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ORIGINAL ARTICLE

The implication of liquid hemostatic matrices to prevent hemorrhages during stereotactic biopsy of brain tumors

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ABSTRACT

Purpose of the study. Development of a method for preventing hemorrhages during stereotactic biopsy of a brain tumor using liquid hemostatic matrices on the example of the drug "Floseal®".

Patients and methods. The target of the biopsy is the most representative area of tumor tissue according to the data of various modalities of MRI neuroimaging, including contrast-enhanced ones. Out of 133 patients, 60 patients with signs of intraoperative bleeding along the biopsy needle cannula were included in the study group. Further, patients with signs of intraoperative bleeding along the cannula of the biopsy needle were divided into 2 subgroups by independent sequential randomization. Control subgroup (n = 45): cases with signs of intraoperative bleeding of varying severity were operated on, according to the standard technique, without the use of the liquid hemostatic drug Floseal®. The main subgroup (n = 15): in case of intraoperative signs of bleeding, the hemostatic fluid drug Floseal® was injected into the area of tumor material removal.

Results. In 6.7 % of patients of the control subgroup, the formation of massive intracerebral hemorrhages was noted in the postoperative period. In 53.3 % of the observations of the control subgroup according to X-ray computer examinations of the brain, there were signs of minor hemorrhages at the point of tumor material collection, which did not require repeated surgical interventions. Postoperative hemorrhages after injection of the Floseal® liquid hemostatic matrix into the biopsy needle in the study subgroup were not detected according to neuroimaging X-ray CT.

Conclusion. A method of hemostasis has been developed to prevent hemorrhages using liquid hemostatic matrices. If signs of bleeding from the biopsy needle appeare, the introduction of a hemostatic matrix in the volume of 2 ml helps to manage bleeding intraoperatively, as well as to prevent the occurrence of hemorrhage in the early postoperative period.

Keywords: brain tumor, stereotactic biopsy, bleeding prevention, hemorrhagic complications of brain biopsy, hemorrhage, hemostasis

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Compliance with ethical standards: this study adhered to the ethical principles outlined in the World Medical Association Declaration of Helsinki, 1964, ed. 2013. The study was approved by the Committee on Biomedical Ethics at the National Medical Research Centre for Oncology (extract from the protocol of the meeting No. 7 dated 08/08/2022). Informed consents have been obtained from all participants of the study

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ОРИГИНАЛЬНАЯ СТАТЬЯ

Использование жидких гемостатических матриц для предупреждения кровоизлияний при выполнении стереотаксической биопсии опухолей головного мозга

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РЕЗЮМЕ

Цель исследования. Разработка способа предупреждения кровоизлияний при выполнении стереотаксической биопсии опухоли головного мозга с использованием жидких гемостатических матриц на примере препарата «Floseal®».
Пациенты и методы. Цель биопсии – наиболее репрезентативный участок опухолевой ткани по данным различных модальностей МРТ нейровизуализации, в том числе и с контрастным усилением.
Из 133 пациентов в изучаемую группу включено 60 больных с признаками интраоперационного кровотечения по канюле биопсийной иглы. Далее, методом независимой последовательной рандомизации пациенты с признаками интраоперационного кровотечения по канюле биопсийной иглы разделены на 2 подгруппы. Контрольная подгруппа (n = 45): случаи с признаками интраоперационного кровотечения различной степени выраженности, оперированы по стандартной методике, без использования жидкого гемостатического препарата «Floseal®». Основная подгруппа (n = 15): при интраоперационных признаках кровотечения в зону изъятия опухолевого материала осуществлялось введение гемостатического текучего препарата «Floseal®».
Результаты. У 6,7 % пациентов контрольной подгруппы в послеоперационном периоде отмечено формирование массивных внутримозговых кровоизлияний. В 53,3 % наблюдений контрольной подгруппы по данным рентген компьютерных исследований головного мозга имелись признаки незначительных кровоизлияний в точке забора опухолевого материала, не требовавшие повторных оперативных вмешательств. Послеоперационные кровоизлияния после введения в биопсийную иглу жидкой гемостатической матрицы «Floseal®» в основной подгруппе по данным РКТ нейровизуализации не выявлены.
Заключение. Разработан способ гемостаза для предупреждения кровоизлияний с использованием жидких гемостатических матриц. При появлении признаков кровотечения из биопсийной иглы введение гемостатической матрицы в объеме 2 мл способствует остановке кровотечения интраоперационно, а также профилактике возникновения кровоизлияния в раннем послеоперационном периоде.

