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Prospective study on the efficacy of low-field intraoperative magnetic resonance imaging in neurosurgical operations

Prospektywna ocena przydatności niskopolowego śródoperacyjnego rezonansu magnetycznego w operacjach neurochirurgicznych

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Abstract

Background and purpose: The application of intraoperative magnetic resonance imaging (iMRI) is related to a series of challenges of both a technical and an organizational nature. We present our experience in the application of low-field iMRI in everyday neurosurgical practice.
Material and methods: A group of 58 patients operated on using low-field iMRI was subject to prospective controlled observation. The significance of differences in the range of preparation time, duration and direct operation results between the iMRI group and controls was analysed. The influence of epidemiological and demographic factors and technical aspects related to iMRI application on direct outcome of the surgery was assessed.
Results: Twenty-eight tumour resections using craniotomy, 17 transsphenoidal resections of pituitary adenomas and 13 stereotactic procedures were conducted in the group of 24 men and 34 women operated on using iMRI. The control group was not significantly different in terms of epidemiological and demographic factors. The preparation and operation times were significantly longer in the iMRI group ($p < 0.001$ and $p = 0.002$, respectively). Longer duration of the surgery was not related to an increased frequency of complications. A higher percentage of postoperative improvement in neurological status (31% vs. 14%, $p = 0.045$), lower complication percentage (10% vs. 28%, $p = 0.03$) and

Streszczenie

Wstęp i cel pracy: W pracy przedstawiono pierwsze doświadczenia w wykorzystaniu śródoperacyjnego niskopolowego rezonansu magnetycznego (iMRI) w codziennej praktyce neurochirurgicznej, z uwzględnieniem wyników prospektywnej obserwacji wpływu jego zastosowania na bezpośrednie wyniki operacji.
Materiał i metody: Prospektywnej kontrolowanej obserwacji poddano grupę 58 pacjentów operowanych z wykorzystaniem iMRI. Grupę kontrolną stanowili pacjenci operowani z wykorzystaniem neuronawigacji optycznej bez zastosowania iMRI. Zbadano istotność różnic w zakresie czasu przygotowań, czasu trwania i bezpośrednich wyników operacji pomiędzy grupą badaną i grupą kontrolną. Oceniano wpływ czynników epidemiologicznych, demograficznych oraz aspektów technicznych związanych z zastosowaniem iMRI na bezpośredni wynik operacji.
Wyniki: W grupie 24 mężczyzn i 34 kobiet operowanych z wykorzystaniem iMRI wykonano 28 resekcji guzów mózgu drogą kraniotomii, 17 przezklinowych resekcji gruczolaków przysadki i 13 procedur stereotaktycznych. Czas przygotowań i czas operacji były istotnie dłuższe w grupie iMRI (odpowiednio $p < 0{,}001$ i $p = 0{,}002$). Wydłużenie czasu trwania procedury nie było związane ze wzrostem częstości powikłań. W grupie operowanej z wykorzystaniem iMRI stwierdzono większy odsetek osób z pooperacyjną poprawą

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a similar time of hospitalization (13 ± 7 vs. 12 ± 4 days, $p = 0.33$) were noted in the iMRI group.
Conclusions: The application of low-field iMRI prolongs the duration of neurosurgical procedures but does not negatively influence their safety. It is associated with above-average functional results and a lower percentage of total complications.

Key words: intraoperative imaging, intraoperative magnetic resonance, neurooncology, neuronavigation.

stanu neurologicznego (31% *vs* 14%, $p = 0{,}045$), mniejszy odsetek powikłań (10% *vs* 28%, $p = 0{,}03$) oraz zbliżony czas hospitalizacji (13 ± 7 *vs* 12 ± 4 dni, $p = 0{,}33$).
Wnioski: Zastosowanie niskopolowego iMRI, choć wydłuża czas procedur neurochirurgicznych, nie wpływa negatywnie na ich bezpieczeństwo. Pozwala przy tym uzyskać lepsze od przeciętnych wyniki funkcjonalne oraz mniejszy globalny odsetek powikłań.

Słowa kluczowe: obrazowanie śródoperacyjne, śródoperacyjny rezonans magnetyczny, neuroonkologia, neuronawigacja.

