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MAGNETIC RESONANCE IMAGING IN THE ASSESSMENT OF FETAL CENTRAL NERVOUS SYSTEM ANOMALIES

MRI SAFETY AND MANAGEMENT OF PATIENTS WITH CARDIOVASCULAR IMPLANTABLE ELECTRONIC DEVICES: LITERATURE REVIEW AND CASE PRESENTATION

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This is an official journal of the Slovenian Society of Radiographers with external reviews. The purpose is to publish articles from all areas of diagnostic imaging (diagnostic radiologic technology, CT, MR, US and nuclear medicine), therapeutic radiologic technology and oncology.
The articles are professional and scientific: results of research, technological assessments, descriptions of cases, etc.

Dear colleagues,

We are introducing the second issue of the Medical Imaging and Radiotherapy journal, volume 38 (2021). The journal's editorial board is proud and happy that good word about our journal was spread and that we are receiving manuscripts from different countries and different topics. The journal remains a free open-access journal available to all readers on the journal's website and in the databases that index the journal. We invite you to view the journal's website, which is available at http://mirtjournal.net/index.php/home. All the necessary information of how to prepare and submit the manuscripts can be found on the mentioned website. Besides that, a complete archive of the journal from its very beginning.

Nejc Mekis
Editor-in-chief of MIRTJ

Spoštovane kolegice in kolegi!

Pred Vami je druga številka revije Medical imaging and Radiotherapy journal, letnik 38 (leto izdaje 2021). V uredništvu nam je v veliko veselje, da se je dobro ime o naši reviji razširilo in da redno pridobivamo članke iz različnih držav na različne tematike. Revija še vedno ostaja brezplačna in prosto dostopna vsem bralcem na spletni strani revije in v bazah, ki revijo indeksirajo. Vabimo vas, da si ogledate spletno stran revije, ki je dostopna na povezavi http://mirtjournal.net/index.php/home. Na omenjeni spletni strani najdete vse potrebne informacije za pripravo in oddajo člankov in prav tako celotno bazo vseh objavljenih člankov od začetka izdaje revije.

Nejc Mekiš
Glavni urednik MIRTJ

Review article

MAGNETIC RESONANCE IMAGING IN THE ASSESSMENT OF FETAL CENTRAL NERVOUS SYSTEM ANOMALIES

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ABSTRACT

Introduction: Fetal central nervous system (CNS) anomalies are among the most severe and common anomalies, with an incidence of 1:100 to 1:500 in newborns. Depending on the type of anomaly, the diagnosis can only be made at specific periods of pregnancy. The prenatal ultrasound (US) is an effective primary imaging modality for depicting these anomalies, and magnetic resonance imaging (MRI) is a method that provides useful confirmation and resolves any doubts regarding the diagnosis made on prenatal ultrasound. In situations where ultrasound examination is difficult, fetal MRI can provide superior information owing to its many advantages. The aim of this study was to determine the importance of prenatal MRI in making an accurate diagnosis and assessment of fetal CNS anomalies after neurosonographic doubt and in detecting additional anomalies that might have been overlooked on ultrasound, which influences clinical decision making and anomaly outcomes.

Material and methods: For this research, which was designed as a systematic review of the primary scientific research literature, numerous articles were used, i.e.17 scientific research papers, published in relevant scientific research online databases such as PubMed, Medline, Google Scholar, and the same were published in English in the period from 2015 to 2021.

Results: From the assessment of the quality of studies with a cohort design, most studies used in this systematic review are high-quality studies (11 in total) and a smaller number are medium-quality studies (6 in total). Out of 575 cases, MRI confirmed the ultrasound diagnosis and agreed with it in 59.8% of cases, while in 20.2% of cases, it changed the diagnosis, i.e., in 16.5%, it rejected the ultrasound diagnosis. Additional anomalies detected only on MRI occurred in 236/1225 cases, which totals 19.3% of additional anomalies. Termination of pregnancy was reported in 82/317 cases, accounting for 25.9%, while in 176 cases, the pregnancy continued. A total of 11 cases of neonatal death were reported, and the number of stillbirths or deaths after birth was reported in 8 cases.

Conclusion: MRI using T2W SSFSE sequences in 3 planes, T1W and DWI in the axial plane, is a complementary modality to prenatal ultrasound in making an accurate diagnosis and assessment of CNS anomalies and detecting associated anomalies previously overlooked on ultrasound.

Keywords: fetal magnetic resonance imaging, fetal neurosonography, fetal central nervous system anomalies, prenatal diagnosis.

INTRODUCTION

Magnetic Resonance Imaging (MRI) of the fetus or prenatal MRI is a non-invasive imaging method that shows the anatomical structures of the fetus without using ionizing radiation (1). Due to a higher contrast resolution than ultrasound, fetal MRI allows better differentiation of normal and abnormal tissue, thus providing detailed imaging data on fetal structures, especially the brain (2). MRI of the fetus is not recommended in the first trimester of pregnancy unless the fetus is life-threatening. The use of intravenous contrast agents is not recommended to reduce the potentially harmful effects on the fetus (3). The key function of fetal MRI is early detection of congenital anomalies incompatible with life that require termination of pregnancy or the detection of those anomalies that will undergo surgery (1). Although fetal ultrasound (US) is the first and basic screening method and an effective primary imaging modality for a depiction of central nervous system (CNS) abnormalities, MRI is a recognized complementary method for identifying fetal CNS pathology. It can provide additional and diagnostically important information, thus adding security to ultrasound diagnosis and assisting in parent counseling (4,5). The CNS anomalies are among themselves the most severe and common anomalies, with an incidence of 1: 100 to 1: 500 in newborns (6). Depending on the type of anomaly, the diagnosis can only be made at certain periods of pregnancy. Half of the anomalies are such that they lead either to the death of the fetus or significantly disrupt life after birth, which is why timely detection and treatment are of great importance (7). In situations where ultrasound examination is difficult, fetal MRI can provide superior information, owing to its advantages such as superior contrast resolution, increased visual field, the ability to shoot smoothly due to ossified skull, increased amounts of adipose tissue on the front abdominal wall, oligohydramnios, fetal bones, a small amount of amniotic fluid, the movements themselves, and an unfavorable position of the fetus are cases where MRI is a method of choice (8,9,10). In addition, a complete examination of the fetal CNS in the three spatial planes is obtained more consistently in the second and third trimesters by MRI than by ultrasound only (11). Prenatal fetal imaging has several challenges that require sequences that can minimize the effects of fetal movement and maternal breathing. The quality and resolution of the image should be such that they can adequately display essentially small anatomical details, and the differences in low tissue contrast should be made as large as possible to adequately define the brain parenchyma (12). The development of a fast retrieval sequence from a single image with refocused echo (T2 weighted) has revolutionized fetal MRI because it has a layer acquisition time of less than a second and allows for effective "freezing" of fetal movements (13). Typically, the fetal CNS assessment protocol includes T2 weighted images following three planes of the fetal head, axial and coronal T1 weighted images, axial diffusion images (DWI), and/or diffusion tensor images (DTI); and additional sequences are performed as needed (9). The aim of this study was to determine the importance of prenatal MRI in making an accurate diagnosis and assessment of fetal CNS anomalies after neurosonographic suspicion and in detecting additional anomalies missed on ultrasound, which influences clinical decision-making and anomaly outcomes.

MATERIAL AND METHODS

Numerous articles were used for this research, designed as a systematic review of the primary scientific research literature. There were 17 scientific research papers published in relevant scientific research online databases such as PubMed, Medline, Google Scholar, and the same were published in English. Based on them, an analysis was conducted, and the basic characteristics of the study were selected (country, author, year of publication, title, type, study objectives, research method, results, and study conclusion). The studies used in this paper were published from 2015 to 2021. Based on them, we compared the results of the two modalities (ultrasound and magnetic resonance). We tried to determine the advantage of magnetic resonance imaging in the accurate assessment of CNS anomalies and the detection of associated anomalies and their impact on decisions about further pregnancy. The criterion for inclusion in the study included those studies that included pregnant women who were diagnosed or suspected of certain CNS abnormalities on prenatal ultrasound diagnosis of the fetus and who were then subjected to magnetic resonance imaging. At the same time, the exclusion criterion included the omission of any inclusion criterion, studies published in the period before 2015, then studies involving other abnormalities outside the CNS, and cases with contraindications for performing magnetic resonance imaging, such as claustrophobia, implanted pacemakers, prostheses, etc. The Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) flow diagram was used to document and report on all decisions made during the study selection process for this review paper, including the initial number of identified studies, the number of excluded and included studies, and the reasons for their exclusion from the research (Diagram 1).

The search keywords were: fetal magnetic resonance imaging, fetal neurosonography, central nervous system anomalies, prenatal diagnosis