Ключевые слова: опухоль головного мозга, стереотаксическая биопсия, профилактика кровотечения, геморрагические осложнения биопсии головного мозга, кровоизлияние, гемостаз

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Соблюдение этических стандартов: в работе соблюдались этические принципы, предъявляемые Хельсинкской декларацией Всемирной медицинской ассоциации (World Medical Association Declaration of Helsinki, 1964, ред. 2013). Исследование одобрено Комитетом по биомедицинской этике при ФГБУ «Национальный медицинский исследовательский центр онкологии» Министерства здравоохранения Российской Федерации (выписка из протокола заседания № 7 от 08.08.2022 г.). Информированное согласие получено от всех участников исследования

Финансирование: финансирование данной работы не проводилось

Конфликт интересов: Кит О. И. является членом редакционной коллегии журнала «Южно-Российский онкологический журнал» с 2019 г., но не имеет никакого отношения к решению опубликовать эту статью. Статья прошла принятую в журнале процедуру рецензирования. Об иных конфликтах интересов авторы не заявляли

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INTRODUCTION

Currently, the stereotactic needle biopsy (STB) of various grades brain tumors is performed in anatomically inaccessible areas of the brain and when the tumor is localized in functionally significant areas of the brain [1–4].

Given the lack of visual intraoperative control of the needle trajectory, a serious complication after STB, is hemorrhage in biopsy material withdrawal as well as along the path of access of the biopsy needle, despite the intervention being minimally invasive [5–9].

The purpose of the study was to develop a method for preventing hemorrhages during stereotactic biopsy of a brain tumor using liquid hemostatic matrices using the example of the drug "Floseal®".

PATIENTS AND METHODS

From 2014 to 2020 133 patients with brain tumors were operated on using the method of frameless needle stereotactic biopsy. Informed consent for surgical intervention was obtained from all participants of the study. In our observations, tumor diseases manifested from 5 to 80 years. The average age of the patients was 56 years. 57 % were men and 43 % were women. 75.5 % were operated on with single foci of brain damage, 10.5 % with two foci. 14 % of patients had multiple unverified CNS lesions.

Neoplasms in 28.3 % of cases were localized in subcortical structures of the brain, in 18.3 % – in various parts of the corpus callosum with bilateral distribution, in 53.4 % of cases in periventricular areas under functionally significant areas of the brain.

Neurological symptoms depended on the localization of the lesion in the brain. Upon admission, the functional status on the Karnovsky scale of 100–80 points was noted in 71.7 % of patients, 70–50 points in 21.7 % of patients, and below 40 points was noted in 6.6 % of cases. All patients underwent a comprehensive assessment of the hemostasis system in the preoperative period.

The tissue sampling point was determined by combining MRT T1 BRAVO with intravenous contrast enhancement with data from DTI, 2D-TOF, 3D-TOF, T2, ASL, SWAN modes. If necessary, in the Brainlab® or Medtronic StealthStation® S7® planning software, the digital model was combined with DICOM positron emission tomography (PET CT) data with 11^{C}-methionine. The trajectory of the biopsy needle insertion was constructed taking into account the data of tractography, with the localization of the tumor in functionally significant areas of the brain (Fig. 1).

The purpose of the biopsy is the most representative area of tumor tissue according to various modalities of MRI neuroimaging, including contrast enhancement. Surgical intervention was performed under general anesthesia, according to the operating regulations of manufacturers of systems for frameless stereotactic biopsy Brainlab® or Medtronic StealthStation® S7® using biopsy needles Biopsy Needle Kit (9733068) or Biopsy Needle Kit Tip A (41778C).

Control computed tomography was performed intraoperatively or within 24 hours after surgery.

