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Availability of Transcatheter Vessel Occlusion Performed by Interventional Radiologists to Treat Bleeding in Germany in the Years 2016 and 2017 – An Analysis of the DeGIR Registry Data

Flächendeckende Versorgung mit radiologisch durchgeführten gefäßverschließenden Maßnahmen zur interventionellen Behandlung von Blutungen in Deutschland in den Jahren 2016 und 2017 – Eine Analyse der DeGIR-Registerdaten

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ABSTRACT

Purpose Acute bleeding is a life-threatening condition that can be effectively treated minimally invasively by interventional radiologists using transcatheter vessel occlusion (TCVO). The purpose of this study was to evaluate the availability of TCVO performed by interventional radiologists in Germany based on the DeGIR registry.

Materials and Methods TCVO interventions from the years 2016 and 2017 were included (DeGIR module B). The number of interventions was assessed by state and region.

Results TCVO interventions were reported by 242 clinics in Germany. 16 763 module B interventions were reported in 2016 and 16 399 in 2017. DeGIR requirements for certification as a training center were fulfilled by 160 facilities in 2016 and by 162 facilities in 2017. Normalized to one million citizens, an average of 211 TCVO interventions were performed in 2016 and 200 in 2017 (standard deviation was 101 and 109); the median was 202 and 222, respectively. In all regions TCVO interventions were reported. Only a minimal number of small regions showed a lower number of clinics offering TCVO interventions.

Conclusion The results from the DeGIR registry indicate comprehensive nationwide availability of TCVO performed by interventional radiologists with the necessary experience in Germany on the state level for the treatment of acute bleeding. Furthermore, the distribution of facilities fulfilling the requirements of training centers allows for good educational possibilities for young interventional radiologists in Germany. Only the distribution of clinics offering TCVO in a few small regions might lead to increased transfer times in the case of acute bleeding.

Key Points:

- As a treatment for life-threatening acute bleeding in Germany, transcatheter vessel occlusion led by interventional radiologists is readily available on the state level.
- Furthermore, the distribution of facilities fulfilling the requirements of training centers allows for good educational possibilities for young interventional radiologists in Germany.
- Due to the good training conditions in Germany, it might be possible to further improve the situation in smaller regions by training more interventional radiologists and employing them in regions with less coverage.

ZUSAMMENFASSUNG

Ziel Aktive Blutungen sind potenziell lebensbedrohliche Notfälle. Diese Blutungen können oftmals sehr effektiv mit interventionell-radiologisch durchgeführten, gefäßverschließenden Maßnahmen therapiert werden. Im Folgenden soll anhand des DeGIR-Registers die deutschlandweite Versorgung zur interventionell-radiologischen Therapie von aktiven Blutungen evaluiert und dargestellt werden, inwieweit eine Flächendeckung mit diesen Therapien erreicht wird.

Material und Methoden Erfasst wurden die Untersuchungszahlen zu gefäßverschließenden Interventionen (DeGIR-Modul B) aus den Jahren 2016 und 2017. Es erfolgte eine Aufschlüsselung der erfassten Leistungsdaten nach Bundesländern bzw. 40 kleineren Regionen (Regierungsbezirke und ehemalige Regierungsbezirke).

Ergebnisse 242 Kliniken in Deutschland erfassten Interventionen im Modul B. Im Jahr 2016 wurden 16 763 und im Jahr 2017 16 399 Modul-B-Eingriffe im Register erfasst. Die DeGIR-Voraussetzung zur Ausbildungszentren-Zertifizierung für das Modul B erfüllten im Jahr 2016 160 Einrichtungen und im Jahr 2017 162. Normiert auf 1 Million Einwohner fanden deutschlandweit 2016 im Durchschnitt 211 und 2017 200 Eingriffe statt (Standardabweichung 101 bzw. 109). Der Median lag bei 202 bzw. 222 Eingriffen pro 1 Million Einwohner. In allen Regionen wurden Eintragungen registriert. Einzelne kleinere Regionen verfügen allerdings über eine geringe Anzahl an Krankenhäusern, in denen die interventionell radiologische Therapie einer akuten Blutung angeboten werden kann.