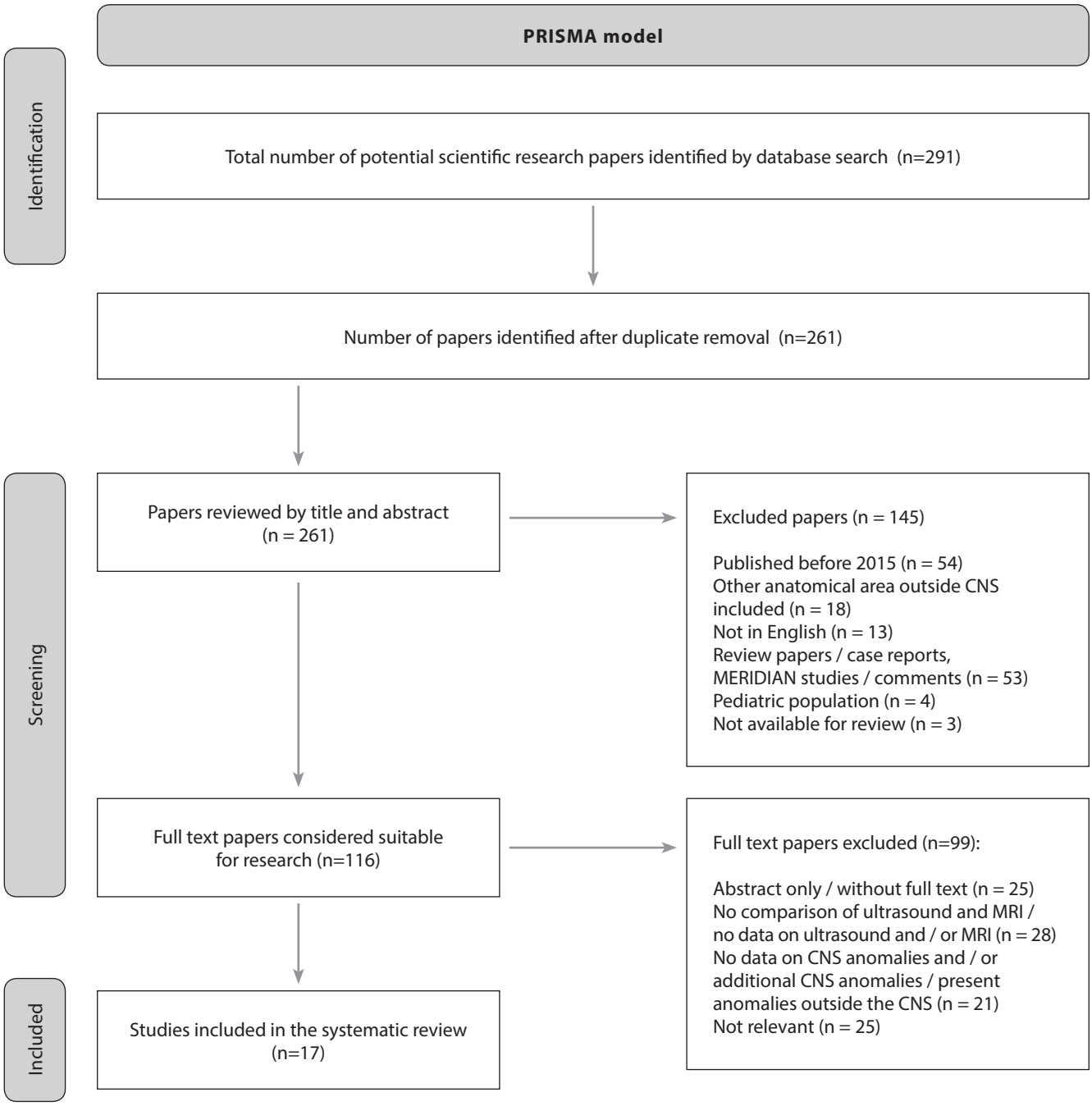

Diagram 1. PRISMA model

RESULTS

The quality assessment of the included cohort design studies (Table 1) was made according to the quality assessment tools developed by the National Heart, Lung and Blood Institute (NHLBI) in 2013 (14).

Studies in which all or nearly all criteria are met and the weaknesses of the study cannot change, the study's findings are qualified as *high-quality studies*. Furthermore, *medium-quality studies* are considered to be those studies in which some of the criteria from the checklist are not met or if the criteria are not satisfactorily described. However, it is assumed that there is little chance that the weaknesses could have changed the study's findings. In addition, there are *inadequate/low-quality studies* that include those studies that meet several or no criteria from the checklist and in such studies, weaknesses may mean that the conclusion of the study is wrong (14)

Table 1. Quality assessment of included studies with a cohort design

Main author, year, country, title	1	2	3	4	5	6	7	8	9	10	11	12	Total assessment quality
The ENSO Working Group, 2020, Italy, Role of prenatal magnetic resonance imaging in fetuses with isolated mild or moderate ventriculomegaly in the era of neurosonography: an international multicenter study	Y	Y	Y	Y	Y	Y	N	Y	Y	Y	N	Y	Medium quality
Tanacan A. et al., 2020, Turkey, Prenatal diagnosis of central nervous system abnormalities: Neurosonography versus fetal magnetic resonance imaging	Y	Y	Y	Y	Y	Y	U	Y	Y	Y	Y	Y	High quality
Sefidbakht S. et al., 2016, Iran, Fetal Central Nervous System Anomalies Detected by Magnetic Resonance Imaging: A Two-Year Experience	Y	Y	Y	Y	N	Y	U	Y	Y	Y	Y	Y	Medium quality
Mazor MM. et al., 2018, Israel, Added Value of Fetal MRI in the Evaluation of Fetal Anomalies of the Corpus Callosum: A Retrospective Analysis of 78 Cases	Y	Y	Y	Y	Y	Y	N	Y	Y	Y	Y	Y	High quality
Raafat RME. et al., 2020, Egypt, The prevalence and the adding value of fetal MRI imaging in midline cerebral anomalies	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	High quality
Turkyilmaz G. et al., 2019, Turkey, Utilization of neurosonography for evaluation of the corpus callosum malformations in the era of fetal magnetic resonance imaging	Y	Y	Y	Y	Y	Y	U	Y	Y	Y	Y	Y	High quality
Irwin K. et al., 2016, Australia, Utility of fetal MRI for workup of fetal central nervous system anomalies in an Australian maternal-fetal medicine cohort	Y	Y	Y	Y	U	Y	U	Y	Y	Y	Y	Y	High quality
Linh LT. et al., 2021, Vietnam, Detecting Fetal Central Nervous System Anomalies Using Magnetic Resonance Imaging and Ultrasound	Y	Y	Y	U	Y	N	N	Y	Y	Y	Y	Y	Medium quality
Raafat M. et al., 2021, Egypt, Fetal brain MRI: how it added to ultrasound diagnosis of fetal CNS anomalies-1 year experience	Y	Y	Y	Y	Y	Y	U	Y	Y	Y	Y	Y	High quality
Jarre A. et al., 2017, Spain, Value of brain MRI when sonography raises suspicion of agenesis of the corpus callosum in fetuses	Y	Y	Y	Y	Y	Y	N	Y	Y	Y	Y	Y	High quality
Kandula T. et al., 2015, Australia, Isolated ventriculomegaly on prenatal ultrasound: what does fetal MRI add?	Y	Y	Y	Y	Y	Y	N	Y	Y	Y	Y	Y	High quality
Mahmod M. et al., 2021, Egypt, The impact of adding fetal MRI to sonographically diagnosed intrauterine ventriculomegaly: a prospective cohort study	Y	Y	Y	U	Y	U	U	Y	Y	Y	Y	Y	Medium quality
Yilmaz E. et al., 2018, Turkey, Additional Findings from Fetal Magnetic Resonance Imaging for Prenatal Sonographic Diagnosis of Central Nervous System Abnormalities	Y	Y	Y	Y	Y	Y	U	Y	Y	Y	Y	Y	High quality
Ziaulhaq P. et al. 2020, India, The comparative study of antenatal magnetic resonance imaging and ultrasound in the evaluation of fetal central nervous system abnormalities	Y	Y	Y	Y	N	U	N	Y	Y	Y	Y	Y	Medium quality
Velipaşaoğlu M. et al. 2018, Turkey, Assessment of the Additional Value of Fetal Magnetic Resonance Imaging to Prenatal Ultrasound in a Single Institution	Y	Y	Y	Y	N	U	N	Y	Y	Y	Y	Y	Medium quality
Katz JA. et al. 2018, USA, Utility of prenatal MRI in the evaluation and management of fetal ventriculomegaly	Y	Y	Y	Y	Y	U	U	Y	Y	Y	Y	Y	High quality
Frick N. et al. 2015, Austria, The Reliability of Fetal MRI in the Assessment of Brain Malformations	Y	Y	Y	Y	Y	U	U	Y	Y	Y	Y	Y	High quality

Checklist for cohorts studies (1) Is the purpose of the study formulated? (2) Were subjects recruited for the cohort satisfactorily? (3) Was the exposure accurately measured? (4) Was the outcome accurately measured? (5) Have the authors identified and/or taken into account all-important/known possible confounders in the design and analysis of the study? (6) Were any of the people in the cohort followed up? (7) Were the people followed up long enough? (8) What is the result of this study? (9) Do you trust the results? (10) Can the results be transferred to practice? (11) Do the results of this study fit with the results of other available studies? (12) What are the implications of this study for practice? (Answers Yes: Y; No: N; Unclear: U)

From the above assessment of the quality of studies with cohort design, it can be concluded that most of the studies used in this systematic review are in the category of high-quality studies (11 in total), with a smaller number of medium-quality studies (6 in total).

Table 2 determines the importance of prenatal magnetic resonance imaging in making an accurate diagnosis and assessment of CNS anomalies after neurosonographically determined suspicions. Significance was observed through several cases in which prenatal magnetic resonance imaging confirmed the diagnosis of previously established suspicion on ultrasound. Even more significant is the number of cases in which MRI changed the ultrasound diagnosis and thus established a final, accurate diagnosis. It also ruled out certain cases of CNS anomalies and declared them a normal finding without the presence of anomalies. Also, the total percentage (%) for each group of the cases mentioned above is shown.

Table 2. Significance of prenatal magnetic resonance imaging in making an accurate diagnosis and assessment of central nervous system anomalies after neurosonographically determined suspicion

Main author/ year of publication	MRI confirmed ultrasound diagnosis (n/%)	MRI changed ultrasound diagnosis or added information (n/%)	MRI ruled out ultrasound diagnosis (normal findings) (n/%)	UZ provided additional information for MRI (n/%)
Tanacan A.et al./2020.	59/110 (53,6%)	13/110 (11,8%)	38/110 (34,6%)	0
Mazor MM. et al./2018.	50/78 (64,1%)	9/78 (11,5%)	19/78 (24,4%)	0
Raafat RME. et al./2020.	21/37 (56,8%)	16/37 (43,2%)	ND	3/37 (8,1%)
Turkyilmaz G. et al./2019.	33/36 (91,7%)	3/36 (8,3%)	ND	0
Irwin K. et al./2016.	26/57 (45,6%)	31/57 (54,4%)	6/57 (10,5%)	0
Raafat M. et al./2021.	23/40 (57,5%)	6/40 (15%)	NP	0
Jarre A. et al./2017.	38/78 (48,7%)	12/78 (15,4%)	28/78 (35,9%)	0
Mahmod M. et al./2021.	45/60 (75%)	1/60 (1,6%)	ND	0
Ziaulhaq P. et al./2020.	9/23 (39,1%)	11/23 (47,8%) 2/23 (8,7%)	ND	1/23 (4,4%)
Frick N. et al./2015.	40/56 (71%)	12/56 (21,4%)	4/56 (7,1%)	0
Total percentage (%)	59,8%	20,2%	16,5%	0,8%

(Notes and abbreviations (since several cases from these studies were used in Table 3, the total percentage in this table is below 100%; ND- no data)

Sequence protocols on which the success of MRI detection itself depends and the importance of magnetic resonance imaging in making an accurate and precise diagnosis of CNS anomalies were also analyzed. Table 3 lists the primary data (magnetic field strength, type of MRI device, sequences used, and sequence parameters) relevant to each study used in this review and related to magnetic resonance imaging of the fetal CNS.

