Cognitive task analysis and prioritization to improve image guidance of TIPS.

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Summary

TIPS placement is one of the most technically challenging procedures in interventional radiology. During TIPS, limited image guidance (IG) is provided, especially during the intrahepatic puncture. To develop a suitable IG system, the aim of this study was (1) to know what parts of the procedure developers need to focus to contribute to a successful TIPS placement and (2) to find possible solutions for the IG system. Action research and co-design methods were applied to define a list of 18 prioritized steps and possible solutions. All seemed to be related to the intrahepatic puncture. The results allow developers to create a system which provides complete and required support to improve TIPS. It shows that prioritizing steps with the end-user makes a development process efficient and will increase the impact of developing new medical technology.

1 Background

Interventional radiology is a medical specialisation. During an interventional procedure, the interventional radiologist (IR) makes little incisions in the patient's neck or groin to insert long, thin instruments in the patient's body. To operate, the instruments are navigated through the patient's body. Radiological images (e.g., fluoroscopy) are used to guide the IR during the procedure. Even though the interventions have a minimal invasive character, the support from the image guidance (IG) can be very limited, making the procedures extremely challenging and causing a lot of (unnecessary) risks. Especially for transjugular intrahepatic portosystemic shunt placement (TIPS), an improvement of the IG systems is needed. TIPS is a lifesaving procedure, but also one of the most technically difficult procedures in interventional radiology. During the procedure, a shunt is created between the two veins in the liver (portal vein (PV), hepatic vein (HV)) to decrease high blood pressure in the PV. Mainly when puncturing through the liver into the target PV, physicians have difficulties to see where to puncture [1].

Our multidisciplinary research team consists of engineers, human factor experts and physicians. The team aims to improve IG during TIPS using real-time three-dimensional ultrasound (real-time 3D US) as the main modality [2]. To facilitate better guidance during TIPS, our team should know what to improve and how to improve the new IG system. Unfortunately, the minimal invasive character of TIPS makes observing and understanding the complex procedure difficult. The procedure is primarily performed inside the covered body of the patient and decisions are made inside the physician's head. As a result, the required system improvements are hard to unveil [3].

The team applies action research [4] to unveil the system improvements. In previous research, a detailed task analysis of TIPS was conducted [3]. During the analysis macro steps were distinguished. A macro step is, for instance, the step 'catheterize the HV'. The steps can be observed and verbally identified. The building blocks of macro steps are micro steps. A micro step can be a micro questions in the mind of an IR (e.g., what is the position of the needle relative to PV?) or a micro action performed by the IR (e.g., position the needle towards the PV). Micro steps are elementary, small, hard-to-express, unobservable steps [3]. Micro steps form a comprehensive set. Overall, to execute safe navigation and treatment within the patient's body no micro step can be eliminated. Unfortunately, to several of these micro questions the current IG systems do not provide answers. Cuijpers et al (2012) revealed 64 mental micro questions for TIPS, and discovered that for 26 out of 64 questions, the IR can find the proper information to answer the question. For 31 of the questions no answers can be found at all, and for the rest support is limited. This means that IRs are often forced to base decisions on their own knowledge of the anatomy and procedure. In the same study the puncture from the HV to the PV (called intrahepatic puncture) was identified as the most crucial, but complex macro step [3]. This is also the step in which most complications do occur [5].

To develop a support for all the 38 identified and poorly supported micro questions at once would be too ambitious. Therefore, we decided to prioritize the micro questions. As mentioned by Freudenthal et al (2008), improving one part first and gradually expanding the improvements allows medical professionals to steer the system in the desired direction and it thus allows developers to make a suitable solution. We wanted to know which part of the procedure should be improved first for maximal impact regarding patient safety (Patient safety being effective treatment as well as avoiding any unnecessary complications). Unfortunately, an overview of priorities was unavailable. Therefore, the aim of this study was (1) to know on what micro questions developers need to focus to contribute to a successful TIPS placement and (2) to find possible solutions to create a suitable IG system.

2 Methods

Methods were used to (a) expose the macro steps and related micro questions; (b) prioritize the micro questions; and (c) generate possible solutions.