Introduction

Radicality of tumour removal is one of the basic factors influencing the long-term outcome in neurooncological cases. This is the main factor, apart from the degree of histological malignancy of the neoplasm, affecting both progression-free survival time and overall survival time [1,2]. Intraoperative assessment of resection radicality, especially in the case of malignant brain gliomas, is extremely difficult and their localisation in eloquent regions is an additional factor complicating the course of the operation. Obtaining real-time intraoperative images of the brain allows the surgeon to maximize the opportunity to perform optimal tumour resection [3]. For many years, different possibilities for the improvement of intraoperative assessment of tumour removal radicality have been elaborated. They were aimed at increasing the radicality of tumour resection without the risk of permanent deterioration in the patient's neurological status [4,5].

Intraoperative magnetic resonance imaging (iMRI) is a method of intraoperative diagnostics enabling real-time operative navigation and an assessment of the extent of tumour removal as well. According to Black *et al*. [6] intraoperative MRI imaging for monitoring of the course of an operation was introduced to neurosurgical practice over 10 years ago.

Presently, two types of iMRI systems, requiring appropriate preparation of the operating rooms and their back-up facilities, are in use in neurosurgical centres worldwide. The first system is based on the application of high-field resonance (1.5 T or more) generating images of perfect quality, allowing a wider range of intraoperative diagnostics including vascular, functional and metabolic examinations [7-9]. By virtue of the necessity to guarantee the proper technical and personnel back-up for high-yield MR, the decision on apparatus installation is usually undertaken at the hospital design stage. The factor that undoubtedly considerably influences the low prevalence of this kind of installation, especially in Europe, is its high cost [10]. Thus, there is an interest in low-field MR machines that do not require additional infrastructure, are cheaper to install and operate, and ensure images of a quality enabling navigation and decisions to be taken during the operation [3,11]. The application of intraoperative imaging increases the degree of procedure complication, often requires additional personnel involvement, and may prolong the time of the preparation for the operation and duration of the operation itself [3,12]. There are not many papers in the available literature that consider the issue of the technical aspects of iMRI application on operation security and direct treatment results. The aim of the paper was a prospective assessment of the results of preliminary experience on the application of low-field iMRI PoleStar N20 during intracranial pathology operations in the Department of Neurosurgery at Wroclaw Medical University.

Material and methods

The patients who were operated on during the period from August 2008 to October 2010 in the Department of Neurosurgery at Wroclaw Medical University using iMRI (PoleStar N20, Medtronic Navigation, Louisville, CO, USA) were subject to prospective controlled observation. The mobile iMRI apparatus generated a constant magnetic field of an intensity of 0.15 T enabling examinations in T1, T2 and FLAIR sequences of a 16 × 9 cm field of view (FOV) to be conducted. All the procedures took place in an operating room adapted for iMRI application. The room was equipped with filters and screens reducing the influence of external interferences of the magnetic field on the quality of conducted examinations.

Preparation for the operation

The informed consent for an operative procedure with iMRI signed by each patient was supplemented with a standardized questionnaire concerning metallic implants, used before the planned diagnostic examinations using high-field MR. Anaesthesiological qualification and anaesthesia management did not differ significantly from accepted standards [13]. The anaesthesia procedure was conducted using a respirator adapted for the operation in a magnetic field (Aestiva/5 MRI, GE Healthcare, Madison, WI, USA).

The positioning of the anesthetized patient and the iMRI apparatus was conducted according to the procedure described by Senft *et al*. [5]. The selection of a sequence for intraoperative MR examination (T1, T2 or FLAIR), scan orientation (axial, sagittal, coronal) and presumptive administration of gadolinium contrast were based on a preliminary analysis of preoperative high-field diagnostic MRI scans.

Table 1. Categories of variables analysed among studied patients

Preoperative factors (group A)
Age
Sex
ASA score
Total Karnofsky score before the operation
Operation type:
craniotomy
transsphenoidal procedure
stereotactic procedure
Localisation:
eloquent area
para eloquent area
non eloquent area
Factors associated with the operation (group B)
Preparation time*
Operation time**
Improvement of neurological status
Complications
Total Karnofsky score after the operation***
Hospitalization time
Technical factors (group C)
Number of positioning scans
Number of intraoperative scans
Pathology visualisation
Influence of iMRI on the change in operation strategy
PoleStar Team participation

ASA – physical status classification system of the American Society of Anesthesiologists
**period from the moment of conscious patient arriving at the operating room to the moment of skin incision*
***period from the moment of skin incision to last suture insertion*
****on the day of discharge*

Operation course

The intracranial tumour resection operations were conducted in a typical manner using classical microsurgical instruments, an operating microscope (OPMI NC4/Pentero, Carl Zeiss Meditec AG, Jena, Germany), ultrasonic aspirator (CUSA EXcell, Integra Radionics, Inc. Plainsboro, NJ, USA), and, in the case of malignant tumours located in eloquent regions, neuroelectrophysiological monitoring (ISIS IOM, Inomed Medizintechnik GmbH, Emmendingen, Germany).