Schlussfolgerung Aus den Registerdaten lässt sich auf Bundeslandebene auf eine gegebene deutschlandweite flächendeckende Versorgung mit interventionell-radiologisch geführten Therapien bei akuten Blutungen mit entsprechender Erfahrung schließen. Zudem zeigt die Verteilung der zertifizierungsfähigen bzw. zertifizierten Ausbildungszentren auch eine gute Ausbildungssituation für jüngere interventionelle Radiologen in Deutschland an. Die Verteilung der Krankenhäuser, welche eine interventionell-radiologische Therapie anbieten, lässt eine verlängerte Anfahrt in einigen wenigen Regionen vermuten. Kernaussagen: In Deutschland liegt auf Bundeslandebene eine gute flächendeckende Versorgung mit interventionell-radiologisch geführten Therapien bei akuten Blutungen vor.

Introduction

Active bleeding is a potentially life-threatening condition that often occurs as a result of trauma or as an iatrogenic complication. Tumor bleeding and coagulation disorders are a less common cause [1–5]. As a result of the good, scientifically verified results and the rapid development and availability of transcatheter vessel occlusion performed by radiologists in German clinics, interventional radiological treatment of bleeding is to be given preference over other alternatives in certain situations, e. g., based on location or in the case of a coagulation disorder, difficult surgical access, a site having undergone extensive prior surgery, or inoperability of the patient [3]. Intubation anesthesia is typically not necessary for interventional radiological treatment. Therefore, angiographic evaluation with interventional radiological treatment to stop the bleeding can be performed immediately after diagnosis of active bleeding. In addition, interventional radiological treatment of bleeding has increasingly been included in the guidelines of other disciplines, e. g. gastroenterology and gynecology, at least as an option [6, 7].

Finally, not only the effectiveness and quality of a certain technique but also its availability and the structural distribution of centers with sufficient practical experience for regional coverage of need are decisive for practical patient care. This was recently evidenced by the rapid development of the interventional radiological treatment of strokes by means of thrombectomy [9].

As part of a quality assurance program, the German Society for Interventional Radiology and Minimally Invasive Therapy (DeGIR) has been recording vascular and non-vascular interventions in a registry run in collaboration with the German Society for Neuroradiology (DGNR) for over 25 years. The registry includes the following modules: Module A (methods for opening and recon-

structing vessels), module B (transcatheter vessel occlusion), module C (diagnostic puncture, drainage, PTCD, TIPSS, etc.) Module D (oncological methods, primarily tumor-specific embolization and ablation), module E (neurointerventions for opening vessels) and module F (neurovascular embolization treatments).

The goal of this overview is to evaluate whether there is nationwide availability of module B interventional radiological treatment of active bleeding for patients in Germany. DeGIR module B interventions are considered particularly challenging special interventions. The literature does not contain any numbers regarding the nationwide availability of methods of surgical and endoscopic hemostasis. Therefore, it is not the goal of this study to compare the interventional technique with these techniques.

Methods

Data collection

The analysis was based on DeGIR registry data from the years 2016 and 2017. The data was recorded during this time using the BQS software (Institut für Qualität & Patientensicherheit GmbH). Data regarding module B interventions entered on a voluntary basis was used as a surrogate for determining performance and experience in relation to interventional radiological hemostasis at clinics. DeGIR module B encompasses methods for occluding vessels including coils, fluid embolization, particles, plugs, and the like.

The number of centers fulfilling the criteria for DeGIR certification as training centers (at least 20 interventions per year) or that are already certified was determined for further analysis. This essentially requires the completion and documentation of at least 20 module B interventional radiological interventions and an interventionalist with personal level 2 module B certification. This personal level 2 certification requires proof of at least 100 completed module B interventions and 30 CME points. “High-volume” centers were defined as having intervention numbers above the 9th decile.