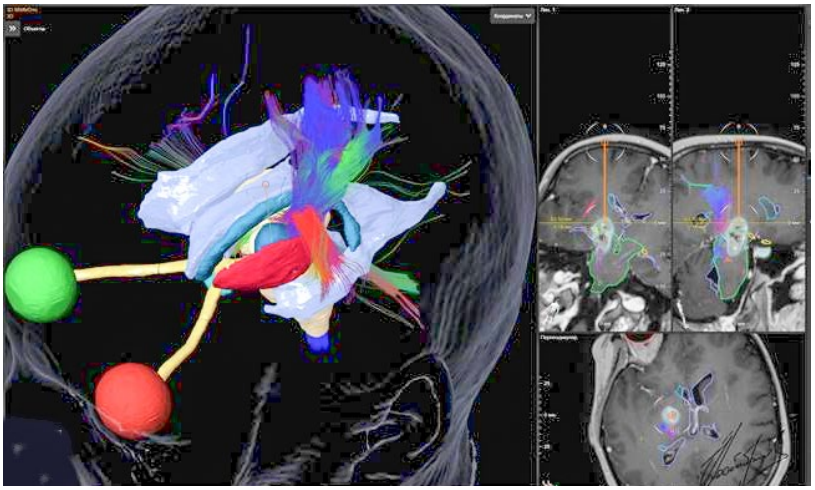

Fig. 1. Planning the access trajectory considering functionally significant areas of the brain

Out of 133 patients, the study group included 60 patients with signs of intraoperative bleeding through the cannula of a biopsy needle (45.1 %). Further, by the method of independent sequential randomization, patients with signs of intraoperative bleeding through the cannula of a biopsy needle were divided into 2 subgroups.

Control subgroup (*n* = 45): cases with signs of intraoperative bleeding of varying severity were operated according to the standard procedure, without the use of liquid hemostatic matrices.

The main subgroup (*n* = 15): with intraoperative signs of bleeding, the hemostatic fluid drug "Floseal®" was injected into the area of removal of tumor material.

The subgroups were comparable in terms of sex, age, localization and histological types of the tumor. We analyzed the complications that arose in these subgroups using the method of X-ray computed tomography performed in the first 24 hours after surgery. All necessary patient data were recorded in the Microsoft Excel electronic database, after

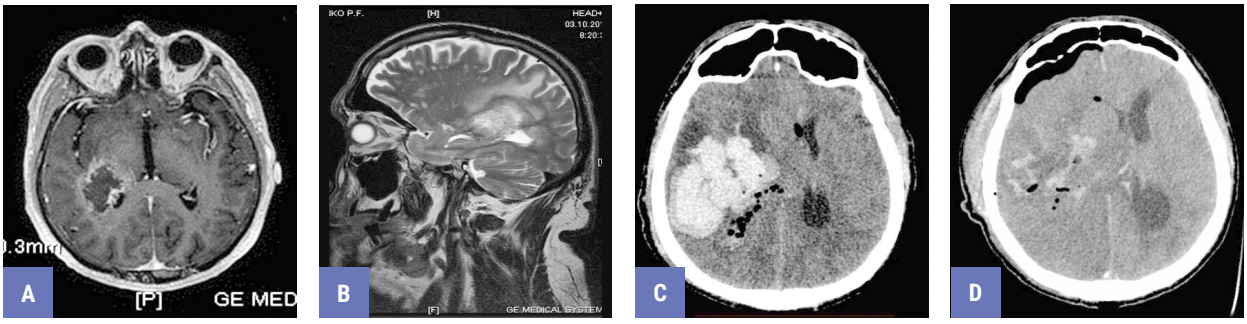

Fig. 2. Patient T., 67 years old. A, B – MRI neuroimaging data of a tumor lesion, hospitalized on 10/07/2016 with a diagnosis of a tumor of the temporal, parietal lobe and islet with a spread to the thalamic tubercle. On 10/10/2016, a stereotactic biopsy was performed. Histological examination: glioblastoma. In the immediate postoperative period, the patient was conscious. 7 hours after the end of the surgery, the patient had a sudden loss of consciousness to coma I, the appearance of right-sided anisocoria, the rapid development of secondary ischemic stem damage in the form of inhibition of pupil photoreaction, loss of oculocephalic reflexes. A brain X-ray computed tomography (CT) scan was performed, extensive hemorrhage (C) in the tumor area with spread to the temporal and parietal lobes of the brain, blood breakthrough into the ventricular system of the brain, pronounced lateral dislocation syndrome to the left, secondary ischemic brain damage was visualized. He was taken to the operating room for vital signs. D – postoperative cerebral CT scan: hematoma and tumor removed. Fatal outcome dated by 10/12/2016