(a) Ethnographic techniques are commonly used by designers for task analysis [6]. The techniques help to gain understanding of the procedure, context and users (see [3][6]). The techniques were used during 42 interventional procedures, of which 8 TIPS procedures.

(a) Generative sessions were conducted with six IRs of four different hospitals. The session gave insights in physicians' tacit knowledge [7]. The sessions made considerations, needs, and values more explicit and open to discussion (see [3]).

(a) From the results of the generative session a list of all recognized micro questions of the intra-operative procedure was created (also see [3]). The micro questions were divided in five macro steps, one cluster of macro steps and a 'general' step:

- (1) Navigate from the jugular vein to the HV;

- (2) Catheterize the HV;
- (3) Intrahepatic puncture: puncture from HV to PV;
- (4) Control the intrahepatic puncture;
- (5) Catheterize the PV;
- Balloon placement, stent placement, check and closure;
- General

Some macro steps were clustered, because they do occur after the intrahepatic puncture and when stable access to the PV has already been gained. For these macro steps, a clear protocol is available. To perform the steps before the cluster is more challenging and requires more experience. The 'general step' involves all micro questions which are more or less performed throughout the whole procedure. For each defined question, the researcher wrote down if support is currently provided and sometimes extra remarks.

(a) Validation list: the list was sent to an IR who had experience of performing TIPS. He was asked to check the list, add comments, and to provide input for unclear parts. Based on his feedback, the list was revised and completed. When comments remained unclear or contradictory, the IR was reconsulted.

(b/c) Prioritize: one workshop and several discussions were held. These were held to validate the most critical part(s) of the workflow, to prioritize the micro questions, and to understand what and how support could be provided for the micro questions.

- Workshop: the researcher visualized the workflow (macro steps) on an A0 sheet. The micro questions which urgently need help were added as well. During the workshop the workflow was discussed with the multidisciplinary research team. Missing micro questions were added and the members were asked to define the macro steps or micro questions for which most improvement is needed. Subsequently, the participants had to pick a defined step or question and create possible solutions. Finally, the team discussed the outcomes. The results helped the researcher to validate and prioritize the micro questions and to define preliminary ideas.
- Discussions: held with multidisciplinary team and two additional IRs. During the discussions the focus points were validated and possible solutions for the micro questions were discussed. The outcomes were used to complement the list.

(b/c) Final validation: based on the outcomes of the workshop and discussions, a list of prioritized micro questions and possible solutions was created. For final improvements, this list was sent (together with the original, complete list) to the interventionist in training (member of the team, and has experience of performing TIPS).

3 Results

The list (table 1) shows that 18 of the 64 questions most urgently need help. For five questions, information is available, but could be improved or made more easily available (column 3 and 4, table 1). This subset was chosen with the idea that support can be provided without changing the whole procedure. Especially the IRs emphasised the need to only improve a distinct part of the procedure and leave most of the intervention unchanged (for now).

To improve TIPS in particular the micro question(s) of the steps *(3) Intrahepatic puncture* and *(4) Control the intrahepatic puncture* and of *General* should be improved first. These steps are the most crucial, but involve little information. This makes completing them very challenging. All need to be improved to provide complete guidance during the intrahepatic puncture.

Possible solutions to support the micro questions (in bold the solutions from column 5, table 1):

- Trajectory Planning: the IR can pre-operatively plan TIPS placement (by assigning **navigation landmarks** in the user interface (UI) and choose a suitable puncture **trajectory**. The trajectory should be visualized on the UI of the IG system. **Details** about critical **structures**, cirrhosis, and distances etcetera should be presented as well. Computed tomography (CT) or US can be used to provide those details.
- Free Selectable Plane: Real-time 3D US was chosen because it allows to select any **free plane** in a generated 3D volume (see [2]). Furthermore, US visualizes the veins (which are key in TIPS) and **anatomy** and the **instruments** in **real-time**. Before the procedure (e.g., during trajectory planning), IRs should be able to freely select the planes they desire to see during the procedure. During the procedure, the system should be able to visualize these planes when needed, in the -for IRs- preferred way. Catheters need to be tracked (e.g., electromagnetic tracking) or redeveloped to make them visible under US. The IR should always be able to interact with the planes; for example to tune the planes and to re-plan the procedure. If desired, artificial **landmarks** or required elements from CT or other pre-operative image could be **added** to the US planes.
- Intra- operative workflow alterations: To visualize desired planes, the 3D US probe will not be manually controlled by an additional IR (see [2]), but alternatively by a probe holder. The planes will not be generated by hand movements, but will be calculated in the US cone. The benefit of this is that visualization of planes become less operator dependent, the operating physician controls what is visualized while being able to solely focus on the procedure (not on acquiring suitable information).
- Instruments: Some problems could be solved by improving the TIPS **instruments** (e.g., steerable or predictable needles).

