Comparing image guidance systems to improve complex navigation in medicine

CF Cuijpers[1], C Klink[2], PJ Stappers[1], A Freudenthal[1]

[1] *Industrial Design Engineering, Delft University of Technology, Delft, the Netherlands*

[2] *Department of Interventional Radiology, Erasmus Medical Center, Rotterdam, the Netherlands*

Abstract: One of the most technically challenging procedure in interventional radiology is a transjugular intrahepatic portosystemic shunt (TIPS) placement. The main problem is the limited image guidance while navigating. The physician basically punctures blind through the liver into the target portal vein, leading to many unsuccessful punctures and unnecessary risks before access to the portal vein is gained. To be able to improve guidance, developers have to be sure to use the most promising image modality available. This paper compares the available modalities for TIPS to various criteria to find which modality is the most suitable to improve the success of the puncture. Results showed that, even though many user interface improvements are required, real-time three-dimensional ultrasound has the most potential to improve the puncture in the future. The study emphasizes the importance of thorough technology analysis before developing medical devices.

Keywords: Image guidance systems, navigation, user interface, modality comparison, three-dimensional ultrasound, transjugular intrahepatic portosystemic shunt

1. INTRODUCTION

In interventional radiology the physician operates by moving thin instruments through the patient's body. The instruments are inserted in small incision in the patient's neck or groin, and the physician is guided by radiological images (Cuijpers et al, 2012). Navigating, or wayfinding, through the body is extremely challenging, especially during the creation of a transjugular intrahepatic portosystemic shunt (TIPS). During TIPS, the interventional radiologist (IR) aims to create a shunt (using a metallic stent) in the liver to treat patients with life-threatening portal hypertension (Boyvat et al, 2006). The shunt decreases portal blood pressure and stimulates bloodflow (Boyvat et al, 2006). Although different hospitals employ different imaging modalities, the X-ray modalities computed tomography (CT) and fluoroscopy (XA) are mainly used as image guidance. CT is used for diagnostic purposes and XA for therapeutic purposes. Although ultrasound (US) and magnetic resonance (MR) do not use X-ray, they are less popular. Yet, both can be used for diagnostics, and US also for therapeutics (Adamus et al, 2009; Rose et al, 2000; Varga & Freudenthal , 2011).

A main problem in TIPS is the information lack (Cuijpers et al, 2012), especially for the intrahepatic puncture (Rose et al, 2000). The physician basically punctures blind while navigating through the liver to gain access to the portal vein (Adamus et al, 2009). This causes unnecessary risks. The IR needs constantly-updated three-dimensional (3D) information about needle position and anatomy (e.g., veins), seen from the best viewing angle. At present, information is unfortunately incomplete, two-dimensional (2D), hardly real-time, only limited planes are available and the user interfaces are not ergonomically well-designed (Cuijpers et al, 2012; Varga et al, 2012). Clearly, more visual assistance is required.

Our project team aims to develop a significantly improved image guidance technique for TIPS. To do this, it is important to choose the most suitable modality, since each of the four modalities enable different guidance. Unfortunately, literature (e.g., Kraus, 1995) does not provide a comprehensive comparison of the different TIPS image modalities for intra-operative use, including medical and non-medical advantages, bottlenecks and desired improvements. Current research groups mainly focus on using X-ray as a basic modality (e.g., Adamus et al, 2009; Jomier et al, 2006). However, X-ray is harmful for patient, physician, society and environment (Frush & Applegate, 2004; Picano 2004; Suhova et al, 2003; Health Council of the Netherlands, 2012). Although TIPS eliminates a potential life-threatening condition and the used radiation dose is therefore justified (Zweers et al, 1998), magnitude X-ray substantially increases health risks. US and MR, are modalities without ionizing radiation (Daffner 1999; Haaga 2001). Yet, image guidance developers consider these modalities less often to improve the blind puncture. Also, the use of 3D US has hardly been explored, even though it shows noteworthy potential for TIPS procedures (Rose et al, 2000).

The aim of this paper is to compare possible TIPS image guidance modalities to a broad range of criteria, and to know which modality has the most potential to improve the intrahepatic puncture on the long-term (figure 1).