Intraoperative examinations

Haemostasis in the operation field was done after the operator made the decision to conduct an intraoperative MR examination. During the operation of pituitary adenoma, the interior of the sella turcica and the sphenoid sinus were filled with neurosurgical cotton moistened with gadolinium contrast [14]. Obtained intraoperative images were transferred automatically to the optical neuronavigation system (StealthStation, Medtronic Navigation, Louisville, CO, USA). This enabled navigation based on current images of the operative area. The sample statement of pre- and intraoperative examinations is presented in Fig. 1.

Analysis of the results

The parameters assessed were divided into three groups: A – preoperative factors, B – factors related to the operation, and C – technical factors. A detailed description of those variables is presented in Table 1.

To analyse the influence of iMRI application on operation course and outcome, the correlations between factors of A, B and C in the iMRI-group were considered.

An attempt to assess the learning process of application of the iMRI system by the surgical team was conducted based on an analysis of both preparation time

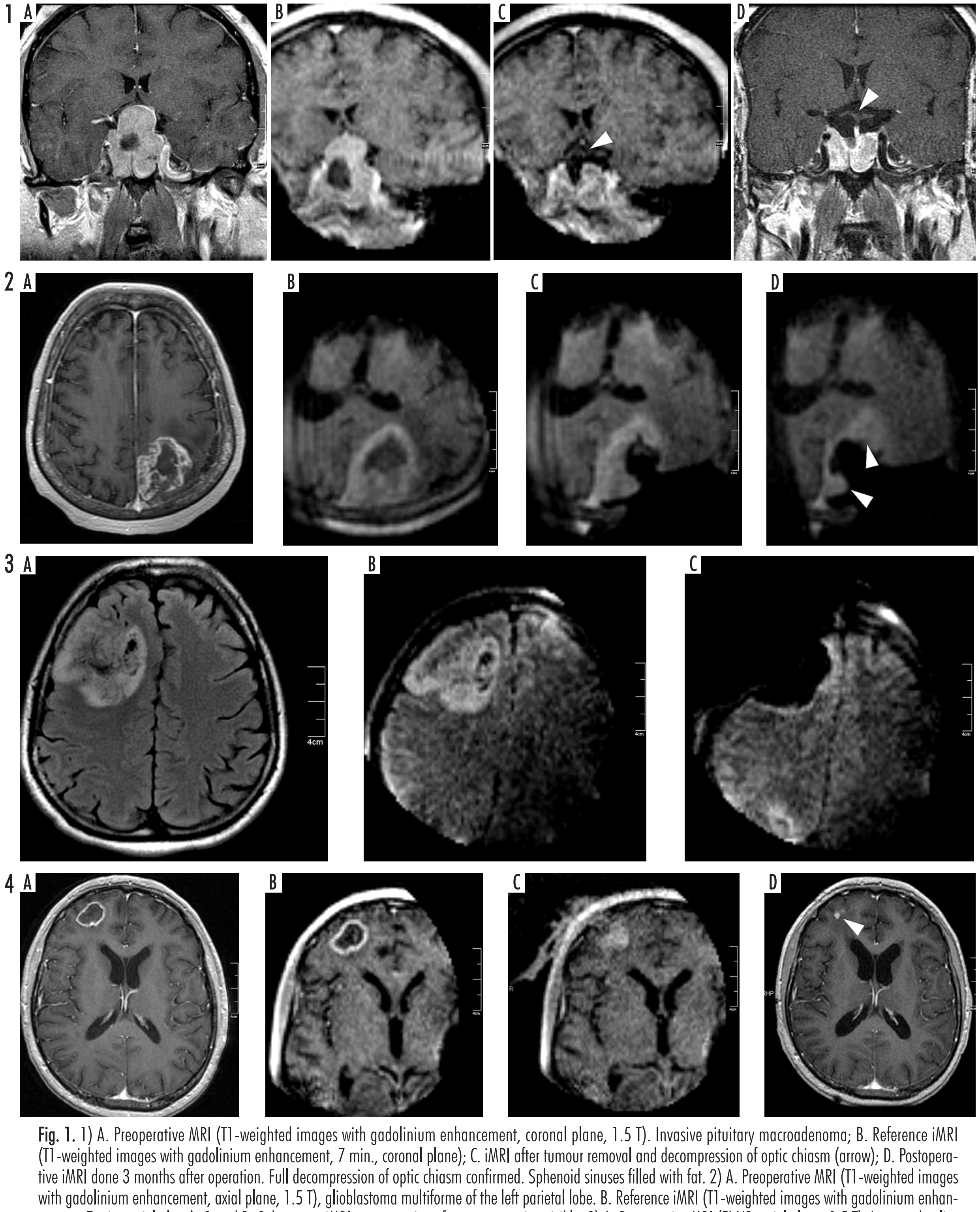

Fig. 1. 1) A. Preoperative MRI (T1-weighted images with gadolinium enhancement, coronal plane, 1.5 T). Invasive pituitary macroadenoma; B. Reference iMRI (T1-weighted images with gadolinium enhancement, 7 min., coronal plane); C. iMRI after tumour removal and decompression of optic chiasm (arrow); D. Postoperative iMRI done 3 months after operation. Full decompression of optic chiasm confirmed. Sphenoid sinuses filled with fat. 2) A. Preoperative MRI (T1-weighted images with gadolinium enhancement, axial plane, 1.5 T), glioblastoma multiforme of the left parietal lobe. B. Reference iMRI (T1-weighted images with gadolinium enhancement, 7 min., axial plane). C. and D. Subsequent iMRI – progression of tumour resection visible. 3) A. Preoperative MRI (FLAIR, axial plane, 1.5 T). Low-grade glioma of the right frontal lobe. B. Reference iMRI (FLAIR, 11 min., axial plane). C. Postoperative iMRI control of resection radicality. 4) A. Preoperative MRI (T1-weighted images with gadolinium enhancement, axial plane, 1.5 T). Fungal abscess of right frontal lobe. B. Reference iMRI (T1-weighted images with gadolinium enhancement, 7 min., axial plane). C. Intraoperative iMRI control after stereotactic aspiration of purulent content. D. Postoperative iMRI done 1 month after operation. Small residue of capsule visible