Analysis of coverage

Data was assessed by state. For detailed analysis of coverage, without making the data of individual clinics visible, the recorded module B interventions were broken down by 40 smaller regions (districts, former districts and states: Arnsberg, Berlin, Brandenburg, Braunschweig, Bremen, Chemnitz, Darmstadt, Dessau, Detmold, Dresden, Düsseldorf, Freiburg, Gießen, Halle, Hamburg, Hannover, Karlsruhe, Kassel, Koblenz, Cologne, Leipzig, Lüneburg, Magdeburg, Mecklenburg-West Pomerania, Middle Franconia, Munster, Lower Bavaria, Upper Bavaria, Upper Franconia, Upper Palatinate, Rheinhessen-Pfalz, Saarland, Schleswig-Holstein, Swabia, Stuttgart, Thuringia, Trier, Tübingen, Lower Franconia, Weser-Ems).

Statistics

R Statistics (R version 3.5.3 (2019–03–11) – “Great Truth”) was used for descriptive statistics [8]. $p = 0.05$ was accepted as the level of significance.

Graphics

The following software was used to create graphics:

Creative Commons Attribution 3.0 License (www.geonames.org), Geojson Germany (https://github.com/isellsoap/deutschlandGeoJSON), https://www.destatis.de/DE/Service/Impressum/copyright-genesis-online.html (Federal Statistical Office of Germany (Destatis), https://krankenhausatlas.statistikportal.de/; data license dl-de/by-2-0, https://www.govdata.de/dl-de/by-2-0

Technical data:

© Data from the Federal Statistical Office according to § 21 of the Hospital Remuneration Act (KHEntgG) 2016

© Population data from the Federal Statistical Office and the statistical offices of the states: Census 2011

Basic data:

© EuroGeographics (2013) national borders in Europe 2013 using scale of 1:3,000,000

© EuroGeographics (2018) national borders in Europe 2017 using scale of 1:250,000

© GeoBasis-DE/BKG (2018) WebAtlasDE

Genesis-Online; data license dl-de/by-2-0), Folium/Geopandas/Shapely/Python (mapping).