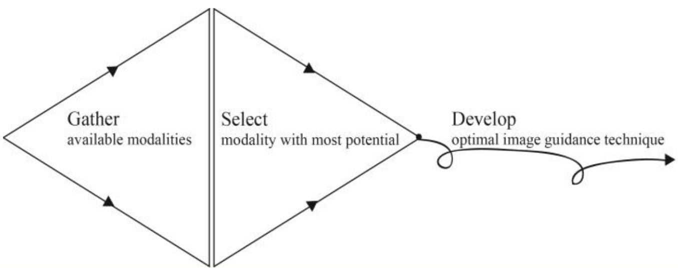

Figure 1. Research approach to select image guidance modality for essential information and minimal development risks.

2. METHODS

According to Freudenthal et al. (2007) comparison of technical solutions to various criteria is needed to support innovation. Therefore, a list of criteria was conducted and the four modalities were compared. The list includes medical and non-medical aspects, clustered in three categories; clinical utility, availability, sustainability. To map the different characteristics of the TIPS image modalities, literature was reviewed and ethnographic studies (e.g., observations, interviews) were performed. Eight TIPS procedures were observed, and generative sessions with six IRs from four different hospitals were held (see Cuijpers et al, 2012). The remaining, unanswered criteria ('easy to use' etc.) were evaluated with specialists' feedback. Trends and advances in cognitive system engineering and imaging technology were defined from literature and listed to know how to make the modalities more suitable for TIPS.

3. RESULTS

3.1 Modalities commonly used in TIPS (details in table 1)

Computed tomography (CT) generates contiguous tomographic 2D images of the patient (Fenster et al, 2011) providing superlative anatomic detail (Haaga, 2001). The image set allows IRs to reconstruct a mental 3D representation of patient's anatomy. The images are made pre-operatively to plan TIPS and are used intra-operatively to extract actual detailed information about the anatomy and to estimate puncture direction. Disadvantages are that the images consist of 'old' information. Besides, CT is expensive and, after natural sources, the largest source of ionizing radiation (Frush & Applegate, 2004).

Magnetic resonance (MR) displays structures similarly to CT (Daffner, 1999), but normally allows better distinction of soft tissue (Jalote-Parmar, 2009). Big advantages are freedom in plane selection and no ionizing radiation (Daffner, 1999). MR is less commonly used, since MR is more sensitive for artefacts (e.g., metal, pulsation) and acquisition of images is time-consuming and expensive (Herfath, 2009; Jalote-Parmar, 2009).

Fluoroscopy (XA) emits continuous X-rays through a body part to make real-time projections of the desired area. Mainly radio-opaque elements (needle etc.) are presented on a screen in 2D (e.g., Daffner, 1999). With foot control, XA can be activated, which allows the IR to use the hands for controlling instruments. Unfortunately, soft tissue is badly visible (Rose et al, 2000) and the high radiation dose restricts XA use. To still achieve spatial orientation, participants said to rely on the CT and their background knowledge.

In two-dimensional **ultrasound** (2D US), information of the internal organs is generated by positioning a hand-held transducer on the patient's skin. The transducer transmits acoustic waves into the body (Ortiz et al, 2012) to create a 2D image plane (with a small field of view). To acquire sufficient, 3D information, the IR positions the transducer in different angles and mentally assembles the data. 2D US is cheap, harmless and the ability of rapidly generating the images, allows the IR to see valuable information in real-time (Herfath, 2009; Obruchkov, 2008). On the other hand, the inefficient acquisition, anatomical constraints (e.g., bone creates acoustic shadows)(Rose et al, 2000), penetration limitations (Ortiz et al, 2012), and a lack of context (Ortiz et al, 2012) make the use challenging (especially in TIPS patients with ascites and cirrhosis (Adamus et al, 2009), inefficient and operator-dependent (Fenstert et al, 2002; Fenster et al, 2011; Ortiz et al, 2012). Next to the operating IR, an additional IR is needed to control the probe and acquire valuable information (Adamus et al, 2009). The need for close collaboration and clear communication makes the use challenging.
In 3D US, 2D planes are created from a volume and displayed on the user interface. Any slice in the 3D US cone can be calculated, allowing to display any desired plane (Fenster et al, 2011; Rose et al, 2000). According to Rose et al (2000) 3D US provides positional and directional information and identifies specific technical errors or altered anatomy. The modality improves understanding of 3D relationships (Rose et al, 2001), overcomes operator dependency (Fenster & Downey, 2000), is 'theoretically free from the most anatomic 2D US constraints and provides planes impossible to view with 2D US (Rose et al, 2000)'. Recently, 3D US systems have the capacity to show real-time 3D images. Real-time 3D US allows the IR to accurately monitor (Fenster et al, 2002), measure, and manipulate the location of an inserted needle and anatomy in 3D (Fenster & Downey 2000; Obruchkov, 2008). However, the user interface is complex and does not fit the current therapeutic workflow (Fenster & Downey, 2000; Obruchkov, 2008).