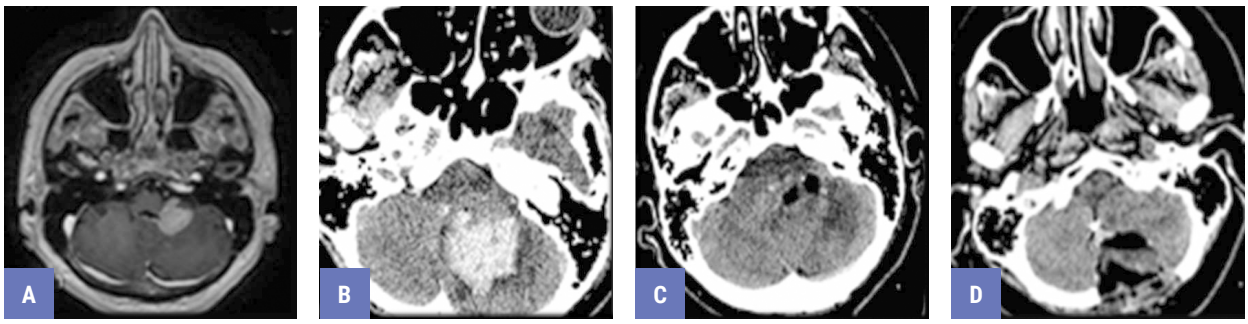

Fig. 3. A–D. Patient Ch., 58 years old, was hospitalized on 11/08/2016 with suspected lymphoma of the left hemisphere of the cerebellum with infiltration of the roof of the 4th ventricle. On 11/09/2016, a stereotactic biopsy of the tumor was performed. Histological examination: non-Hodgkin's lymphoma. Due to the formation of a hematoma in the tumor biopsy area on 11/10/2016, an urgent installation of the Arendt cerebrospinal fluid drainage system into the anterior horn of the right lateral ventricle was performed, 11/10/2016. – subtotal removal of a tumor of the left hemisphere of the cerebellum with growth into the cerebellar bridge angle using neurophysiological monitoring, intraoperative fluorescence microscopy, removal of an intracerebral hematoma in the bed of a removed tumor of the left hemisphere of the cerebellum. In the future, the postoperative period proceeded without complications. Control X-ray CT of the brain dated 11/11/2016: condition after recraniotomy in the suboccipital region. There are areas of reduced density in the surgical area, the postoperative cavity is 3.7 × 3.5 × 3.1 cm. The median structures are not displaced. The patient was discharged in a satisfactory condition

which the data was analyzed in the Statistica 10.0 program. When processing the obtained patient data in the control and main groups, an assessment was carried out based on the nonparametric Pearson's chi-squared test (χ^2).

STUDY RESULTS

In a group of 133 observations, neoplasms were morphologically verified in all cases. In 43.7 % of cases, Grade III–IV gliomas of high malignancy were verified, Grade II – in 40.5 %, CNS lymphomas in 11.4 %, metastases of glandular and squamous cell carcinoma in 4.4 %.