and operation time, and on a number of positioning scans with respect to those made previously by the surgical team. On the basis of collected data, dot diagrams complemented by multinomial trends were prepared.

In order to assess the differences between standard neurosurgical operations and operations using iMRI, the data of the study group were compared to the corresponding data of the control group. The control group consisted of patients operated on in the same period using optical navigation without iMRI. It was chosen based on the assumption of the lack of significant differences with respect to the study group over the range of preoperative factors (A group factors). The differences in the range of B group factors were subject to an assessment.

Statistical analysis

Statistical analysis was conducted using the Statistica 9.0 package. Normality of variable distribution was analysed using the Shapiro-Wilk test. Because of skewed distribution of all the data, nonparametric Mann-Whitney *U*-test and ANOVA Kruskal-Wallis rank test were used to assess the significance of differences. To examine the strength of correlations, an assessment of Fi correlation coefficient was used. The significance level was set at $p < 0.05$.

Results

Fifty-eight operations using iMRI were conducted during the analysed period. The demographic and epidemiological factors in the study and control groups with the results of statistical analysis are presented in Tables 2 and 3.

Two positioning scans and two intraoperative scans on average were done during each operation using iMRI. T1 sequence after intravenous injection of gadolinium contrast was used in 44 (76%), FLAIR in 8 (14%) and T2 in 6 (10%) cases. Very clear visualization of the pathology was obtained in 47 (81%) and satisfactory images in 11 (19%) operations. Surgeons who had iMRI professional training (authors P.T and M.C.) took part in 50 (86%) operations. In half of the cases, the application of iMRI influenced an intraoperative change of procedure strategy (range widening or abandoning further, previously planned resection).

No influence of the magnetic field generated by iMRI on microsurgical instruments and neuronavigation or neurophysiological apparatus was observed.

The results of comparative analysis of B group factors of the experimental and the control groups are presented in Table 2. Postoperative improvement in neurological status was mainly observed in patients after the operation of gliomas and pituitary macroadenomas. The rate of patients' neurological status impro-

Table 2. Comparison of study and control groups with respect to preoperative factors and those associated with the operation