Table 3. Technical parameters based on which magnetic resonance imaging was performed

Main author/year of publication	Magnetic field strength/ type of MRI device	Sequence protocol
The ENSO Group/2020.	ND	ND
Tanacan A.et al./2020.	1,5 T Siemens	T2W HASTE (TR/TE 2290/185ms, thickness 3mm); T1 FLASH (TR/TE 140/2,4; FA=70^o); DWI (TR/TE 4800/116ms; bmax 600s/mm^2
Sefidbakht S.et al./2016.	1,5 T Siemens Avanto	T2W HASTE and TRUFI SP (thickness 4-6mm); T1 FLASH
Mazor MM. et al./2018.	1,5 T GE Optima	T2W SSFSE (TR/TE 1298/90ms; matrix 320x224; FOV 24-30cm; thickness/ gap 3-4/0mm); spoiled T1 GRE(TR/TE 160/2,3ms; FOV 40cm; thickness/ gap 4/0,5mm); DWI (b= 0 and 1000 or 700s/mm^2)
Raafat RME. et al./2020.	1,5 T Philips Achieva XR	T2W SSFSE; SSTSE; spoiled T1 GRE
Turkyilmaz G. et al./2019.	1,5 T GE- Explorer	T2W SSFSE (thickness 2-3mm); T1 WI
Irwin K. et al./2016.	1,5 T Siemens Avanto	T1, T2 (HASTE, FLASH), DWI (thickness 3-5mm)
Linh LT. et al./2021.	1,5 T GE Signa HD	T2W SSFSE in 3 planes; axial T1W and DWI
Raafat M. et al./2021.	1,5 T Philips	T2W B-FFE (TR/TE 3,5/1,7ms; matrix 256x256; FOV 300-400mm; thickness/ gap 5/0mm; FA=80^o); T2W SSFSE (TR/TE 1500/120ms; matrix 169x256; FOV 200-300mm; thickness/gap 3-4/0,5mm; FA=90^o); T1W (TR/TE 120/4ms; matrix 166x256; FOV 300mm; thickness/gap 5/0,5mm; FA=70^o)
Jarre A. et al./2017.	1,5 T Siemens Avanto 1,5 T GE Signa Excite	T2W FSE (HASTE/SSFSE) (thickness/gap 3/0,3mm); True Fisp/FIESTA (thickness/gap 4/0,4mm; FOV 260-320mm); EPI DWI (b=600s/mm^2)
Kandula T. et al./2015.	1,5 T Siemens Avanto	T2W HASTE
Mahmod M. et al./2021.	1,5 T Philips	ND
Yilmaz E. et al./2018.	1,5 T Siemens	T2W HASTE (TR/TE 1200/91ms; matrix 192x256; thickness 3mm, FOV 207x100; FA 150^o); axial T1 FLASH(TR/TE 199/4ms; matrix 134x256; thickness 4mm; FOV 300x75; FA 70^o); sag and cor T1 FLASH in suspected bleeding and parenchymal lesions
Ziaulhaq P. et al./2020.	3T Siemens Skyra	T2W SSFSE; DWI (b=0-600s/mm2)
Velipaşaoğlu M. et al./2018.	3T GE	SSFSE (CUBE) sequence (ND)
Katz JA. et al./2018.	1,5T and 3T GE	T2W SSFSE sequence in 3 planes (ND)
Frick N. Et al/2015.	1,0T Siemens 1,5T Ingenia Philips 3T Achiva Philips	T2W SSFSE (TR/TE 2100/90ms; thickness 5mm; FOV 330x300mm; matrix 138x256; acquisition time 40s); T1W axial; TRUFI SP-sag; DWI; FLASH; FLAIR (rarely used sequences)

Abbreviations: T (Tesla); DWI (diffusion weighted imaging); W (weighted); HASTE (Half-Fourier Acquired Single-shot Turbo spin Echo); FLASH (fast low angle shot); SSFSE (single shot fast spin-echo); TR/TE (time to repeat/time to echo); TRUFI SP (True FISP); FOV (Field of view); FA (flip angle); GE (General Electric); GRE (gradient echo); SSTSE (single shot turbo spin-echo); B-FFE (Balanced Fast Field Echo); FIESTA (Fast Imaging Employing Steady-state Acquisition); EPI (Echo-planar imaging); WI (weighted imaging); sag (sagital); cor (coronal); FLAIR (fluid attenuated inversion recovery); ND (no data)

Then, if additional anomalies detected only by magnetic resonance are considered, Table 4 was created for this purpose in which the incidence of fetal CNS anomalies missed on ultrasound imaging and diagnosed on magnetic resonance imaging was analyzed. Relevant data from 12 studies were used for this analysis, which offered the exact number of cases in which MRI revealed additional anomalies missed on prenatal ultrasound. For easier analysis, in addition to the number of cases of additional anomalies, the table also lists the initial ultrasound suspicions or diagnoses and, most often, additional anomalies detected within each study by magnetic resonance

Table 4. Anomalies of the central nervous system missed on ultrasound and detected by prenatal magnetic resonance imaging

Main author/year of publication	Initial ultrasound suspicion/ diagnosis	Additional anomalies were identified on MRI and missed on ultrasound (n / N /%)	Most common additional anomalies (n)
The ENSO Group/2020.	Isolated mild or moderate VM	30/556; 5,4%	ICH (8); polymicrogyria (6); lissencephaly (4); hypoplasia of CC (2)
Sefidbakht S.et al./2016.	Suspicion of CNS anomalies / the most common indication of isolated VM	18/107; 16,82%	DW variants (3); Chiari II malformation (3); PACC, CACC, aqueductal stenosis (2)
Mazor MM. et al./2018.	Suspicion of corpus callosum anomalies	22/78; 28,2%	Calpocephaly (13); intrahemispheric cysts (4); ventricular asymmetry and gyration disorder (2)
Turkyilmaz G. et al./2019.	Suspicion of corpus callosum anomalies	3/36; 8,1%	PFA (1); cortical malformations (2)
Linh LT et al./2021.	Suspicion of CNS anomalies	8/66; 12,1%	Intracranial hemorrhage (6); vascular malformations (2)
Raafat M. et al./2021.	Suspicion of CNS anomalies	11/40; 27,5%	Meningocele (4); polymicrogyria (2); PACC (2); vermian hypoplasia (2)
Jarre A. et al./2017.	Suspected agenesis of the corpus callosum	28/45; 62,2%	VM (22); cortical malformations (15); PFA (7); midline malformations (3)
Kandula T. et al./2015.	Bilateral or unilateral VM	10/59; 17%	ICH; lesions of the corpus callosum; periventricular anomalies; CSP anomalies (1)
Mahmod M. et al./2021.	Isolated ventriculomegaly	14/60; 23%	CC and CSP lesions (29%); PFA (28%); cortical malformations (21%)
Yilmaz E. et al./2018.	Suspicion of CNS anomalies / the most common indication of VM	22/54; 40%	Subependymal nodules (2); cortical tuber (2)
Velipaşaoğlu M. et al./2018.	The most common indication is isolated ventriculomegaly	12/50; 24%	Posterior fossa defects (36,4%)
Katz JA. et al./2018.	All cases of ventriculomegaly	58/74; 78%	Cortical anomalies; PFA; midline; additional vascular anomalies
Total percentage (%)		19,3%	

Abbreviations: UZ (ultrasound), MRI (magnetic resonance imaging), CNS (central nervous system), VM (ventriculomegaly), ICH (intracranial hemorrhage), CC (corpus callosum), CSP (cavum septum pellucid), PFA (posterior fossa anomalies), DW (Dandy-Walker), CACC/PACC (complete/partial agenesis of corpus callosum)

Finally, Table 5 depicts an analysis of the impact of prenatal magnetic resonance imaging on clinical decision-making and outcomes of central nervous system anomalies. Data from 7 studies were used for this analysis, which provided information on the number of cases of termination and continuation of pregnancy and data on neonatal death and the number of stillbirths. In several studies, some cases were lost for follow-up. In contrast, in others, postnatal MRI was not available, so only certain studies could compare their data with postnatal MRI data and provide information on the outcome of the anomalies.

Table 5. The impact of prenatal magnetic resonance imaging on clinical decision making and outcomes of central nervous system anomalies

Clinical outcomes	**ACCEPTABLE STUDIES**						
	Tanacan A. et al./2020.	Turkyilmaz G. et al./2019.	Irwin K. et al./2016.	Raafat M. et al./2021.	Jarre A. et al./2017.	Kandula T. et al./2015.	Ziaulhaq P. et al. /2020.
Termination of pregnancy	14/72 12,7%	18/36 50%	11/57 19%	7/40 17,5%	21/30 47,7%	4/59 6,8%	7/23 30,4%
Continuation of pregnancy	ND	17/36 47,2%	46/57 81%	33/40 82,5%	9/30 20,5%	55/59 93,2%	16/23 69,6%
Neonatal death	3/72 2,7%	ND	1/46 2,2%	4/40 10%	ND	3/55 5,5%	ND
Stillborn	2/72 1,8%	1/36 2,8%	2/46 4,3%	2/40 5%	1/9 11%	ND	ND
Characteristics of the study	Termination of pregnancy in 50% of cases of ACC	Normal neurodevelopment in 8 cases and developmental delay expected in the remaining 8 cases	Developmental delay in 14/43 cases; childbirth (33%)	27/40 (67.5%) studies resulted in childbirth	In 8 live births, postnatal MRI confirmed the prenatal diagnosis of ACC	Greater MRI specificity results in additional important information that can help advise parents on the clinical outcome, the likelihood of recurrence	The study did not provide data on postnatal imaging and follow-up of patients

Abbreviations: ND (No data), ACC (agenesis of corpus callosum), MRI (magnetic resonance imaging)

DISCUSSION

In the 10 studies applied in Table 2 and 575 cases, MRI confirmed the ultrasound diagnosis in 59.8% of cases. In contrast, in 20.2% of cases, it changed the diagnosis established on ultrasound, or in 16.5% of cases in which ultrasound established the diagnosis, MRI confirmed the normal finding. Our results are consistent with the results of the study conducted by Jarvis D. and colleagues (32), who in their meta-analysis confirmed the agreement of ultrasound and magnetic resonance imaging in 55% of cases; discrepancy in 23% of cases and 25% of cases in which ultrasound established the diagnosis, MRI confirmed the normal finding. Also, Van Doorn M. and colleagues (33) noted in 65% of cases the agreement of these two modalities; in 26% of cases, MRI provided additional or different pathology, and 12% rejected ultrasound diagnosis. In our study, only 2/10 of the studies, conducted by Raafat RME et al., and Ziaulhaq P. et al. (19,28), provided data in which ultrasound provided additional information to magnetic resonance imaging. These rates were 8.1% (19) and 4.3% (28) and mainly related to facial abnormalities and restriction of intrauterine growth, which can be explained as technological advances in ultrasound and the skills of the radiologist performing the examination. While Rossi AC. and colleagues (34) in their study recorded only 2% of cases in which ultrasound was more accurate than MRI.