Contrast agents are used to visualize the lumen of blood vessels on XA. The dye is extremely noxious for patient (can cause renal failure) and sometimes even causes life-threatening allergic reactions (e.g., Daffner, 1999). Therefore, the use is constantly balanced (Freudenthal et al, 2007). In some cases, the dye cannot be used (Rose et al, 2000), significantly diminishing the usefulness of XA. Contrast dye is also used to intensify the MR, CT or US image (Daffner, 1999), but is not standard and the amount needed is less.

Table 1. Comparison of TIPS image modalities used for the intrahepatic puncture (see endnote)

	MR	**CT**	**2D US/3D US**	**XA**
Clinical utility				
Achieved pre- or intraoperative?	Pre-operatively	Pre-operatively	Intra-operatively (sometimes both)	Intra-operatively
Real-time	No	No [7]	**Yes** [24]	Yes, but short moments
Details of bony structures	Medium [18]	**Good** [18]	Poor [18]	**Good** [5]
Details of soft tissue	**Good** [18]	Medium [18]	**Good** [8]	No [8]
Details of veins	Medium	Medium, with contrast	**Good**	Good, with contrast
Hand-controlled transducer	**No**	**No**	Yes [24][10]	**No**
Field of view	**Wide** [18]	**Wide** [18]	Small [8] and limited penetration [24]	**Wide**
3D information	**Yes** [10]	**Yes** [10]	2DUS No, **3D yes** [18]	No [5]
Visualize any plane without moving the patient	**Yes: any plane** [18]	No [18]; axial and transverse [5]	2D: not any plane. **3D theoretically does** [29]	Limited [29]
Quality depending on operator (objective and reproducible)	**Medium**	**Medium**	2D: Yes, **3D: Medium**	**Medium**
Easy to use for reference	**Yes, on screen.**	**Yes, on screen.**	No; manually control	**Yes, on screen.**
Easy to generate	No: time-consuming [18]	Medium, limited scans. Physician needs to leave the examination room [7]	**Yes**; easily accessible, but much experience required [5]	**Yes;** fast [5], but toxic: limited XA time applicable/ careful use, leave examination room, wear protections
Easy to learn	Medium	**Yes**	Difficult [24]*	**Yes**
Trust in system (deviations)	**High**	**High**	Medium	Low
Patient comfort	Low	Medium	**Ok**	**Ok**
Availability				
Relative costs (device & scan)	Very high [16]	High	**Low** [24][32]	**Low** [5]
Portability device	No	No	**Yes** [24]	Yes, portable devices are available, but more heavy and cumbersome than US.
Quickly available for/during TIPS	No	Medium	**Yes**	**Yes**
Time to complete scan (minutes)	30 [18]	**5** [18]	**5**	**5**
Mean time modality used (minutes)	30	5	Less than XA	38.7 [22]
Require harmful ionizing radiation	**No** (magnets & radiofrequent waves) [5]	Low Dose [32]	**No** (soundwaves) [24]	High Dose [22]
Possible reduction of life expectancy	**No** [32]	Yes [32]	**No** [32]	Yes [32]
Risks from modality	**Nihil****, but screen patient for contra-indications.	Low [7] risk of cancer [13][16]	**Nihil** [24]	Low [7]: radiation injury skin patient [22], cancer risk physician[16]
Usable when child/pregnant [e.g.,15]	**Yes**	Last option	**Yes**	Last option
Risks from contrast-dye: dye basis	Low: Gd	Medium: I	**No:** N + NaCl	Medium:I/CO2[5][1]
Mean amount of dye used for TIPS	Unknown	80 ml	25 + 5 ml	200 ml
Sustainability				
Specific critical materials (apart from basic electronics) [17]	He, Al, N, magnets (often Nb, Ti, Cu)[27]	Be, Al, Si, W, Re, Cu, B, Xe, Pb[27][31][3]	**Pb, Zr, Ti** [30]	Ti, Al, Na, Cs, I, Sb, Zn, Cd, S, Ag, W, Re [31][35][3]
Risk for resources scarcity	?	?	?	?
Energy consumption	High	Medium	**Low**	**Low**
Biohazards impact	**No** [32]	Yes [32]	**No** [32]	Yes [32]
Other				
	**Valuable for diagnosing abnormalities. Unusable when metal in patient. [18]	Detects subtle difference tissue Need contrast dye to see soft tissue [18]	* Bone and air can decrease visualization [18][5]. Images lack context	
Total amount of listed advantages compared to other modalities (**bold**=the most advantageous per criteria**)**	13	9	2D US:16, **3D US: 19**	12