Variables	Patients operated on with the use of iMRI	Control group	*p*-value
Preoperative factors			
Sex (women/men)	24/34	23/35	0.79*
Age [years]	54 ± 30	54 ± 29	0.79**
ASA score	2 ± 1	2 ± 1	0.49**
Karnofsky scale before the operation	90 ± 10	80 ± 10	0.33**
Factors associated with the operation			
Preparation time [min]	95 ± 50	50 ± 45	< 0.001**
Operation time [min]	220 ± 155	130 ± 135	0.002**
Karnofsky scale after the operation	90 ± 10	80 ± 30	0.005**
Improvement of neurological status, % of patients	31%	14%	0.045*
Complications, % of patients	10%	28%	0.03*
Hospitalization time [days]	13 ± 7	12 ± 4	0.19**

Values are presented as % or as median with interquartile range
iMRI – intraoperative magnetic resonance imaging
ASA – physical status classification system of the American Society of Anesthesiologists
χ^2 test
**Mann-Whitney U-test*

Table 3. Comparison of pathological diagnoses, types of procedures and localization of lesions between patients operated on with intraoperative magnetic resonance imaging (iMRI) and controls (ANOVA Kruskal-Wallis rank test)

	Patients operated on with the use of iMRI (n = 58)	Controls (n = 58)	p-value
Pathological diagnosis			0.29
High-grade glioma	15	12	
Low-grade glioma	16	7	
Pituitary adenoma	18	9	
Abscess	4	0	
Meningioma	1	5	
Metastatic tumour	2	10	
Neurosurgical procedure			0.75
Craniotomy	28	33	
Transsphenoidal approach	17	8	
Stereotactic procedure	13	17	
Localisation of the lesion			0.92
Eloquent	19	18	
Para eloquent	13	14	
Non eloquent	26	26	

iMRI – intraoperative magnetic resonance imaging

vement was positively affected by the modification of operation strategy on the basis of the results of intraoperative iMRI (Fi = 0.30; p = 0.02) and by the contribution of the PoleStar Team member during an operation (Fi = 0.27; p = 0.01). It was associated with better pathology visualization (Fi = 0.68; p < 0.001).

No statistically significant correlation between the time of preparation for the operation and its duration and the percentage of complications was observed (Fi = 0.12, p = 0.23 and Fi = 0.09, p = 0.49, respectively). The frequency of complications observed was significantly influenced by the localisation of the change in eloquent area (Fi = 0.37, p = 0.007) and the degree of tumour malignancy. Complications in the form of new neurological deficits (5 cases, 8%) and one case (2%) of infection of the operation site concerned only patients after resection of brain gliomas.

Learning curve

Proficiency in patient positioning ensuring pathology visualisation was obtained after 10 operations (Fig. 2). Average preparation times stabilized at a level of 100 minutes on average after 20 operations. The average operation time during the analysed period remained at a relatively stable level of about 230 minutes.

Discussion

The application of intraoperative imaging using iMRI positively influences the results of operative treatment of numerous pathologies of the central nervous system [15-17]. The radicality of resection in surgical treatment of gliomas is associated with the prolonged recurrence-free survival time and an improvement in patients' quality of life [18-22]. The application of iMRI enables the identification and precise localisation of unremoved parts of neoplastic tissue due to neuronavigation use [23-26]. The decision of their resection should be made based on an intraoperative functional analysis of the significance of brain parts adjacent to the tumour, and in the case of tumours in para-eloquent or eloquent areas also on the basis of intraoperative neuroelectrophysiological methods [2,9,27]. In case of macroadenoma, intraoperative imaging of the area of the sella turcica enables the verification of the degree of

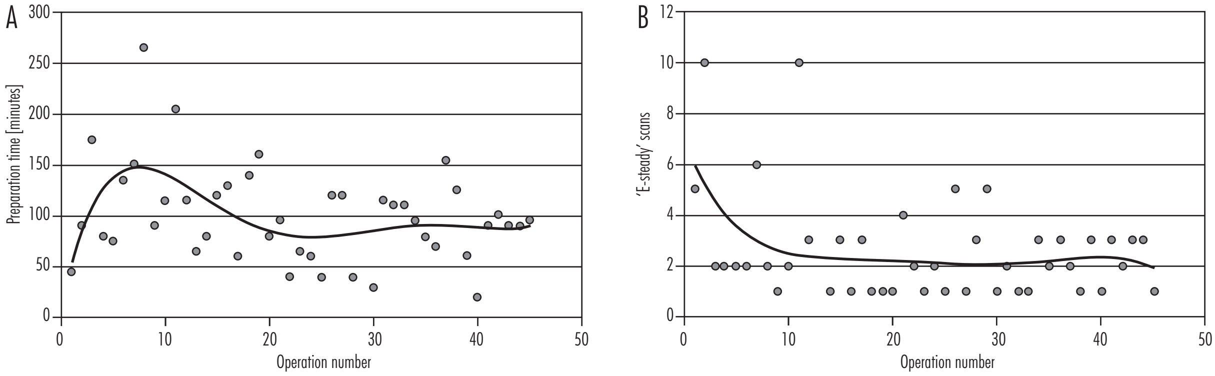

Fig. 2. A. Learning curve established on the basis of the time of preparation for the operation. B. Learning curve established on the basis of the number of positioning scans. Dot diagrams with multinomial trend line. Detailed description in the text