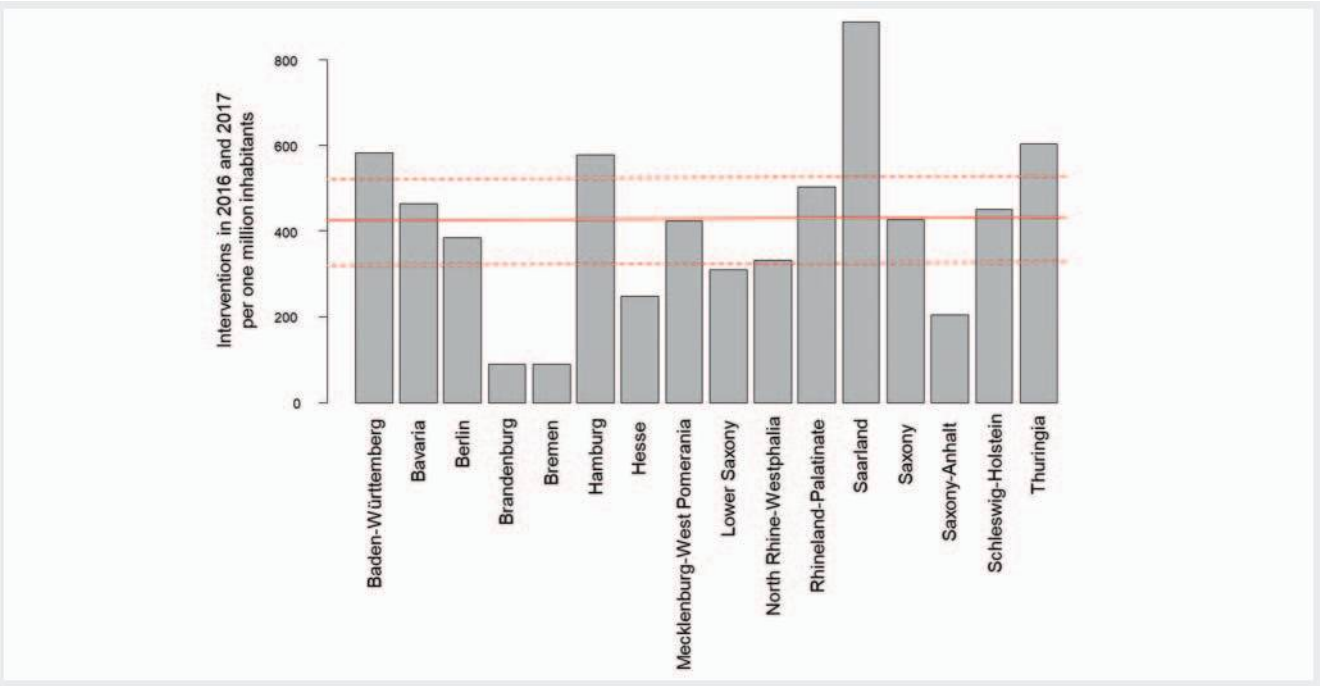
Results

Registry data from 242 clinics in Germany was evaluated for the analysis of DeGIR module B. 16,763 module B interventions in 2016 and 16,399 in 2017 were recorded in the DeGIR registry via voluntary entry. Changes over the course of the two years were not statistically significant. The median number of interventions performed per facility was 41 in 2016 and 40 in 2017. The DeGIR requirement for certification as a module B training center was met by 160 clinics in 2016 and 162 in 2017. The total number of interventions performed at high-volume centers was constant in 2016 and 2017 (over 500 interventions per year at 23 clinics).

Availability of care

Normalized to one million inhabitants, an average of 211 interventions were performed in 2016 and 200 in 2017 in Germany (standard deviation = 101 and 109, respectively). The median was 202 and 222, respectively, per one million inhabitants. The combined result for 2016 and 2017 was a median of 425 per one million inhabitants (standard deviation = 205). The interquartile range (IRQ) was 293–521 interventions per one million inhabitants with the lowest value in Bremen (87) and the highest in Saarland (888). ▶ **Fig. 1** provides an overview of the recorded interventions per million inhabitants for every state.

The analysis of the districts and former districts yielded an average of 430 interventions in 40 regions per year (calculated for 2016 and 2017) with a standard deviation of 302. The median is 413 interventions per year. There are no districts without recorded interventions. ▶ **Fig. 2** shows the absolute number of interventions by state and region as well as the development. ▶ **Fig. 3** shows the combined number of interventions per million inhabitants for every state from the years 2016 and 2017. How-



▶ **Fig. 1** Performance of different states. In Fig. 1 the number of interventions is illustrated by a bar plot for each state in Germany. The number is a summary of 2016 and 2017 and normalized to one million citizens. The red line illustrates the median of 425. The lower dashed red line illustrates the first quartile (293) and the upper red line the third quartile (521).

ever, individual smaller regions have a smaller number of hospitals in which interventional radiological treatment of acute bleeding can be offered.