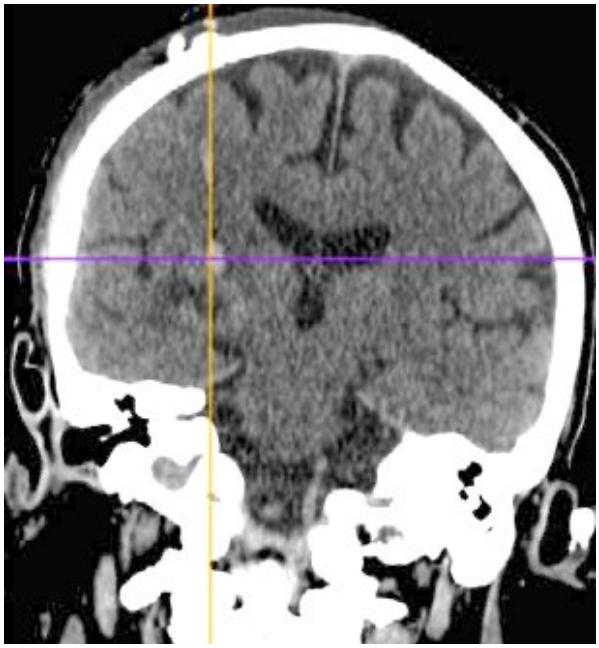

Fig. 4. X-ray CT neuroimaging of postoperative, clinically insignificant microbleeding in the area of biopsy material withdrawal

Mortality after STB in a group of 133 patients was 0.75 % (in one patient, in the immediate postoperative period, the formation of a massive intracerebral hematoma was noted, which required urgent surgical intervention of a tumor localized in a functionally significant area of the brain (Fig. 2)).

We found that in 6.7 % of patients of the control subgroup, the formation of massive intracerebral hemorrhages was noted in the postoperative period (Fig. 3), requiring repeated surgical interventions, removal of both intracerebral and intracerebral hemorrhages with forced cytoreduction of the tumor in a functionally significant area. The mortality rate in the control subgroup was 2.2 %.

In 53.3 % of the observations in the control subgroup, according to X-ray computed studies of the brain performed in the first 24 hours after surgery or intraoperatively, minor hemorrhages were detected at the point of collection of tumor material, requiring a delay in the patient's stay in the hospital and repeated neuroimaging methods (Fig. 4).

The technique of frameless stereotactic needle biopsy in the main subgroup (n = 15) was standard. If signs of bleeding were noted during the withdrawal of tumor material with a biopsy needle, in the form of the release of blood clots, rare, frequent drop or jet bleeding, the hemostatic matrix "Floseal®" was prepared according to the instructions for use of the drug (Fig. 5). The drug is approved for use in the territory of the Russian Federation (RU No. 2019/8305 dated 04/18/2019). "Floseal®" is widely used in abdominal, vascular, and neurological surgical fields as an applicative local hemostatic [10].

A liquid hemostatic matrix was injected into the cannula of the inner stylet of the biopsy needle until

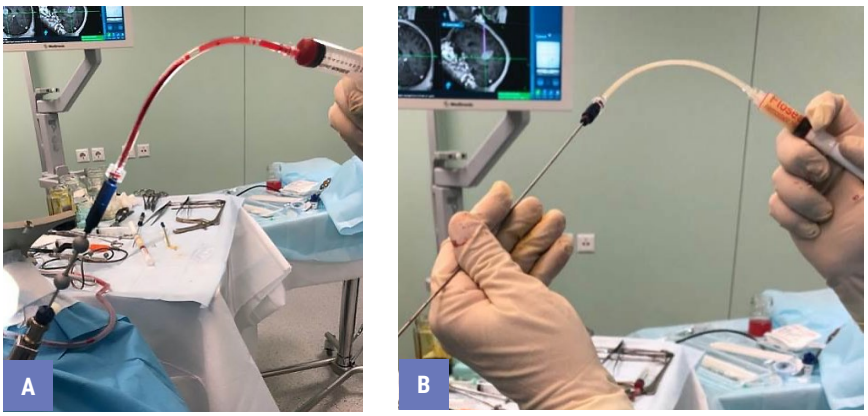

Fig. 5. A. Intraoperative signs of bleeding – the release of blood clots from a biopsy needle. B. After preparing the liquid hemostatic matrix "Floseal®" and filling the inner stylet of the biopsy needle with it, the liquid hemostatic matrix is subsequently injected in a volume of 2 ml

it was completely filled. After the cannula was inserted into the biopsy needle, a hemostatic matrix was additionally injected in a volume of about 2 ml. We have established a satisfactory possibility of injecting this drug into the postoperative cavity through the needle hole for stereotactic biopsy. Next, the biopsy needle was removed, the milling hole was filled with bone chips, ensuring hermetically sealed closure of the bone defect followed by suturing of soft tissues. Intraoperatively, or within a few hours after waking up, the patient underwent CT neuroimaging of the brain to assess postoperative changes and exclude hemorrhagic complications (Fig. 6).

