 minutes.

TUSL – Targeted Ultrasound of the Liver

Figure 2: Box plot of the ultrasound time by clinical indication for the pre and post TUSL cohorts. The central bar is equal to the median ultrasound examination time, the boxes the interquartile range, the bars three standard deviations and the dots the outliers. The clinical indication categories are: 1 - HCC, 2 - cirrhosis or fatty liver, 3 - portal hypertension. Significant examination time reduction was seen in all three clinical indication categories after the introduction of TUSL with the largest reduction seen in category 1 reducing from 23.9 minutes to 8.1 minutes.

TUSL – Targeted Ultrasound of the Liver
Table 1: Targeted Ultrasound of the Liver matrix. Guidelines for Chronic Liver Disease studies.¹

Look at both the examination request and the clinical notes to determine the real nature of the request. For the indications below there is no routine need for renal and pancreas study unless there is some specific indication or finding. “Survey Liver” means careful examination of liver for focal lesions – do not study gallbladder, bile ducts, kidneys, pancreas, spleen or portal vein Doppler unless findings during the examination indicate this is appropriate. These guidelines should not replace clinical judgment. If in doubt ask the supervising radiologist before starting.

<table>
<thead>
<tr>
<th>Column 1</th>
<th>Column 2</th>
<th>Column 3</th>
<th>Column 4</th>
<th>Column 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Request</td>
<td>Survey for focal liver lesions</td>
<td>Cirrhosis images:</td>
<td>Lig teres (PUV)</td>
<td>Portal &amp; hep veins, PUV and spleen for Portal HT</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- hi res surface</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>- hi res left lobe</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Table 2: Ultrasound request clinical indications grouped into three main clinical indication categories and correlated with the Targeted Ultrasound of the Liver matrix.

<table>
<thead>
<tr>
<th>Category</th>
<th>Request</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 - ?HCC</td>
<td>Surveillance/screen for HCC ?focal liver lesion</td>
</tr>
<tr>
<td></td>
<td>Known cirrhosis ?HCC</td>
</tr>
<tr>
<td></td>
<td>?Cirrhosis ?HCC</td>
</tr>
<tr>
<td></td>
<td>?fibrosis ?cirrhosis</td>
</tr>
<tr>
<td></td>
<td>HBV/HCV initial study</td>
</tr>
<tr>
<td></td>
<td>?FLD/fatty liver disease/NAFLD/NASH</td>
</tr>
</tbody>
</table>

Table 3: Breakdown of Pre and Post Targeted Ultrasound of Liver intervention cohorts by clinical indication category (1: ?HCC, 2: ?cirrhosis or fatty liver, 3: ?portal hypertension) and number of sonographers completing the examination.

<table>
<thead>
<tr>
<th>Category</th>
<th>Pre-TUSL (%)</th>
<th>Post TUSL (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total</td>
<td>230 (61.0)</td>
<td>147 (39.0)</td>
</tr>
<tr>
<td>Category</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>143 (62.2)</td>
<td>93 (63.3)</td>
</tr>
<tr>
<td>2</td>
<td>73 (31.7)</td>
<td>43 (29.3)</td>
</tr>
<tr>
<td>3</td>
<td>14 (6.1)</td>
<td>11 (7.5)</td>
</tr>
<tr>
<td>Sonographers</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>200 (87.0)</td>
<td>129 (87.8)</td>
</tr>
<tr>
<td>2</td>
<td>30 (13.0)</td>
<td>18 (12.2)</td>
</tr>
</tbody>
</table>

TUSL – Targeted Ultrasound of the Liver, HCC – hepatocellular carcinoma
US time by indication for pre- and post-TUSL

Category

HCC Cirrhosis/Fatty liver Portal HTN

Pre Post

Overall US time for

60 40 20

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