Development between 2016 and 2017

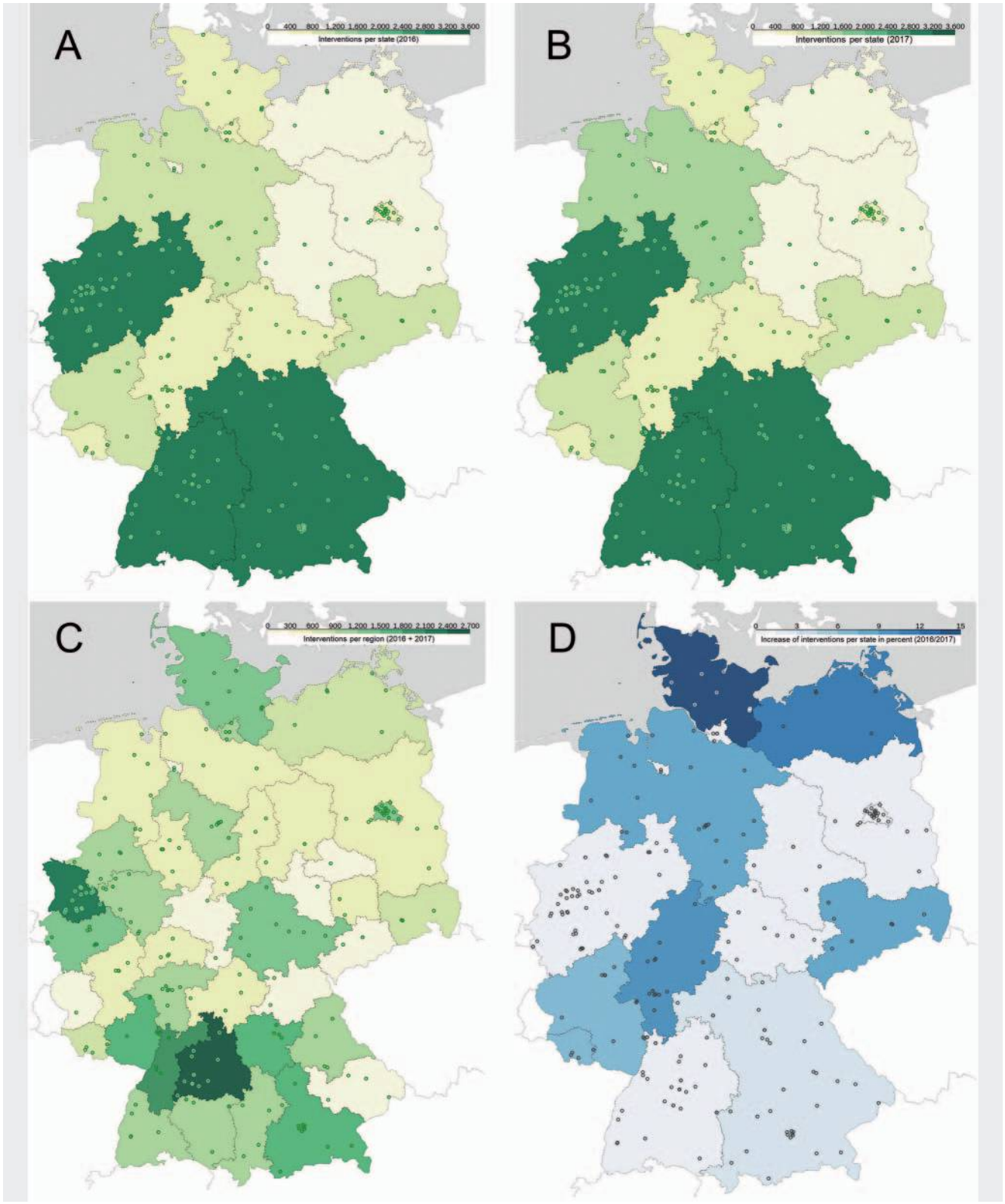
In cases recorded between 2016 and 2017, there were no statistically relevant changes. However, there were some significant differences locally on the district and former district level as described above. On average, the percentage change was + 0.02 % with a standard deviation of 37 %. The maximum decrease in a region between the two years was 96 % while the maximum recorded increase in a region was 88 %. ▶ **Fig. 2D** shows the development between 2016 and 2017 for the individual states.