Consequently, based on the data from Table 3, it is possible to conclude that a 1.5T MRI device was most often used to record the fetal CNS, while 3T devices were used in our work in only 4/17 studies. As the best protocol based on the data offered by our studies, we can accept the one that contains the first SSFSE (HASTE) T2 weighted sequences in the sagittal, coronal and axial planes, as they are key to reducing fetal movement (thus reducing artifacts). In addition, most studies as additional sequences, and depending on the indications themselves, most often used T1 weighted sequences (FLASH, GRE) in the axial plane, which proved to be the best for detecting bleeding, fat and calcifications or myelin; and DWI sequences in the axial plane which, as an advanced technique, enable the distinction between developmental and destructive pathologies.

Based on our results in Table 4, anomalies missed on ultrasound and detected on MRI occurred in 236/1225 cases, totaling 19.3% of additional anomalies. The most common additional anomalies were: intracranial hemorrhage; cortical anomalies, medial anomalies; and PFA. This rate of additional

anomalies in the study conducted by Reda AM. and colleagues (35) was slightly higher, 22.5%. Also, studies conducted by Jarvis D. and colleagues and Rossi AC. and colleagues (32,34) were reported additional information provided by MRI in 15% and 22.1% of cases, respectively. Most authors claim that the risk of finding additional CNS abnormalities in fetuses with isolated ventriculomegaly is high and that it increases with the increasing severity of ventriculomegaly (36,37). This confirms that in 7/12 of the studies used in Table 4, with a significant incidence of associated anomalies, the initial suspicion or diagnosis on ultrasound was precisely ventriculomegaly. This is also supported by the study results conducted by Di Mascio D. and colleagues (37), who reported 3.5% and 22.6% of associated anomalies detected on MRI and missed on ultrasound in fetuses with isolated mild, that is, moderate ventriculomegaly.

The detection of these additional anomalies by MRI indicates its importance in making clinical decisions and enabling parents to make a more conscious decision about their pregnancy. All of our 7 studies from Table 5 were provided information on the number of terminations of pregnancy that occurred in 82/317 cases, accounting for 25.9%. One study that was used did not provide data on the continuation of pregnancy, so based on the remaining studies, the pregnancy was continued in a total of 176 cases. Data on neonatal deaths were not available in the 3 studies used, and 11 cases of neonatal death were recorded in other studies. The number of stillbirths or deaths after birth was reported in 8 cases, as 2 studies did not provide data. Di Mascio D. and colleagues (37) sought to determine whether the detection of associated anomalies by MRI led to a change in prenatal management of pregnancy due to a higher risk of abnormal neurodevelopment outcomes. They proved that 4.6% of fetuses who had an isolated VM on ultrasound and then an additional anomaly on MRI had a significant change in perinatal treatment (mostly termination of pregnancy at the parents' request). Furthermore, in their study Mazor MM. and colleagues (18) state that MRI contributed to a change in management of pregnancy for 28 fetuses (35.9%), of which 25 fetuses (32.1%) are in favor of preserving pregnancy.

CONCLUSION

Ultrasound is the standard way of recording anomalies in the second and third trimesters. Still, MRI using T2W SSFSE sequences in 3 planes, T1W and DWI in the axial plane, is a complementary modality to prenatal ultrasound in making an accurate diagnosis and assessment of CNS anomalies offering a significant percentage of change cases or complete exclusion of previously established ultrasound suspicion. The incidence of additional detected CNS anomalies on magnetic resonance imaging, which were previously missed on ultrasound, indicates the benefit of performing the same in cases when ultrasound examination is unclear or incomplete and when these additional anomalies are far beyond the range and ability of ultrasound to diagnose them. Finally, prenatal MRI with the diagnosis of associated / additional CNS abnormalities may influence clinical decision-making regarding the continuation or termination of pregnancy and, finally, the preparation of family and clinicians for postnatal care depending on the presence or absence of abnormal neurodevelopmental outcomes.

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Review article

MRI SAFETY AND MANAGEMENT OF PATIENTS WITH CARDIOVASCULAR IMPLANTABLE ELECTRONIC DEVICES: LITERATURE REVIEW AND CASE PRESENTATION

MAGNETNORESONANČNA VARNOST IN OBRAVNAVA PACIENTOV Z VSTAVLJENIMI KARDIOVASKULARNIMI ELEKTRONSKIMI NAPRAVAMI: PREGLED LITERATURE IN ŠTUDIJA PRIMERA

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ABSTRACT

Introduction: MRI has long been contraindicated in patients with CIED devices due to the risk of adverse effects through electromagnetic interference. Recent developments in engineering have led to the introduction of MRI conditional CIED devices that do not cause significant clinical harm to patients undergoing MRI, when specific imaging conditions are met. Safe access to MRI has become a crucial need for patients with CIED devices.

Aim: The purpose of this paper is to present an overview of how to manage patients with implanted CIED devices and to present a case report of a patient with CIED undergoing prostate MRI examination.

Methods: This paper explores MRI Safety and the management of patients with implanted CIED devices through an extensive literature review and case presentation. The literature search was conducted using medical scientific electronic databases such as PubMed, Cinahl, Wiley Online Library and ScienceDirect. We examined a patient with a CIED device undergoing a prostate MRI examination.

Results and discussion: We performed an examination of the described patient in accordance to the guidelines presented in this paper. The MR conditionality status was determined using the device identification card and the manufacturer's technical manual. The MRI examination of the patient was completed without complications; therefore, no adverse effects were reported. The MRI images were without artefacts.

Conclusion: Recent clinical studies and published guidelines suggest that MRI of the patients with either an MRI conditional or MRI non-conditional CIED device is relatively safe under specific conditions. Multidisciplinary pre-procedure planning, a strict screening process, monitoring and device evaluation protocols are of key importance for ensuring safe MRI imaging in patients with CIED.

IZVLEČEK

Uvod: Magnetna resonanca je dolgo časa veljala za absolutno kontraindikacijo pri MR preiskavah pacientov z vstavljenimi CIED napravami. Tehnološki napredek na področju razvoja CIED naprav je doprinesel k uveljavitvi MR pogojno varnih kardiovaskularnih elektronskih naprav v kliničnem okolju. MR pogojno varne CIED naprave ne predstavljajo kliničnega tveganja za paciente s tovrstnimi napravami, če so upoštevani specifični pogoji uporabe. Varna izvedba MR slikanja je postala ključnega pomena pri zdravljenju tovrstnih pacientov.

Namen: Namen te raziskave je predstaviti pregled področja obravnave pacienta z vstavljeno CIED napravo med MR slikanjem in predstaviti primer MR slikanja prostate pri pacientu s CIED napravo.

Metode: V študiji smo predstavili pregled literature na področju MR varnosti in obravnave pacientov z vstavljenimi CIED napravami. Predstavili smo tudi primer obravnave MR slikanja prostate pri pacientu s CIED napravo. Literaturo smo zbirali s pomočjo elektronskih podatkovnih baz PubMed, Cinahl, Wiley Online Library in ScienceDirect.

Rezultati in razprava: Preiskavo smo izvedli v skladu s priporočili, predstavljenimi v tem dokumentu. MR status naprave smo ugotovili na podlagi pregleda identifikacijske kartice naprave in proizvajalčevih priporočil o uporabi naprave v MR okolju. Preiskava je bila opravljena brez kliničnih zapletov. Na MR slikah ni bilo prisotnih popačenj zaradi prisotnosti CIED naprave.

Zaključek: Najnovejše klinične študije in izdana priporočila ugotavljajo, da je MR slikanje pacientov s CIED napravami relativno varno v specifičnih pogojih ne glede na to, ali gre za MR pogojno varne naprave ali ne. Ključnega pomena pri zagotavljanju varnosti pri MR preiskavah tovrstnih pacientov je predhodno multidisciplinarno načrtovanje preiskave, natančen varnostni pregled/screening pacienta, kakovosten nadzor nad pacientom med preiskavo in ocena delovanja naprave po preiskavi.

INTRODUCTION

Magnetic Resonance Imaging (MRI) is a non-ionizing radiation dependant imaging modality that provides excellent soft tissue spatial resolution. MRI has long been contraindicated in patients with cardiovascular implantable electronic devices (CIED) due to the risk of adverse effects through electromagnetic interference (1). Recent developments in engineering have led to the introduction of MRI conditional CIED devices that do not cause significant clinical harm to patients undergoing MRI when specific imaging conditions are met (2).

Classification of CIED

CIED is a term that comprises pacemakers (PPM), implantable cardioverter defibrillators (ICD) and cardiac resynchronization therapy devices (CRT). CIED system traditionally consist of two components – the pulse generator and thin insulated wires called leads (3). These devices have proven to be an invaluable tool in the practice of cardiology and treatment of a variety of cardiac arrhythmias. They can be divided further based on the functionality of the device and lead placement in the human heart. Therefore, we differentiate among single chamber CIED devices, dual chamber devices and biventricular (triple chamber) devices (4). Single chamber devices consist of a single lead that attaches either to the right atrium or right ventricle. Dual chamber devices use two leads that are placed in the right atrium and right ventricle. Biventricular CIED devices are divided into two groups: CRT-P devices, which stands for Cardiac Resynchronization Therapy Pacemaker and CRT-D devices, that stands for Cardiac Resynchronization Therapy Defibrillator. Biventricular devices deliver small electrical impulses to the left and right ventricle. Leads are placed into the right atrium, right ventricle and coronary sinus. The latter delivers electrical impulses to the left ventricle (3,5). Recently a new type of CIED device has been introduced for clinical use. Leadless pacemakers were designed to eliminate some of the complications associated with transvenous pacemakers and leads: pocket infection, hematoma, lead dislodgement and lead fracture. The device is 90% smaller than the transvenous system and it consists of a small cylindrical capsule that contains a battery, an electronic control unit and a single tip electrode. The leadless pacemaker is implanted into the right ventricle myocardium via a femoral vein transcatheter approach. The downside of this device is that it provides only single-chamber ventricular pacing and lacks defibrillation capacity (3,6,7).