3.2 Desired user interface changes

To really benefit the IR, the user interface of future's visualization system should be intuitive and user-friendly, and information needs to be conform experts' decision making strategies (Jalote-Parmar, 2009). In general, users wish to see planes which visualize the 3D relationship of the exiting needle in the hepatic vein, the target portal vein and surrounding critical structures (Adamus et al, 2009; Rose et al, 2000) in real-time (Cuijpers et al, 2012). The required information should be provided for each and every macro and micro step, on the desired moment and in the desired way, without increasing cognitive load (Cuijpers et al, 2012). Finally, the UI-interaction should be intuitive, fast (Fenster et al, 2011) and accessible (table 2).

In the near future, emerging advances in medical technology (table 2) could solve some of the current disadvantages (see 3.1) of each modality. To enhance perception and comprehension of critical information, the future's image guidance interface could integrate information of different modalities with registration and segmentation tools (Fenster et al, 2011; Jalote-Parmar et al, 2010). The information can be filtered to only visualize desired elements. However, the probability that a proper TIPS visualization system can be created varies per modality. To illustrate, we will discuss the required user interface changes per modality.

Currently, **CT** is a reliable image modality in which structures can easily be distinguished. However, to improve the interface the IR should not manually scroll through the whole dataset, instead the interface should automatically present preferred, oblique slices and less extensive information. More important, information should become real-time. Unfortunately, it will require a lot of radiation to achieve this. Besides, the intra-operative workspace becomes limited and the needle will cause artefacts.

To improve the **MR** interface, information should also become real-time and less extensive. However, the limited workspace in a MR scan and the magnetic character of MR will then hinder the procedure since special, MR compatible, products are required.

For **XA**, the user interface should also constantly visualize the hepatic vein and portal vein. Besides, the IR should be able to constantly achieve real-time information from two directions. Unfortunately, the radiation does not allow this.

The desired **US** interface should present information without artefacts, regardless of patient characteristics and contact of the probe with patient's skin. The information should provide less focused information, but instead provide more overview of the body (i.e. depth, surrounding structures). Furthermore, to make US usable for TIPS, probe control should be effortless.

These results illustrate that to choose the most suitable modality, not only the different criteria, but also the realizable interface changes should be taken into account.

Table 2. Desired and possible user interface changes. Sources: [34][19][33][10][4]

Trends in Cognitive System Engineering
Support physician's cognition, e.g.: Information: • Improve information visualization for spatial orientation • Easy navigation • Decrease cognitive load • Conform expert decision-making strategies • Support all levels of complexity • Minimal learning curve • Trustworthy Control: • Minimal user intervention • Intuitive • Transparent • Predictable • Tolerance of errors
Conform workflow, e.g.; • For each micro step • On preferred time • Usable by different users • Fast • Convenient • Appropriate interaction
Advances in Medical Imaging Technology:
Image registration and fusion Instrument tracking Path planning (3D) Compensation for motion & deformation Rendering method Segmentation Imaging data automation