intracranial structure decompression, such as optic chiasm or cavernous sinuses [28,29]. With the application of low-field iMRI in pituitary adenoma operations, because of its high sensitivity, it is possible to increase the percentage of radical resection by over one-fourth [12,30,31]. The filling of the sella turcica with neurosurgical cotton moistened with gadolinium contrast also decreases the percentage of false positive results [14]. The application of iMRI in everyday neurosurgical practice, however, is associated with an increased time of preparation and surgery that may itself be a controversial issue [12]. Although Senft *et al*. mention a lack of influence of low-field iMRI application on an increase in the percentage of complications [32], there are no papers in the available literature providing a detailed analysis of the problems of effects of technical aspects of the application of low-field iMRI on operation safety and patient state during the perioperative period.

The present paper is the first prospective controlled observation of a heterogeneous group of patients operated on with the application of low-field iMRI. The iMRI group and the control group were comparable with respect to basic demographic and epidemiological parameters, and this was the condition for a reliable statistical analysis. The formation of the control group on the basis of an operation using optical neuronavigation without iMRI allowed the analysis of the influence of the intraoperative imaging factor alone on the course and direct result of the operation.

The percentage of complications at the level of 10% observed in the iMRI group is within the mean values (7-18%) observed in experienced centres [15,32-34]. Furthermore, it is significantly lower than in the control group. Increased operation time related to iMRI application was not related to an increase in risk of complications. The application of iMRI in various types of operations thus allowed achievement of safety levels close to generally agreed and accepted standards.

A significantly higher percentage of neurological status improvement, and shorter – albeit insignificantly – hospitalization time after iMRI operations could have been related to the possibility of intraoperative optimization of the range of resection both of brain gliomas and pituitary macroadenomas. Neuronavigation based on current images of the area operated on allowed precise orientation eliminating the negative influence of the *brain shift* phenomenon [35].

Based on our own observations we can propose that work with an intraoperative imaging system should be started with technically straightforward operations, e.g. frameless stereotactic biopsies. Also, proper training of the group of surgeons prepared for the operation and optimal utilization of low-field iMRI capability are of extreme importance.

The quality of obtained MR images obtained using a magnetic field of only 0.15 T intensity remains a debatable issue. In our opinion, the quality of images generated by the iMRI scanner we used was in the vast majority of cases sufficient for estimation of surgical goals. Similar conclusions were also drawn by the authors of previous papers [11,12,24,28]. Although high-field apparatus (1.5 or even 3 T) allow high quality images of diagnostic value to be obtained, very high installation costs and problematic intraoperative service significantly reduce their application [5,25].

High heterogeneity in the presented group of patients is a factor that makes assessment of the results difficult. The negative effect of inclusion of patients subjected to various operations was equalised by the proper choice of the control group. Our aim was not to assess the influence of iMRI application on remote treatment results, but to examine the influence of technical complications during the operation on its course and direct results. The analysis of the results of treatment of patients with particular pathologies was recognised as unjustified at this stage due to the relatively small size of subgroups. The collection of wider and homogeneous clinical material will enable in the future the conduction of a reliable statistical analysis and the publication of its results.

Despite the fact that our examination was the first conducted in a prospective and controlled manner, the patients were not subjected to a randomization process. In view of the lack of specified guidelines, the decision concerning iMRI application was usually influenced by individual preferences of the operator. For that reason it seems to be justified to conduct a prospective randomized multicentre study assessing the usefulness of low-field iMRI application in the surgical treatment of patients with selected brain pathologies [10,36].

Conclusions

1. Although the application of low-field iMRI increased the duration of neurosurgical procedures, it did not negatively influence their safety. It is associated with above-average functional results and a lower percentage of total complications.
2. Proper training allows the team to obtain full utilisation of low-field iMRI scope after about 20 self-dependent operations.
3. Reliable assessment of low-field iMRI usefulness in operations of intracranial pathologies may require a randomized multicentre study.

Disclosure

Authors report no conflict of interest.

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