MRI Safety Labelling of CIED

Safe access to MRI has become a crucial need for patients with CIED devices. An estimated 50-75% of these patients may have a clinical indication to undergo MRI after the implantation over their lifetime. For this reason, new generations of cardiovascular implantable electronic devices have been designed to allow such patients to safely undergo MRI provided that specific conditions are met during the scan (8). CIED devices that are labelled as MRI conditional need to be tested in a specific MRI environment, including induced torque and force, current induction, RF heating and potential electromagnetic interference. MRI conditional labelling for CIED devices generally includes requirements for static magnetic field strength, maximum spatial field gradient, maximum gradient slew rate, maximum specific absorption rate-SAR or an alternative RF exposure parameter such as $B1+_{RMS}$ (root mean square of the flip angle). The conditions of safe use also specify the configuration of the device, allowed implant locations, device reprogramming requirements during the scan, exclusion zones, specific patient monitoring demands and required staff for device programming and monitoring. Cardiovascular implantable electronic devices that do not meet the criteria for MRI conditional labelling are considered as non-MRI-conditional. This classification includes CIED devices that have one system component labelled as MR Conditional and the other component as non-MR conditional. For example, a system that has a pulse generator labelled as MRI conditional and pacing leads that do not have MRI-conditional labelling is considered as non-MRI-conditional (2,9).

Interactions of MRI environment with CIED

The interaction of the MRI environment with CIED systems has been the root cause of a historical contraindication to the presence of a cardiovascular implantable electronic device in patients undergoing MRI. These interactions include translational attraction or torque on device components due to the spatial magnetic field gradient (8). The magnitude of the translational force will vary based on the position of the device in the MRI scanner. Stronger translational forces are exerted on the device just outside the scanner bore. However, torque is strongest in the isocenter of the MRI scanner (10).

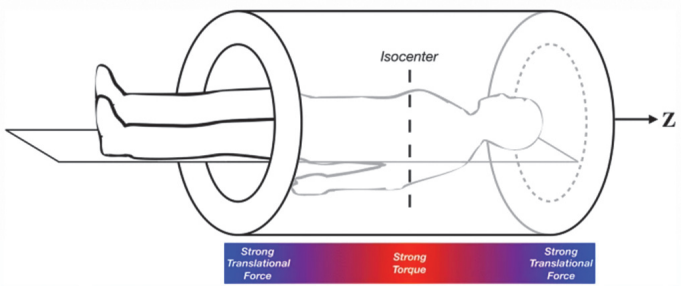

Figure 1: The schematic of excerted translational forces and torque on a CIED relative to the position in the scanner (10).

Radiofrequency pulses can cause ohmic heating via tissue absorption of the energy. This is measured using the specific absorption rate-SAR or an alternative method referred to as the root mean square of the flip angle $B1+_{RMS}$. SAR is a measure of the amount of RF energy the MR scanner produces and that may be absorbed by the tissue. The American Food and Drug Administration approves two SAR levels during an MRI examination; normal operating mode (≤ 2 W/kg whole-body SAR) and first-level mode (≤ 4 W/kg whole-body SAR). The specific absorption rate is a patient dependant measurement of RF energy deposit and SAR calculations vary between different MRI scanner vendors. The alternative method for estimating the applied RF energy is the time-averaged RF magnetic field measurement called root-mean-square or $B1+_{RMS}$. Root-mean-square is solely dependent on the MRI exam parameters and not patient specific parameters such

as height, weight, age and gender. It is calibrated by the MR system software during the pre-scan phase or measurements. Pacemaker leads can concentrate RF energy at their tip and potentially cause excessive heating, which can lead to damage of the local myocardium. In the literature, this occurrence is referred to as the antenna effect, where continual rotation of RF in a polarized magnetic field generates an electric field by Faraday's law of induction. This leads to the concentration of RF energy at the tip of the pacemaker lead. Gradient magnetic fields can induce a current in electrically conductive wires by turning on and off, which can result in myocardial stimulation (9-13).

Potential hazards to the patient with CIED

Initial reports of deaths in patients with CIED who were undergoing MRI are related to the absence of appropriate screening, reprogramming and patient monitoring. These reports, dating back to the late 1980s and early 2000s, contributed to the theory that CIEDs and the MRI environment were not compatible, and, therefore, were contraindicated. Other significant adverse events commemorated in early experience reports are dislodgements or movement of the device, radiofrequency heating of the hardware and surrounding tissue, activation of tachycardia therapies and increased pacing thresholds (14,15,16). Over the past two decades, CIEDs have been designed to reduce the potential risks associated with MRI. Preclinical and clinical studies of newer generation devices show that many issues noted with older devices are no longer present. Modern devices contain less ferromagnetic materials and better electromagnetic interference protection, resulting in a significantly lower rate of adverse events during the MRI examination (14,17). The European Heart Rhythm Association consensus on the prevention and management of interference due to medical procedures in patients with CIEDs has listed the possible effects of electromagnetic interference on these devices. Possible effects include inappropriate automatic mode switching, modification of measured pacing/sensing thresholds, over-sensing related adverse events, sudden battery depletion and power-on reset (16). Power-on reset is a specific type of reprogramming that reverts the device to the factory default settings when the battery voltage falls below a critical level (15). Recent clinical studies evaluated the safety of MRI examinations in patients with CIEDs according to the incidence of the mentioned possible effects. The MagnaSafe Registry was a prospective, multicentre study that was established to determine the frequency of cardiac-related clinical events and device setting changes among patients with non-MRI-conditional devices who underwent nonthoracic MRI at 1.5T magnetic field strength. It is the largest published registry that examined the outcomes of 1,500 patients with non-MRI-conditional CIEDs. Substantial changes in the device setting were infrequent and did not result in clinically adverse events; moreover, no device or lead failure was reported (18,19). Similar findings are presented in the systematic review and meta-analysis done by Munawar et al., that included 35 studies of non-conditional CIEDs in the MRI environment. The rate of adverse events was the highest in regards to significant changes in pacing lead impedance (incidence of 4.8%) and battery voltage (incidence of 2.2%). Findings of this meta-analysis are in accordance with the growing number of studies (1,11,15,18-25) demonstrating that comparatively minor device alterations such as a slightly depleted battery or altered pacing thresholds do not result in significant adverse outcomes.

While there is a growing body of evidence supporting the safety of MRI in patients with conditional and non-MRI-conditional devices, the evidence base supporting the safety of thoracic MRI examinations in such patients is limited to few single-centre studies (26-28). These studies demonstrate that with adherence to a standardized protocol and established exclusion criteria, thoracic MRI examinations in patients with CIEDs can safely be performed without clinically significant changes of device functions or adverse outcomes.

Recommendations for the management of patients with implanted MRI-conditional devices undergoing MRI (2,9,16,29).

1. Confirm the need for MRI: evaluate the risk-benefit ratio before making the decision to perform MRI on a patient with a CIED device. Factors that influence the risk-benefit ratio should be identified and discussed with the team of electrophysiologists and radiologists.
2. Determine whether the CIED system meets the MRI conditionality requirements. CIED systems that combine individual MR conditional leads and other device components from different manufacturers should be regarded as non-MRI-conditional. Another indicator of a non-MRI-conditional system is the presence of abandoned leads, extenders or adaptors, lead remnants or fractured leads.
3. Identify the manufacturer's specific instructions for safe use in the MRI environment. Manufacturer's instructions include a full evaluation of the CIED and leads. Conditions of safe use can include the region being scanned and associated exclusion zones, scanning parameter restrictions and active reprogramming of the device before and after the scan. In general, the majority of devices have been approved for scanning with 1.5T, gradient slew rate≤200 T/m/s, a maximal SAR ≤2 W/kg or alternative RF exposure parameter ($B1+_{RMS}$), and a limited number and length of imaging sequences.
4. Reprogramme the CIED system to one of the available company-specific pre-programmed settings. Pacing should be programmed to an asynchronous mode (VOO/DOO). Anti-tachycardia therapies and automated specialized algorithms must be switched off for all types of devices (16,29).
5. Monitor the patient using continuous real-time ECG and pulse oximetry. Device reprogramming can potentially impact the patient's rhythm status. For example, untreated tachyarrhythmia or absence of bradycardia pacing can occur. Therefore, it is recommended that ECG and pulse oximetry monitoring is continued until clinically appropriate CIED settings are restored. During the scan, professional oversight should be sought for the duration of time that the patient's device is reprogrammed. This professional oversight should be performed by personnel with the skill to perform advanced cardiac life support, including expertise in the performance of CPR, arrhythmia recognition, defibrillation, and transcutaneous pacing (2,29).

Recommended guidelines for non-MRI-conditional systems (2,9,16,29)

1. Confirm the need for an MRI scan.
2. Identify the MRI conditional status of the implanted device. Mind the presence of any abandoned, fractured or temporary pacing leads.
3. Determine whether the patient is pacing dependant or not. Patient pacing dependency is defined by the intrinsic heart rate. Pacing dependant patients are defined by an intrinsic heart rate below 50 beats per minute or by hemodynamic instability or symptoms of presyncope with device turndown (16,20). Reprogramming of the device should be based on this information.
4. Interrogate and reprogramme the device. Device interrogation include measures of lead impedance, pacing threshold, sensing amplitude and P- and R-wave amplitude. Pre and post MRI measures of this device parameters should not alternate. The cardiac electrophysiology team should determine the appropriate pacing mode for the patient. For patients who are not pacing dependant, it is required to reprogramme the device to either a nonpacing mode (ODO/OVO/OAO) or an inhibited mode (DDI/VVI/AAI). For patients that are pacing dependant, the required pacing mode will most likely be an ansynchronous mode (DOO/VOO/AOO) that does not compete with the intrinsic rate. Anti-tachycardia therapies and automated specialized algorithms must be switched off for all types of devices (2,29,30).
5. MRI is limited to 1.5T, using Normal Operating Mode for SAR. Local transmit/receive coils may only be used if they are not positioned directly over the CIED device. The gradient magnetic field slew rate is limited to ≤ 200T/m/s, the root mean square of the flip angle must not exceed 2.8μT (B1+RMS ≤ 2.8μT). The number and length of sequences should be minimized.
6. Monitor the patient using continuous real-time ECG and pulse oximetry. It is recommended that ECG and pulse oximetry monitoring is continued until clinically appropriate CIED settings are restored (2,29).
7. The CIED device should be reprogrammed to its original settings. Evaluate the device parameters as listed above (section 4). All changes in the device parameters and any adverse events, if observed, should be documented in the patient's medical record.