Hemorrhages and postoperative complications were not observed in patients of the main subgroup (n = 15) (χ^2 = 3.99; p = 0.0458).

In the control subgroup (n = 45), the percentage of clinically significant hemorrhages was 6.7 %, which required repeated interventions, removal of both intracerebral and intracerebral hemorrhages. The percentage of clinically insignificant hemorrhages in the control subgroup was 53.3 %. The mortality rate in the control subgroup was 2.2 %.

DISCUSSION

In an international study by Malone Hani et al. [11] 7514 patients after STBs were analyzed. The most common complication of STB was surgically significant intracerebral bleeding, which was diagnosed in 5.8 % of patients. The risk factors for bleeding in this study were associated with age above 40 years, hydrocephalus and cerebral edema. Inpatient mortality according to the study was 2.8 % [11].

In other publications with different series of patients, the risk factors for bleeding after STB are not clearly defined or were associated by the authors with varying degrees of reliability, i. e. with the localization of a pathological focus, e. g. in the brain stem [8, 9], with arterial hypertension, with impaired liver function, with the malignant nature of a central nervous system tumor [12, 13].

According to K. K. Kukanov and co-authors, after performing the control CT neuroimaging, the presence of hemorrhages was noted in 40 % of the observations [14]. Of these, clinically insignificant ones were noted in 25 %, large diffuse hemorrhages with a clinical picture in 5 %, intraventricular hemorrhages with a pronounced clinical picture in 10 % of cases. Researchers see a reduction in the risk of intracranial hemorrhages after the tumor tissue STB procedure in careful preoperative planning of the biopsy trajectory, the use of modern stereotactic devices and biopsy cannulas, as well as the use of preoperative hemostatic therapy in patients with suspected high degree of tumor anaplasia [14].

In the article De Quintana-Schmidt C. with co-authors (2019) [15] published the results of a thrombin-gelatin matrix inmlication in three cases of intense bleeding during the STB procedure. Preliminary results of the work have shown that injection of a thrombin-gelatin matrix is a safe and effective procedure for the treatment of persistent surgical bleeding that cannot be performed by traditional hemostatic methods used in neurosurgery [12].

The presented studies do not provide a clear idea of how to improve the safety of performing stereotactic biopsy. The neurosurgeon faces urgent issues: what to choose as a reliable hemostatic agent, which method of administration to use, how to calculate the administered dose of the drug?

Based on the data of our study conducted from 2014 to 2020, a reliable method of hemostasis was

Fig. 6. Example of brain neuroimaging X-ray CT data 40 minutes after surgery in a patient using "Floseal®". A reduced density corresponding to the biopsy point is visualized in the left temporal lobe. No hemorrhage was found in the area of tumor tissue removal

found in a sufficient sample of patients using stereotactic techniques for collecting tumor material. We have proposed a technique for the introduction of a liquid hemostatic matrix as a preventive measure for intraoperative bleeding during STB.

In the course of our study, it was noted that there were no complications, clinically significant hemorrhages or microbleeds in the subgroup of patients with biopsy needle bleeding after the introduction of a liquid hemostatic matrix. On the contrary, in the subgroup of patients with the standard stereotactic biopsy procedure, in cases of intraoperative bleeding on a biopsy needle, macro and micro hemorrhages were observed in 60 % of patients, repeated surgical interventions were performed in 6.7 % of cases, and the mortality rate was 2.2 %.

CONCLUSION

If signs of bleeding from a biopsy needle appear during a stereotactic biopsy of a brain tumor, it is possible to inject a liquid hemostatic matrix in a volume of 2 ml into the point of removal of tumor tissue. The proposed method of preventing hemorrhages demonstrates the potential solution to the only serious type of complications in this minimally invasive diagnostic intervention. A liquid hemostatic matrix as intraoperative hemostasis method at the point of biopsy sampling following the stereotactic intervention helps to prevent the development or even stop bleeding intraoperatively, it also prevents the occurrence of hemorrhages and complications in the early postoperative period.

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Kit O. I. – development of the research design, critical revision with the introduction of valuable intellectual content, final approval of the published version of the manuscript.