4. DISCUSSION

To make the complex navigation process in TIPS less challenging, image guidance improvements are needed. Image guidance modalities were compared as well as the required changes per modality. Results show that each modality provides unique information, but also have their shortcomings. As a result, physicians combine different modalities to obtain the necessary information. CT visualizes veins and other structures well, but information is not real-time. XA projects the needle movement in real-time, but only in 2D and for short moments in time, and lacks visualization of soft tissue. Besides, both modalities are harmful. MR uses non-ionising radiation and can visualize any plane, but acquisition is expensive and time-consuming. Besides, images are not real-time and sensitive for artefacts. 2D US can visualize anatomy and instruments in real-time, without risks. The modality is inexpensive and widely available, but visualization of anatomy is limited (e.g., depth, size), difficult to generate and operator dependent. Furthermore, an extra IR is needed to control the transducer. Real-time 3D US has the benefits of real-time 2D US, but with less disadvantages. Any plane in the 3D cone can be freely selected and information is 3D. However, the user interface is complex and is not usable in its current form. Results also show that, of all modalities, the real-time 3D US user interface needs least technical changes and thus the development will be less time-consuming. Information is already 3D and real-time, and US also allows sufficient workspace and the interface improvements do not require changes in materials (such as non-magnetic needle), an increase of radiation or extra contrast dye.

Clearly, real-time 3D US has the most potential to guide the physician during the blind puncture, and to improve the navigation process. Some may take this conclusion as obvious; nevertheless, such a comprehensive study and conclusion has not yet been reported in literature. The modality is still far from perfect, but contains the most benefits and demands harmless improvements compared to other modalities. By adding desired data from other modalities, such as available CT, visualization barriers will be minimized while acquisition of extra (harmful) data is unnecessary; minimizing the impact on health and cost. Nevertheless, cognitive requirement need to be uncovered first, to decrease the complex control of the modality and make it more intuitive. IRs should be able to acquire and interpret the image in a (for IRs) useful and efficient way, for each step of the workflow and for each situation, without requiring an extra physician and without increasing cognitive load.

Sustainability was included in the comparison, mainly because the use of critical materials can increase the chance of supply problems. Companies could go short to produce or supply and, subsequently, procedures cannot be performed. Although limited information is available, results imply that US is the most sustainable. More awareness and actions are needed to avoid such serious problems in the future.

In this paper, we did not weigh each criterion neither we used another ranking approach. Instead, we desired to simply designate the most advantageous modality per requirement. The criteria were not prioritized, since prioritising depends on expertise and is thus subjective. However, we are aware of the fact that other approaches are available, such as the fuzzy set approach (De, 1992). Nevertheless, we expect that the different approaches would all lead to the same overall conclusion.

Research on TIPS workflow and physicians' needs and cognition was already conducted by Cuijpers et al. (2012). Together with the result of this paper, a thorough basis to support innovative development is thus created. In future research, we will make, test and present technical improvements. First, we will analyse the information provision and control of an existing real-time 3D US device. The insights will allow our multi-disciplinary team to redesign the real-time 3D US user interface and iteratively test ideas. When information from other modalities is needed (e.g., CT), we will integrate the required information in the user interface. To bridge the gap between technology and user (Freudenthal et al, 2007), technology developers will closely collaborate and constantly interact with the end-users. An advantage of US is that testing is harmless, which allows quick design iterations and an increased chance of improving the interface. In the end, we think US will become a very useful TIPS technique.

5. CONCLUSIONS

Currently, image modalities do not sufficiently guide the physician during the intrahepatic puncture. The study showed that real-time 3D US has the most potential to improve the guidance during the puncture on the long-term. However, the real-time 3D US user interface should be re-designed to improve usability, and registration with CT is needed to rule out visualization barriers. Although improvements are still needed, the prospect for successful development of US-based interventions appears promising. This suggests a new generation of equipment which satisfies a broad range of quality criteria, including navigation support, but also reduction of scarcity and hazardous side-effects. Overall, this paper shows the importance of a thorough technology comparison to support innovation in medicine.

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ENDNOTE

The materials listed in 'specific critical materials' (Table 2) are mainly based on popular sources cited, not on scientific sources or product specifications of manufacturers, since that information was not available.

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