Modified WHO Surgical safety check-lists for MRI-related safety in hybrid operating room

Poster No.: C-0014
Congress: ECR 2016
Type: Educational Exhibit
Authors: M. Cherkashin¹, N. Berezina¹, V. Kuplevatsky²; ¹Saint-Petersburg/RU, ²St. Petersburg/RU
Keywords: Management, Professional issues, MR, Intraoperative, Education and training, Quality assurance
DOI: 10.1594/ecr2016/C-0014

Any information contained in this pdf file is automatically generated from digital material submitted to EPOS by third parties in the form of scientific presentations. References to any names, marks, products, or services of third parties or hypertext links to third-party sites or information are provided solely as a convenience to you and do not in any way constitute or imply ECR’s endorsement, sponsorship or recommendation of the third party, information, product or service. ECR is not responsible for the content of these pages and does not make any representations regarding the content or accuracy of material in this file.

As per copyright regulations, any unauthorised use of the material or parts thereof as well as commercial reproduction or multiple distribution by any traditional or electronically based reproduction/publication method is strictly prohibited.

You agree to defend, indemnify, and hold ECR harmless from and against any and all claims, damages, costs, and expenses, including attorneys’ fees, arising from or related to your use of these pages.

Please note: Links to movies, ppt slideshows and any other multimedia files are not available in the pdf version of presentations.

www.myESR.org
Learning objectives

Operating room management is the serious and complex task for hospital managers and the common approach is to develop relevant standard operational procedures. From patient and staff safety perspective, operating room management should be well-studied and hospital should identify and address any potential risks. Simultaneous usage of different imaging and less-invasive treatment technologies demands strong management control.

We propose to attend to the following objectives:

- to develop standard operational procedure as a part of management system
- to modify and implement standard World Health Organization's Surgical Safety Check-list for magnetic resonance visualization systems equipped hybrid operating room

Background

Implementation of standard validated tools, especially in safety-related area, is the obvious part of diagnostic and treatment processes management. Since 2008 WHO's «Safe surgery save lives» program was implemented worldwide and the Surgical Safety Checklist (SSCL) is the international standard validated tool for operating room management and the part of real clinical practice [1]. This program currently is covering more than 3900 hospitals in 122 countries; 25 countries declared this initiative as a national project [2]. Nowadays based on epidemiological studies, it is considered that SSCL usage significantly and reliably reduces mortality (from 1.5% to 0.8%) and postoperative complications rate (from 27.3 to 16.7 for 100 cases) [3 - 5].

In case of hybrid operating theater with intraoperative magnet-resonance imaging (MRI) this management strategy looks like not only recommendation but a necessary condition and a standard for processes control. Simultaneous usage of different visualization and less-invasive treatment technologies are characterized by potential influence on patient safety. In general, MRI has a good safety profile, but there are some identified risks:

- displacement forces on ferromagnetic objects in the high-energy magnetic field,
- risks of thermal injury due to RF-induced heating,
- risk of MRI noise-related hearing impairment

MR-compatible medical devices should meet following criteria:

- not to possess any known hazards in its intended configuration,
• not to have its intended functions deteriorated by the MRI system,
• not to significantly affect the quality of the diagnostic information

According to these criteria the most part of the operating room equipment are MR-unsafe and MR-incompatible (surgical tools, operating table, ventilator, light sources, imaging systems, angiography devices etc). This fact demands a precise hybrid theater design and planning and management processes standardization [8]. Intraoperative MRI in high-energy field (1.5 - 3.0T) followed with strong conditions for ferromagnetic and non-magnetic surgical tools control and accurate patient logistics and routing [9]. All MR-Unsafe equipment must have clear marking to avoid any risks. Anesthesiology care also is the important question in case of intraoperative MRI [10]. For vital functions monitoring and support a hospital needs to have the MR-compatible anesthesiology equipment (special ventilator, infusion pumps, pulse oximeters, catheters, needles etc) [8].

In general, modified surgical safety checklist is the applicable tool for the safety risks ensuring and allows the strong MR-related challenges control.

Findings and procedure details

On the first stage the risk minimization roadmap was developed. We have analyzed the existing decisions; surgery and intensive care units' plans; corridors and rooms zoning taking into account the influence of magnetic field and potential radiofrequency induction; air-conditioning, ventilation, electrical, water and medical gases communications; MR-scanner placement and magnetic field power; operating table, C-arm and radiation safety, anesthesiology equipment and other medical devices placement. Each function’s representative received the individual specific list of questions for discussion. Regular workshops were organized for potential risk assessment and risk avoiding and minimization plans/scenarios creation and implementation.

On the second stage of "Hybrid operating room management" the standard operational procedure was developed. It was a detailed description of intra hospital and intra departmental (operating room - intensive care unit) patient routing; surgery room zoning with sterility and magnetic field conditions; algorithm for MR-compatible and MR-unsafe tools and medical devices usage, marking, registration and control.

Our previous experience (since 2013) of building and exploitation of the hybrid operating room equipped with C-arm and radiolucent table facilitated greatly the SOP development and justification. In addition, in 2014 - 2015 we have performed 76 direct in-bore MRI-guided tumor biopsies with different localization. Biopsies were conducted with special coils (for body tumors) or Leksell frames (for intracranial tumors) and non-magnetic needles with in-bore positioning control by high-field MRI (3.0 #). Also we
have performed on the regular basis 105 3D-navigation supported (C-arm) Lexsell frames positioning before Gamma Knife radiosurgery for arteriovenous brain malformations. Thus MR-related and radiation safety challenges and MR-assisted invasive technologies management (with MR-compatibility, non-magnetic tools, operating room space zoning etc) were not unexpected for us.