Implementation notes:

A. Patient monitoring hardware: It should be noted that although continuous monitoring of the cardiac rhythm is the primary objective, the electrocardiogram (ECG) might not be interpretable during the use of many MRI sequences. ECG and peripheral gating waveforms displayed on the MRI console are not sufficient for robust physiologic monitoring. Therefore, a dedicated MRI conditional patient monitoring system is likely required. Transcutaneous pulse oximetry which is relatively unaffected during MRI sequences can confirm a change in pulse rate in the absence of a technically adequate ECG signal (2,9,16,29).

B. Personnel requirements: Personnel who perform the interrogation of the CIED device prior and post scan, the evaluation of the patient and monitoring of the patient during the scan are required to complete basic and advanced life support training (BLS and ACLS). An external defibrillator should be located just outside Zone III. The institution must have a written plan for managing the patient, including immediate evacuation to this location in the event of a cardiac emergency. For patients that require higher level monitoring (pacing dependant patients) it is recommended that a cardiac electrophysiologist is present during the MRI study (2,9).

C. Presence of abandoned leads: Significantly higher heating in abandoned leads compared with leads terminated at the pulse generator have been discovered in some phantom studies. Currently, available guidelines do not provide specific recommendations for abandoned leads (2,16,29). However, the 2017 Heart Rhythm Society consensus does not exclude imaging of these patients when the clinical indication exists (29).

D. Pacing modes: Cardiovascular implantable electronic device pacing modes are denoted with a three-letter code. The first letter describes which area/chamber is being paced and the second letter stands for the area/chamber being sensed. The third letter describes how the device responds when a beat is being sensed. For example, in VOO (asynchronous mode) pacing, the ventricle is paced at the fixed rate with no device sensing. Therefore, the device paces at the programmed rate regardless of the intrinsic electrical activity of the heart (31).

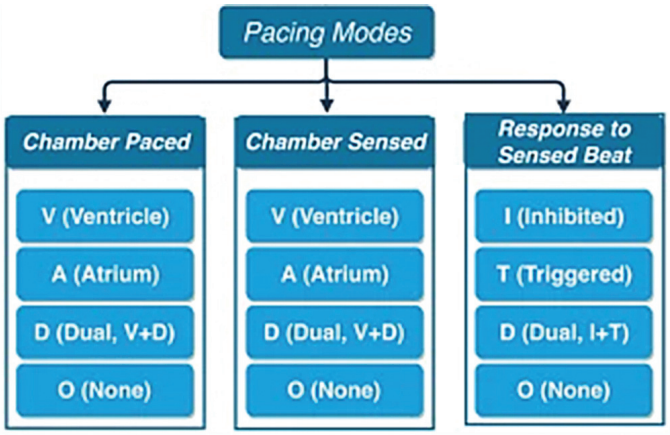

Figure 2: Types of pacing modes for CIED.

AIM

The purpose of this paper is to present an overview of the literature-based management of patients with CIED devices and to present a case of a patient with a CIED with exclusion zone requirement during a prostate MRI examination at our institution.

METHODS

This paper explores the MRI safety and managing of patients with implanted CIED devices through an extensive literature review and case presentation. The study was approved by the ethics committee of the Oncology Institute Ljubljana, Slovenia (research permission number: ERIDNPVO-0058/2022). The literature search was conducted using medical scientific electronic databases such as PubMed, Cinahl, Wiley Online Library and ScienceDirect during the period from January to

April 2022. The search used keywords of "magnetic resonance imaging" AND "pacemaker" OR "implantable cardioverter defibrillator" OR "cardiac resynchronization therapy" OR "CIED". The search was limited to articles in the English language and human studies. Published studies were reviewed manually for proposed diagnostic pathways/protocols, practice recommendations, guidelines and published manuals on MRI safety of CIED devices. Clinical studies were included if the following criteria were met: enrolment of patients with conditional and non-conditional CIEDs undergoing MRI, assessment of device alterations and adverse outcomes. Articles published before 2010 and clinical studies that included fewer than 10 patients were excluded from the review. The BIOTRONIK ProMRI technical manual was acquired using the Magresource online database that stores the MRI safety status of the implantable medical devices.

Case presentation

We examined a 52-year-old patient with a CIED device undergoing a classic prostate MRI examination. The scan was performed with a GE Optima™ MR450w 1.5T scanner using an anterior phased array for the pelvic region. The implanted device was a combination of a triple chamber pacemaker model called Entovis HF non-US and a lead model Solia S 53. The Biotronik ProMRI technical manual labelled this combination as MR conditional, under specific conditions. The permissible positioning zone had to be maintained during the MRI scan, denoting that the isocenter of the high-frequency coil had to be at the level of the greater trochanter for the duration of the scan. Other specific conditions included the limitation of the mean specific absorption rate to 2W/kg, limitation of the maximum slew rate (<200T/m/s) and use of a clinical MRI scanner with a closed bore, cylindrical magnets, and a static magnetic field strength of 1.5 T.

RESULTS AND DISCUSSION

We performed the examination of the described patient in accordance with the guidelines presented in this paper. The need for an MRI examination for this particular patient was confirmed by the referring physician, radiologists and anaesthesiology team at our institution. The pacemaker identification card was examined in order to acquire information about the type of device and attached leads. The presence of any abandoned leads, extenders or adaptors, lead remnants or fractured leads was not identified. The MRI conditionality status was determined using the device identification card and the manufacturer's technical manual. The latter was acquired using the Magresource database. The combination of the device (Entovis non-US) and pacemaker leads (Solia S53) was identified as MRI conditional under specific conditions that include the use of an exclusion zone.

On the examination day, the patient was first appointed to the pacemaker clinic where the anaesthesiology team interrogated the functionality of the device and patient device dependency. They discovered that the patient is not pacemaker dependant and in accordance with this, the CIED system was reprogrammed to the asynchronous mode DOO. Device parameters, capture threshold, lead impedance, sensing amplitude and battery status were measured.

	HF and HF-T	
	Entovis Evia	Eluna 8 Epyra 8 Etrinsa 8
Safio S / Setrox S 45; 53; 60	1.5 T EXZ	
Solia S / Siello S 45; 53; 60		
Solia JT / Siello JT 45; 53		
Solia T / Siello T 53; 60		
Corox (ProMRI) OTW BP 75; 85		
Corox (ProMRI) OTW-S BP 75; 85		
Corox (ProMRI) OTW-L BP 75; 85		
Sentus (ProMRI) OTW BP L 75; 85; 95		
Sentus (ProMRI) OTW BP S 75; 85; 95		

Figure 3: Combinations of device types and pacemaker leads that require an exclusion zone at 1.5T according to the Biotronik ProMRI technical manual.

Measurements were in the normal range for all parameters. After the device interrogation and reprogramming, the patient was appointed to the MRI department where we performed the standard MR safety screening process. MRI scanner conditions were adjusted according to the Biotronik ProMRI technical manual. The technical manual allows the use of a clinical MRI scanner with a closed bore and a static magnetic

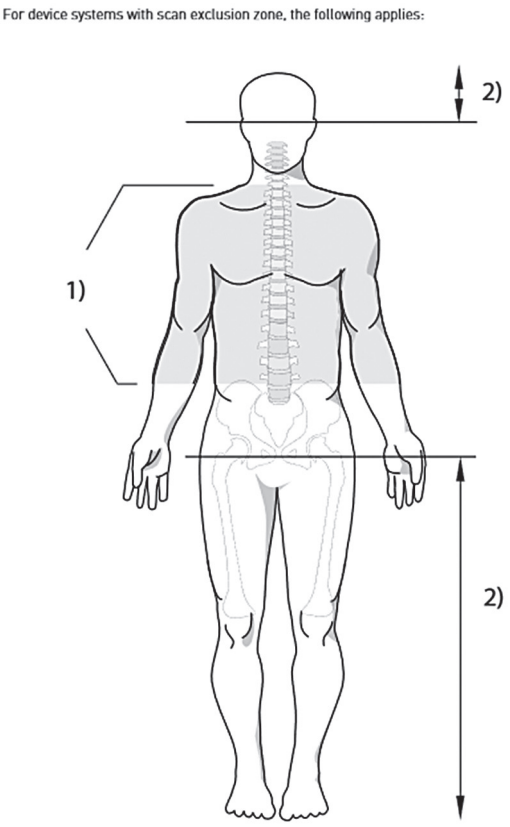

Figure 4: Defined isocenter levels and exclusion zones for CIED.

field strength of 1.5T for this particular device. The maximum slew rate of the gradient fields was limited to 200T/m/s and the mean specific absorption rate did not exceed 2W/kg. For this combination of the pacemaker model and attached leads, the permissible positioning zone must always be maintained for the duration of the MRI scan. In accordance with the manufacturer's technical manual, we adjusted the isocenter of the high frequency coil to the level of the greater trochanter as presented in Figure 4.

Patient monitoring was performed and maintained by the anaesthesiology team for the duration of the MRI examination. We used continuous real-time ECG monitoring and pulse oximetry consulting the technical manual and recommendations for the management of patients with implanted MR conditional devices presented in this paper. ECG monitoring was performed with the Invivo MRI Patient Monitoring System, Model 865214 that is compatible with the strong magnetic fields in the MRI environment. Monitoring was continued until the patient was removed from the MRI Scanner. The patient was appointed back to the pacemaker clinic where the anaesthesiology team reprogrammed the device to its original settings and interrogated the functionality of the device and possible changes in device parameters. No changes of device parameters were discovered. The MRI examination of the patient was completed without complications; therefore, no adverse effects were reported. MRI images were without artefacts.

CONCLUSION

In the past decades, cardiovascular implantable electronic devices shifted from being a complete contraindication in the MRI environment to not presenting a significant risk for MR conditional devices in controlled situations. This step forward was enabled by the advances in engineering to limit interactions between the device and MRI magnetic fields. Interactions were minimized with the use of optimised imaging and screening protocols for patients with a CIED undergoing MRI examinations. Recent clinical studies and published guidelines suggest that MRI of patients with either MRI conditional or non-MRI-conditional CIED devices are relatively safe under specific conditions. Multidisciplinary pre-procedure planning, strict screening process, monitoring and device evaluation protocols are of key importance for ensuring safe MR imaging in patients with a CIED. Multidisciplinary management requires cooperation between the referring physician, radiologist, radiographer and the cardiac electrophysiology team. The screening process and device evaluation protocols must determine the MRI conditionality of the device and patient device dependency status. Based on this information, appropriate device reprogramming should be performed. The MRI protocol for imaging MRI conditional CIED devices must be in compliance with manufacturer's technical manual recommendations. Some device models require the use of exclusion zones denoting that the isocenter of the high frequency coil must not be placed over this anatomic area (usually the thorax region). Recommendations for imaging MR non-conditional CIED devices include the limitation of a static magnetic field to 1.5T, limitation of the maximum gradient field slew rate to ≤ 200T/m/s and use of the Normal Operating Mode for specific absorption rate (<2W/kg). Patient monitoring must be performed using continuous real-time ECG and pulse oximetry. It is recommended that ECG and pulse oximetry monitoring is continued until clinically appropriate CIED settings are restored.