4 Interpretation

The results show for which macro steps and which of their micro questions sufficient support is needed to improve TIPS in the most efficient way. The physicians and the multidisciplinary team defined 18 micro questions of two macro steps (i.e., intrahepatic puncture, control the intrahepatic puncture) and a general step. By improving all 18 micro questions, the IR will be able to effectively puncture in the PV and the puncture becomes less challenging. The new IG system can be applied during these two macro steps and the remaining steps can still be conducted in the conventional way. Future research may see how much improvement can be gained from applying IG in the other steps.

Several research groups tried to improve the IG for the intrahepatic puncture. However, these IG systems answer only a few of the micro questions that are needed to perform the puncture. For example, Adamus et al. (2009) aimed to guide the puncture from HV to PV. They used two two-dimensional projections to create 3D path planning on real-time fluoroscopy. The solution helps to answer questions as 'What is the position of the needle relative to PV? and 'What is the best place to puncture the PV?' However, according to Maleux (2010) the solution does not include essential anatomical information and therefore injury may still occur. This indicates that the solution is incomplete since questions such as ‘What is the 3D position of materials in relation to veins, environment of veins, structures?’ and ‘Will/ did I not cause collateral damage?’ remain unanswered. Also for other groups (e.g., [10]) the same seems to happen (e.g., not supports the micro question ‘what is the best place to puncture the PV?’). This confirms the need to improve more than only a few micro steps. It presumes that providing support for all listed micro questions of table 1 is essential, to facilitate an effective puncture, fast recovery after miss puncture, and to safeguard patient safety. The result of this paper can help research groups to make solutions more complete.

The list also contains micro questions which cannot be solved by improving the IG alone. For example, to sufficiently control the needle is challenging due to the current instrumentation. This suggests that also additional improvements are needed. A new IG system will benefit the navigation process, but additional help (e.g., improved needle) will benefit the procedure even more. Unfortunately, during our research project, we will not be able to redesign additional aids. Though, we trust other research teams to develop this idea further.

Next to a list of prioritized micro questions, the results also provide innovative solutions for each micro question in order to improve the puncture. For example, solutions which require planning do exist (e.g., [8]), but to freely select a plane is a new and promising solution. The planes will be very informative, match the needs of the IR and will probably improve the efficiency during the procedure. Technical possibilities to create the solutions are already available, making the possibility of creating the innovative solutions highly likely. For example, automatic registration between real-time 3D US and pre-operative CT can be successfully achieved (e.g., [11]). Also, registration of 3D US volumes to intra-operatively visualize the planned US planes is possible [12]. The option to track instruments on 3D US is already researched for other interventional procedures [13] and we thus expect that applying this in TIPS will be possible as well.

Although the intrahepatic puncture was defined as the most complex step [3][5], we did not research this macro step alone. Nevertheless, while 64 questions were originally unveiled [3], this paper claims that developers should focus on 18 micro questions which are all related to the intrahepatic puncture. There are several reasons for this extensive analysis. First of all, we did not want to overlook important micro questions. With the complete list we were able to judge if other micro questions could really be left out (the results show that this is not the case). Secondly, we desired to let IRs indicate the focus for system improvement. They know best for which parts of the procedure support is most essential. Furthermore, the analysis provides in depth understanding of the whole procedure (e.g., actions, thoughts, concerns, teamwork, materials used) and all small steps. As mentioned in the introduction, having an overview of all small steps and gradually improving them (e.g., by constantly checking), suits the common approach in medicine [4].