For patient intraoperative routing and adequate safety monitoring ensuring standard WHO surgical safety check-list was modified. SSCL includes three simple and easy-to-use blocks of questions, grouped by the surgery stages (Fig.1)

**Fig. 1**: Standard WHO Surgical Safety Checklist

**References**: World Health Organization

Therefore, SSCL is covering all important surgery-related risks and potentially helps to avoid complications.

SSCL is the individual control tool for the concrete operation, the copy of list usually archived in the patient's medical records. All collected data typically used for surgical service efficacy analysis. Standard SSCL was implemented in our hospital since 2015 for C-arm equipped hybrid theatre and currently all surgery is usually performed with this
management system, but for MRI-equipped room this list was modified in accordance with magnetic field-related challenges and concerns.

Currently two MR-scanner's placement concepts for hybrid surgery exist: the machine in the additional room (garage) with patients' moving during operation or sliding gantry (with ceiling rails). Both concepts have some advantages and restrictions but we have decided to avoid the movable scanner due to potential images' quality issues and sterility concerns. Therefore, we have concentrated on safely patients' routing. As a result of the expert panel discussion and local/international guidelines, legislation and scientific literature analysis we suggest the following statements for the MRI-equipped hybrid operating room design:

- Clear colour marking of magnetic field lines on the operating room floor (safe surgery is possible outside of 0.5 mT - 5 Gauss magnetic field power) (Fig.2);

Fig. 2: Safety magnetic field space zoning in MRI-equipped hybrid operating room

References: DTC IIBS - Saint-Petersburg/RU
- MR-scanner room separation with locked door and electronic controlled staff access;
- Clear and obvious marking for all MR-unsafe devices;
- Strong control for non-magnetic surgical tools (storage and sterilization in separate set, placement during surgery on separate colour-marked table, calculation and accounting with records on the special lists);
• In case of endovascular interventions (stents placement, embolization etc) it should be performed after MRI due to potential safety and image quality issues (just one exception - diagnostic angiography);
• Strong continuing control for all surgery stages with modified surgical safety checklist.

Regarding MR-safe or compatible device marking we have used commonly accepted approach - special colour marks (Fig.3).
Fig. 3: MR-safety/compatibility-related equipment labelling

References: U.S. Food and Drug Administration, American Society for Testing and Materials. It is easy to use stickers/badges for tables and equipment or corresponding colour marks for small items.

Also, based on WHO SSCL, we have developed two additional blocks of questions for intraoperative magnetic resonance investigation (table 1).

<table>
<thead>
<tr>
<th>Before intraoperative MRI</th>
<th>After intraoperative MRI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgeon and nurse confirm:</td>
<td>Radiologist confirm:</td>
</tr>
<tr>
<td>- imaging area</td>
<td>- magnetic resonance scanner turning off</td>
</tr>
<tr>
<td>- ferromagnetic tools and devices absence</td>
<td>- coil removal</td>
</tr>
<tr>
<td>- quantity of non-magnetic tools in the operating field</td>
<td></td>
</tr>
<tr>
<td>Anesthesiologist confirm:</td>
<td>Anesthesiologist confirm:</td>
</tr>
<tr>
<td>- patient's readiness for transportation and switch to non-magnetic ventilator</td>
<td>- patient's readiness for transportation and switch to standard ventilator</td>
</tr>
<tr>
<td>- start of ventilation by non-magnetic ventilator</td>
<td>- start of standard ventilation</td>
</tr>
<tr>
<td>- ferromagnetic devices absence</td>
<td></td>
</tr>
<tr>
<td>Radiologist confirm:</td>
<td>Surgeon and nurse confirm:</td>
</tr>
<tr>
<td>- coil placement</td>
<td>- non-magnetic devices quantity</td>
</tr>
<tr>
<td>- coil sterility</td>
<td>- start of next surgery stage</td>
</tr>
<tr>
<td>- staff absence</td>
<td></td>
</tr>
<tr>
<td>- magnetic resonance scanner turning on</td>
<td></td>
</tr>
</tbody>
</table>

For our facility concept with separated MRI-room the anesthesiology care is the serious challenge. Conventional MR-unsafe ventilator's usage is prohibited within high-energy static magnetic field, therefore in MRI room special non-magnetic ventilator should be placed and the patient will be connected to it directly before investigation. Thus the most important task is the adequate patient's preparation for switching from conventional to non-magnetic ventilation and to support vital functions during transportation and imaging procedure.
Thus we would like to note that strong high-energy magnetic field risk assessment, adequate operating room space design, safety protocol development and implementation are helpful for surgery management optimization and complications avoiding. In general, surgical safety checklists, as a part of operating room management system, improving safety results. SSCL's adoption and modification is declared by World Health Organization as the positive practice.

**Conclusion**

Intraoperative magnetic resonance imaging characterized by the potential influence on patient and staff safety and demands a serious planning on the facility design stage. The optimal way is the involvement of a group of different specialists, including healthcare providers for the planning process. Operating space zoning with the MR-related safety challenges and controlled staff access is the important point. It is obvious to have a strong managerial control of ferromagnetic devices and anesthesiology care. Hybrid operating room management demands the special protocol (standard operational procedure) development and implementation. We support the practice of the Procedure Safety Officer appointment and strong staff training. Modified surgical safety checklist implementation for MRI-assisted surgery potentially may improve the operating room management and increase patient and staff safety.

**Personal information**

**References**