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Review article

DIAGNOSTIC REFERENCE LEVELS IN DENTAL RADIOLOGY: A SYSTEMATIC REVIEW

Diagnostične referenčne ravni v dentalni radiologiji - Sistematični pregled literature

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ABSTRACT

Purpose: The purpose of this work was to review published articles in the field of diagnostic reference levels in dental radiology, and to determine which areas have not been covered yet and require further scientific studies. The aim was also to determine if there are any dose optimization procedures suggested after DRL establishment.

Materials and methods: A systematic review was performed using the Science Direct, PubMed, CINAHL (via EBSCOhost) and Dentistry & Oral Sciences Source (via EBSCOhost) databases, following the Cochrane Network study design guidelines. Articles were analysed and presented by author, year of publication, country of origin, technology (e.g. digital radiography, computed radiography and film-screen), radiographic type (e.g. intraoral, panoramic and CBCT), units of measurement and main conclusions for each study.

Results: Thirteen scientific articles on dose reference values in dental radiology were evaluated. Full-access articles published between 2001 and 2021 were used, and both reviews and original research articles were included. The studies address the definition or analysis of DRLs in intraoral and panoramic dental imaging and in dental CBCT imaging. Many studies report results based on different image-receiving systems (e.g. DR, CR and film-screen). The film-screen system yielded the highest dose values of all three systems. All studies reviewed describe DRLs for the adult population, while only four also describe paediatric DRLs.

Conclusion: Most EU countries have not yet set national DRLs for dental radiology. Most studies set or revise DRLs at the national level and compare them with guidelines from literature and from similar studies conducted in other countries. Most of these studies observed DRLs in the adult population. DRLs should also be set in the field of dental CBCT imaging, as the use of this technology is rapidly increasing and the dose levels are incomparably higher than in general dental radiography.

Keywords: dental radiography, diagnostic reference levels, intraoral imaging, panoramic dental imaging.

IZVLEČEK

Namen: Namen tega dela je pregledati objavljene članke s področja diagnostičnih referenčnih ravni v dentalni radiologiji, določiti področja znotraj slednje, ki še niso bila obravnavana in ki zahtevajo nadaljnje raziskave, pa tudi raziskati, ali po vzpostavitvi diagnostičnih referenčnih ravni študije predlagajo katero od oblik optimizacije doze.

Materiali in metode: Izvedli smo sistematični pregled literature z uporabo podatkovnih baz Science Direct, PubMed, CINAHL (preko EBSCOhost) ter Dentistry & Oral Sciences (preko EBSCOhost). Pri zasnovi študije smo delno sledili smernicam Cochrane omrežja. Članke smo analizirali in razvrstili glede na avtorje, leto objave, državo nastanka, tehnologijo (digitalna radiografija, računalniška radiografija, sistem folija-film), vrsto slikanja (intraoralno, panoramsko, CBCT) in uporabljene merske enote, za vsako študijo pa smo zapisali glavne ugotovitve.

Rezultati: Trinajst znanstvenih člankov, ki obravnavajo diagnostične referenčne ravni v dentalni radiografiji, smo analizirali in ocenili. Uporabili smo članke s polnim dostopom, objavljene med leti 2001 in 2021. Upoštevali smo tako izvirne kot pregledne znanstvene članke. Raziskave obravnavajo vzpostavitev ali analizo DRR-jev pri intraoralnem, panoramskem in zobnem CBCT slikanju. Velik delež raziskav poroča in ločuje rezultate glede na slikovni sprejemnik (DR, CR, folija-film). Sistem folija-film se je izkazal kot sistem z najvišjimi doznimi vrednostmi. Vse analizirane raziskave obravnavajo odraslo populacijo, le 4 opisujejo tudi DRR-je za pediatrijo.

Zaključek: Večina držav Evropske unije še nima vzpostavljenih DRR-jev na nacionalnih ravneh za področje dentalne radiologije. Večina obravnavanih raziskav vzpostavlja DRR-je na nacionalni ravni in jih primerja s smernicami iz literature ali s podobnimi študijami, izvedenimi v drugih državah. Večina raziskav obravnava odrasle paciente. Pojavlja se pomanjkanje raziskav s področja DRR-jev za dentalno CBCT slikanje, saj je uporaba te tehnologije v strmem porastu, dozne ravni zanjo pa so občutno višje v primerjavi s splošno dentalno radiologijo.

Ključne besede: dentalna radiografija, diagnostične referenčne ravni, intraoralno slikanje, panoramsko slikanje

Introduction

Technological development in dental radiology began after 1919, when adequate electrical insulation made it possible to safely perform intraoral imaging techniques. Panoramic dental imaging was developed and introduced for general use in the 1960s, while computed tomography has been used since the 1970s (1).

The newest technology in dental radiology is cone beam computed tomography (CBCT), the use of which is rapidly increasing. It was developed for the maxillofacial region in 1995 and has been available for commercial use since 1999. Its use is popular primarily because it is a low-cost diagnostic technology that enables treatment planning and image-guided surgical and operative procedures (2).

Ionizing radiation exposure in dental radiology contributes to approximately 2.5% of the effective dose received during medical examinations. The average adult effective dose for intraoral radiographs is 0.005 mSv for panoramic radiographs 0.01 mSv, and 0.011 to 1.073 mSv for dental computed tomography (3).

According to the European guidelines for radiation protection in dental radiology, 96 to 449 dental radiological examinations are performed per 1,000 inhabitants in the countries of the European Union that have provided such data (4). Because of the large number of professionals performing such procedures and because many examinations in dentistry involve the use of ionizing radiation, certain radiation protection measures must be considered for patients exposed to a certain dose of ionizing radiation during these imaging examinations. One way to ensure optimal performance by a healthcare provider when using ionizing radiation is to determine diagnostic reference levels (DRLs)

DRLs are usually easy to measure and are directly related to the radiation dose received by the patient (5). DRLs are the dose levels for ionizing radiation in diagnostic radiologic procedures that should not be exceeded if the procedure is optimized. They are determined using measured dose levels for patients undergoing a specific diagnostic examination. It is recommended that they be measured on as many x-ray machines as possible. The DRL is determined by the value of the third quartile of all doses received (6).

Diagnostic reference values for radiological procedures in adults have been established for 72% of the 36 European countries. According to the European Commission report, the specific DRL values for dental radiology have only been applied at the national level in Finland and France (7). The European guidelines for radiation protection in dental radiology also state that few countries have conducted national or similar studies to determine DRLs and that there are no published DRLs for dental radiography at the European level (4). The establishment of national and local DRLs is proposed by the International Atomic Energy Agency for all medical examinations and procedures, for all clinical indications and for all patient groups (adults and size-dependent groups of children) (8).

Because of the aforementioned large number of radiologic procedures performed annually in dentistry, the establishment of DRLs for this profession is of great importance. Specifically, for CBCT imaging, there is also a great need to establish DRLs, as the doses of ionizing radiation received in this technology are considerably higher than those received in intraoral or panoramic dental imaging and are comparable to those received by the patient during radiographs of the pelvis or abdomen (7).

We use different units of measurement to determine DRL values. In general radiography, air kerma product (KAP or PKA) and entrance surface air kerma (Ke) are commonly used. CTDIvol (computed tomography dose index) or dose length product (DLP) are used in computed tomography, while the received dose is considered in terms of activity delivered to the patient or activity per kilogram of body weight in nuclear medicine. Literature recommends using incident air kerma (Ki) for intraoral dental imaging and PKA for dental panoramic imaging (8).

The authors of the articles discussed in this paper also use the unit PED (patient entrance dose) instead of ESD (entrance skin/surface dose). It is defined as the absorbed dose in air measured at the end of the spacer 'cone' for typical examinations without backscatter from the patient (9).

Aim of the study

The aim of this systematic review was to investigate how many countries, health facilities or radiology departments have already established diagnostic reference values for dental radiology. The aim was also to determine which areas of dental radiology (intraoral, panoramic or CBCT imaging) these DRLs cover and whether their establishment has suggested dose optimization for patients.

Methods

We performed a systematic review of literature. We relied in part on the guidelines of the Cochrane network when designing our study (10).

Sources

The Science Direct, PubMed in CINAHL (via EBSCOhost) and Dentistry & Oral Sciences Source (via EBSCOhost) scientific databases (11–14) were used to perform the search via the University of Ljubljana's and Central Medical Library's remote access.

Inclusion and exclusion criteria

A search algorithm based on a combination of keywords and logical operators was used in this review and is described in Table 1. No exclusion criteria in the first search (for example the use of logical operator NOT) were applied.

In the next step of the process, other conditions were set: full access articles, not older than 10 years (published between 2001 and 2021), and the inclusion of reviews as well as original research articles. After the initial search, which yielded 134 documents, exclusion criteria were applied and, at the end of the process, 13 articles were considered for inclusion in this review. The step-by-step process of document selection is shown in Figure 1.

The results of the review were then presented in Table 2. Studies were listed by author, year of publication, country of origin, technology (e.g. digital radiography, computed

Table 1: Keywords and logical operators

1st keyword	Logical operator	2nd keyword	Logical operator	3rd keyword
dental	OR	dentistry	OR	oral
Logical operator: AND				
x- ray	OR	radiology	OR	radiography
Logical operator: AND				
DRL	OR	diagnostic reference levels		

radiography and film-screen), type of radiography (e.g. intraoral, panoramic and CBCT), units of measurement, and main conclusions for each study.

Results

By using search terms and exclusion criteria described earlier and after further analysis of titles and abstracts, 13 studies were eligible for inclusion in this systematic review and are presented in Table 2.

This systematic review analysed 13 scientific articles from 10 different countries that address the area of diagnostic reference values in dental radiology. Most of them deal with the establishment and/or analysis of DRLs in general radiography (intraoral and panoramic dental imaging), while only two studies deal with CBCT imaging (17, 21). The DRLs are considered at the national level, while the authors performed comparisons between institutions and a larger number of radiographic units. Only Izawa et al (20) specify local DRLs and a comparison of three units at an institution with the aim of optimising and standardising the institution's imaging protocols.