Overall, prioritizing steps seems essential during the development process. It allows creating an IG system which provides the required support. Prioritizing prevents developers to just build a fancy technological solution which is incomplete, or has functions which are superfluous. However, this process would not have been possible without applying action research and co-design. When developing new medical technology for complex procedures, the methods allow the development process to be efficient and to increase clinical impact.

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Table 1. The selected critical micro questions of TIPS. These micro questions, as a complete set, should be supported most urgently.

Macro step/task	***Relevant Micro question***	***Information available to IR?***	***Remarks***	***Possible Solutions, e.g.;***
1. Navigate from jugular vein to the HV				
2. Catheterize the HV				
3. Intrahepatic puncture (puncture from HV to PV)	8.Where is the target vein positioned in 3D?	*Limited*	*If a radiopaque marker was used, the 3D position can be required by rotation of the C-arm.*	*Free plane, landmarks*
	9.What is the position of the needle relative to PV?	*Limited*	*2D position known when using PV visualization tools. Turning the C-arm, shows 3D position*	*Free plane, real-time, landmarks, details structures, trajectory*
	10.What is the real-time 3D position of materials compared to veins, environment of veins, structures?	*No*		*Free plane, real-time, landmarks, trajectory, details structures*
	11.What is the best place to puncture the PV?	*No*	*Only based on estimation.*	*Free Plane , landmarks, details structures*
	12.What is the desired catheter shape and direction to arrive correctly at the target point??	*Limited*	*Can be estimated if aid to visualize PV is used/ the c-arm is rotated for 3D information. Otherwise, based on estimation, experience, and trial & error and only clear afterwards, when gained PV access.*	*Trajectory*
	14.How much force should be applied on the needle?	*Yes*	*- anticipate on severity of cirrhosis* *- Needle bends/curves, pops away , shoots through, or complications occur (harm to patient)*	*Trajectory, landmarks added, details structures, real-time instruments*
	15.Do I puncture in a fluent line, without a kink?	*Yes*	*- Angle of needle to PV axis* *- Angiography when stent is placed*	*Trajectory, real-time instruments*
	17.Will I sufficiently control the instrument when puncturing to the PV?	*Limited*	*-Before procedure: see cirrhosis on CT.* *-During procedure: needle movement visible on fluoroscopy provides feedback on actual density and needle behavior.* *-Anesthetist will tell if blood rate drops.* *-Blood in ascites drain* *After first puncture, acquired knowledge will help to estimate needle behavior.*	*Trajectory, real-time, instruments, details structures*
	18.How will the needle move, during each puncture?	*No*	*Estimate on experience*	*real-time instruments, instruments*
	19.Will I not puncture outside the liver?	*No*	*Estimation*	*Trajectory, free plane, real- time, added landmarks*
	20. Will/ did I not cause collateral damage?	*Yes*	*- Materials: shoot away* *-Anesthetist will tell the IR if blood rate of the patient drops.* *-blood in ascites drain*	*Trajectory, instruments, landmarks, real-time*
	22.How to handle complications? *Note: not thoroughly researched* Possible questions are: Where is the damage? How to repair the damage?	*Yes*	*Complications afterwards, contrast dye to find a leak, and to repair damage. If it is serious and leak cannot be found; surgeon will operate the patient and tell the IR what happened*	*Real-time, free plane*
4. Control the intrahepatic puncture	23.Did I puncture inside the PV?	*Yes*	*Feel resistance, blood aspiration, contrast dye* *- DSA with CD to see anatomy/PV*	*Free plane, details structures, real-time*
	24.Did I puncture on the edge of PV?	*No*	*guess*	*Details structures, real-time, free plane*
	26.Do I puncture the PV 1-3 cm above the PV bifurcation?	*No*		*Real-time, landmarks, trajectory*
	27.Why did I not puncture the PV?	*No*	*Guess*	*Free plane, trajectory*
	28.How can I improve my puncture?	*No*	*Estimation and background knowledge*	*Free plane, trajectory*
5. Catheterize the PV				
Place stent etc.				
General	44.What is the safest route? E.g., in case of large tumor?	*No*	*CT will help to plan*	*Free plane, trajectory, landmarks added, details structures*