The authors of studies also frequently reported results on different image-receiving systems (e.g. DR, CR and film-screen). In all studies that made such a comparison, the film-screen system was found to have the highest dose levels of all three systems.

All studies reviewed describe DRL values for the adult population, while only four studies (9, 19, 22, 25) also describe paediatric DRL values. The importance of the latter is particularly emphasised in Holroyd's study, as it describes cephalometric imaging and the associated dose burden. Since cephalometric imaging is most commonly used in orthodontics and the patients are mostly children, special attention should be paid to optimal (as low as possible) dose exposure in this type of dental radiology, since children are more sensitive to ionising radiation, which can cause more damage in children than in adults (19).

Discussion

All articles studied report specific DRL values, i.e. the value of the 3rd quartile of measured doses from their data. The values are then compared with literature, with guidelines or, as in the study by Manousaridis et al. (23), with previous studies from the same country. This shows the importance of national DRL facilities everywhere, including Slovenia.

Some authors emphasise the legal reasons for conducting these types of studies. For example, Alcaraz et al (15) mention the legal status of mandatory annual DRL reviews as part of the quality assurance programme in Spain. This may serve as a reason for conducting such studies. These reviews are mandatory in most European countries, but not all countries specify the time frame for their implementation. For example, Slovenian legislation does not specify how often a DRL review should be performed, but does states that the institution responsible for radiation protection should set DRL values based on systematic reviews of patient exposure and that it should follow European and other international recommendations in this area (27).

Considering the small number of studies performed in CBCT imaging DRLs, this area of radiology seems very suitable for further research. The use of this technology is rapidly increasing, but dose levels can be up to 26 times higher than in dental panoramic imaging (18).

Dose optimization for specific imaging modalities should always be considered. This applies to exposure parameters for general radiography, as well as FOV and resolution (these two can be controlled by the user) for CBCT imaging. It is especially important to establish and regularly revise DRLs, as they are one of the key factors that guide all parties involved in the process (dentists, radiographers, radiologists, medical physicists and service technicians) toward a high-quality work process that causes the least possible harm to patients.

Limitations

The fact that there are significantly fewer studies in the field of dental radiology compared to general radiography (X-ray or computed tomography) is the reason why this systematic review has limitations. When the sample is larger, the results are easier to interpret. In our case, we can only compare them in terms of their main results and derive some guidelines for possible further research, for example, the recommendation to extend the research to the field of CBCT imaging and the associated dose burden. Another problem that appears in our review is the problem of comparing the studies correctly because they do not all use the same units of measurement. Some even suggest the use of new units of measurement, although literature recommends using Ki for intraoral and PKA for panoramic images.

Table 2: Review of studies

Author	Year	Country	Sample	Technology	Radiography type	Units of measurement	Main conclusions
Alcaraz et al. (15)	2012	Spain	16175 official reports, gathered between 2002 and 2009	DR, CR, film-screen	Intraoral	ESD	Eight-year-long observation (2002–2009). DRL value in 2009 was 3.1 mGy (which is 35.4 % less than in 2002 when the value was 4.8 mGy). EU guidelines for intraoral imaging in 2004 recommended a value of 4 mGy; 83.4 % of institutions are below this value. DRL values also change which each system used (DR has the lowest, while film-screen has the highest one). Regular revisions are suggested, at least every three years (Spanish legislation even requires them every year) as part of the QA programme in dental offices. Limitation: there is no data on how many expositions were repeated.
Alcaraz et al. (16)	2015	Spain	34143 official reports gathered between 1997 and 2014	DR, CR, film-screen	Intraoral	ESD	DRR observation from 2002–2014. In 2014, the value was 2.8 mGy (41.7 % less than in 2002 when the value was 4.8 mGy). In the last three years since their last study, DRL values stabilised. It is assumed that this happened because of the stabilisation in technology system changes and the establishment of digital systems. For every x-ray machine, 10 exposures were made, measured in mGy, for upper second molar.
Christofides et al. (9)	2016	Cyprus	20 machines	Film-screen	Intraoral	DAP	They stress the importance of DRL establishment for all age groups (this study also included children) and the calculation of PED value. DRLs are between 7.23 mGy (upper molar, adults) and 1.88 mGy (lower incisor, children). The DRLs are slightly higher than those of EU guidelines, although those are expressed as ESD values, while the ones from this study are in PED value, which does not include backscatter radiation. There are significant differences between the 20 locations (x-ray machines). Dose value standardisation and reduction are supposed to be achieved in the future, primarily by transitioning to digital receivers.
Deleu et al. (17)	2020	Switzerland	227 machines	DR	CBCT	P_{KA}, $CTDI_{vol}$	Besides DRL establishment, the study also suggests the establishment of certain guidelines and recommendations on FOV (field of view) sizes, even though their results showed that mostly small size FOV are used (average area 25 cm^2, which means this aspect of dose reduction is already considered and in use). The suggested DRLs in this study are normalized to the FOV dimension. Head and neck CBCTs were also considered in this study, not only dental, although the indications still mostly require dental CBCTs, so the establishment of DRLs in this area is especially important.

Author	Year	Country	Sample	Technology	Radiography type	Units of measurement	Main conclusions
Han et al. (18)	2011	South Korea	129 machines	DR	Intraoral, panoramic, cephalometric, CBCT	DAP	The measured values for intraoral examinations are 55.5; 46 and 36.5 mGy*cm^2 (for upper molar, premolar and incisor, respectively) and 120.3; 146 and 3,203 mGy*cm^2 for extraoral examinations (for panoramic, cephalometric and CBCT imaging, respectively). In intraoral dental imaging, the DAP value relates to tube current and exposure time product (mAs), while the CBCT imaging's DAP is more closely linked to the FOV. There are some differences in the measured dose values between private clinics and university hospitals.
Holroyd et al. (19)	2011	Great Britain	42 machines	DR, CR, film-screen	Cephalometric	DAP	A phantom study. DAP values for adults: 40 mGy*cm^2 for digital systems and 42 mGy*cm^2 for screen-film. For children: 25 mGy*cm^2.
Izawa et al. (20)	2017	Japan	3 machines (local DRLs)	Film-screen	Intraoral	P_{KA}, PED	Local DRLs were established taking into account a possible difference between genders. The dose values are slightly lower in women, which is supposed to be a consequence of the difference in size, since women ae usually smaller, so the operator should adjust exposure parameters. PED values are 1.56 ± 0.27, 1.09 ± 0.31, 1.92 ± 0.38, mGy for upper incisors, premolars and molars, respectively, and 1.27 ± 0.22, 2.42 ± 0.33 in 1.59 ± 0.20 mGy for lower incisors, premolars and molars, respectively.
Kim et al. (21)	2012	South Korea	126 (104 considered in the study) machines	DR, CR, film-screen	intraoral	DAP, PED	The study recommends DRL values for South Korea: 3.1 mGy (PED) and 87.4 mGy*cm^2 (DAP) for lower molar for adults. This study also shows lower dose values in digital systems compared to those in film-screen systems. They also considered the installation duration of the machine (<5 years in >6 years) and the type of dental x-ray machine (e.g. wall-mounted fixed type and hand-held portable type). There were no statistically significant differences with respect to equipment installation duration and type of dental X-ray system.
Manousaridis et al.(22)	2015	Greece	519 machines	DR, CR film-screen	panoramic	K_i	Three categories were analysed: children, petite adults and average adults. Recommended DRLs were 2.2; 3.3 and 4.1 mGy, respectively. Three systems were compared as well (DR, CR and film-screen), with dose values at the 3rd quartile of 3.5; 4.2 and 3.7 mGy, respectively. As we can see, the highest dose value is recorded with the CR system.

Author	Year	Country	Sample	Technology	Radiography type	Units of measurement	Main conclusions
Manousaridis et al. (23)	2013	Greece	529 machines	DR, CR, film-screen	Intraoral	K_i	DRL value for upper molar is set at 0.95 mGy for digital systems and 2.90 mGy for film-screen, which is comparable to or even lower than in those countries that at the time of this study provided such data (Spain, USA, Romania, Great Britain and previous studies in Greece).
Praskalo et al. (24)	2020	Bosnia and Herzegovina	41 machines	DR, film-screen	Intraoral	K_i, P_{KA}	New DRLs for the film-screen system (3.5 mGy) and for digital receivers (1.2 mGy) are recommended and are significantly lower than those established until now at the national level with a DRL value of 7 mGy. This value was taken from literature and not established as a result of a national study. There are considerably lower doses for digital receivers.
Suliman, Abdelgadir (25)	2018	Sudan	14 machines	DR, film-screen	Intraoral, panoramic	K_i, P_{KA}	The study recommends new DRLs for intraoral imaging: 1.45 mGy (DR), 4.45 mGy (film-screen) and 3.01 mGy (combined). For panoramic dental imaging, only average values are stated (and not the 3rd quartile, which is specific for DRLs): 70.4 mGy*cm^2 for children and 103.4 mGy*cm^2 for adults. The study describes significant differences between hospitals. This shows the there is a lot of room for protocol optimisation.
Walker et al. (26)	2010	Ireland	83 machines	*data unavailable*	Intraoral, panoramic	ESD, DWP (dose width product)	Suggested DRLs from this study are 2.4 mGy for lower molar for intraoral imaging and 60 mGy mm for panoramic imaging of adults. The study also recommends the introduction of a new reference quantity 1 mGy/mAs, which considers dose as well as exposure time. The recommended DRL for intraoral imaging with this new unit is 1.03 mGy/mAs. DRLs are comparable to literature, sometimes even lower due to new technologies.

Conclusion

As stated in the introduction from the European Commission Guidelines for Radiation Protection in Dental Radiology, most EU countries have not yet established national DRLs for dental radiology. In this systematic review, 13 original research articles on local or national DRLs in dental radiology for the EU and other countries were discussed. Most of these studies focus on intraoral and panoramic dental imaging, with only a few on CBCT imaging. This implies that there is room for further research in this area. Most studies set or revise DRLs at the national level and compare them with guidelines from literature and from similar studies conducted in other countries. Only one study is the result of local DRL establishment with the goal of protocol optimization. In our selection of articles, DRLs are mostly set for the adult population, and only in four cases for paediatric patients, although they require special consideration in terms of dose optimization.

In the future, DRLs should also be set in the field of dental CBCT imaging, as the use of this technology is rapidly increasing, and dose levels are incomparably higher than for general dental radiography. All EU countries should set DRLs for radiographs and for dental CBCT imaging, as suggested in guidelines or recommendations issued by European institutions responsible for radiation protection.

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