Discussion

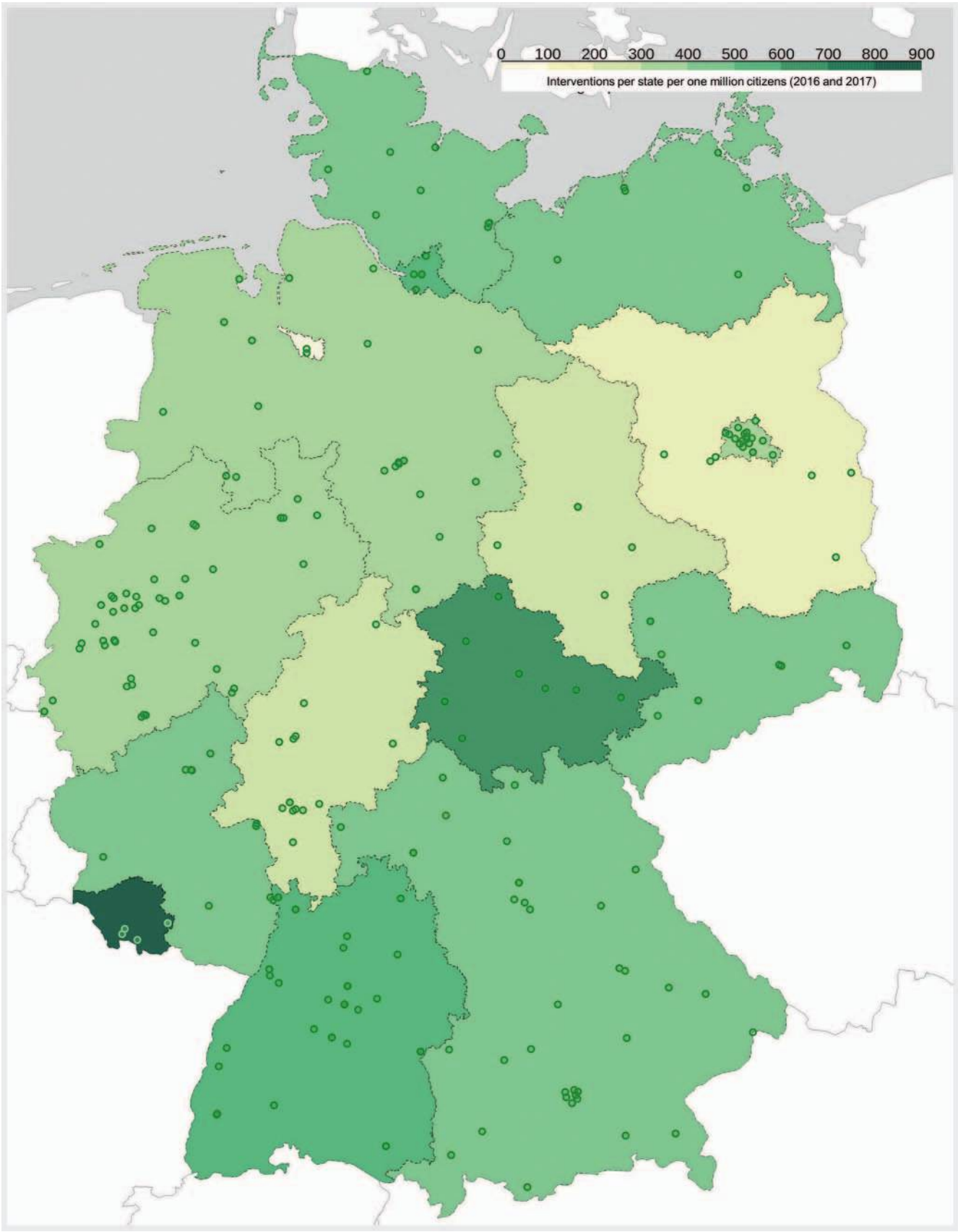
The analysis of the DeGIR registry data from the years 2016 and 2017 regarding the comprehensive Germany-wide availability of transcatheter vessel occlusion (module B) for assessing the interventional radiological treatment of acute bleeding showed that i) there is good nationwide availability on a state level and ii) the distribution of experience regarding the necessary procedures is almost equally high among the individual regions. White dots on the map coincide with regions that have a lower density of hospitals and thus have relatively poor coverage, see ▶ **Fig. 4**.

Interventional radiological treatment of acute bleeding has increasing clinical value and also a significant benefit for patients since the chances of successfully correcting this life-threatening condition are very high. In addition, interventional radiological treatments are minimally invasive with high efficiency and effectiveness and low procedural stress for the patient. In contrast to open surgery and often also endoscopic procedures, endovascular treatment is usually highly targeted and is gentle to surrounding tissue structures. In addition, intubation anesthesia is sometimes not necessary [9].

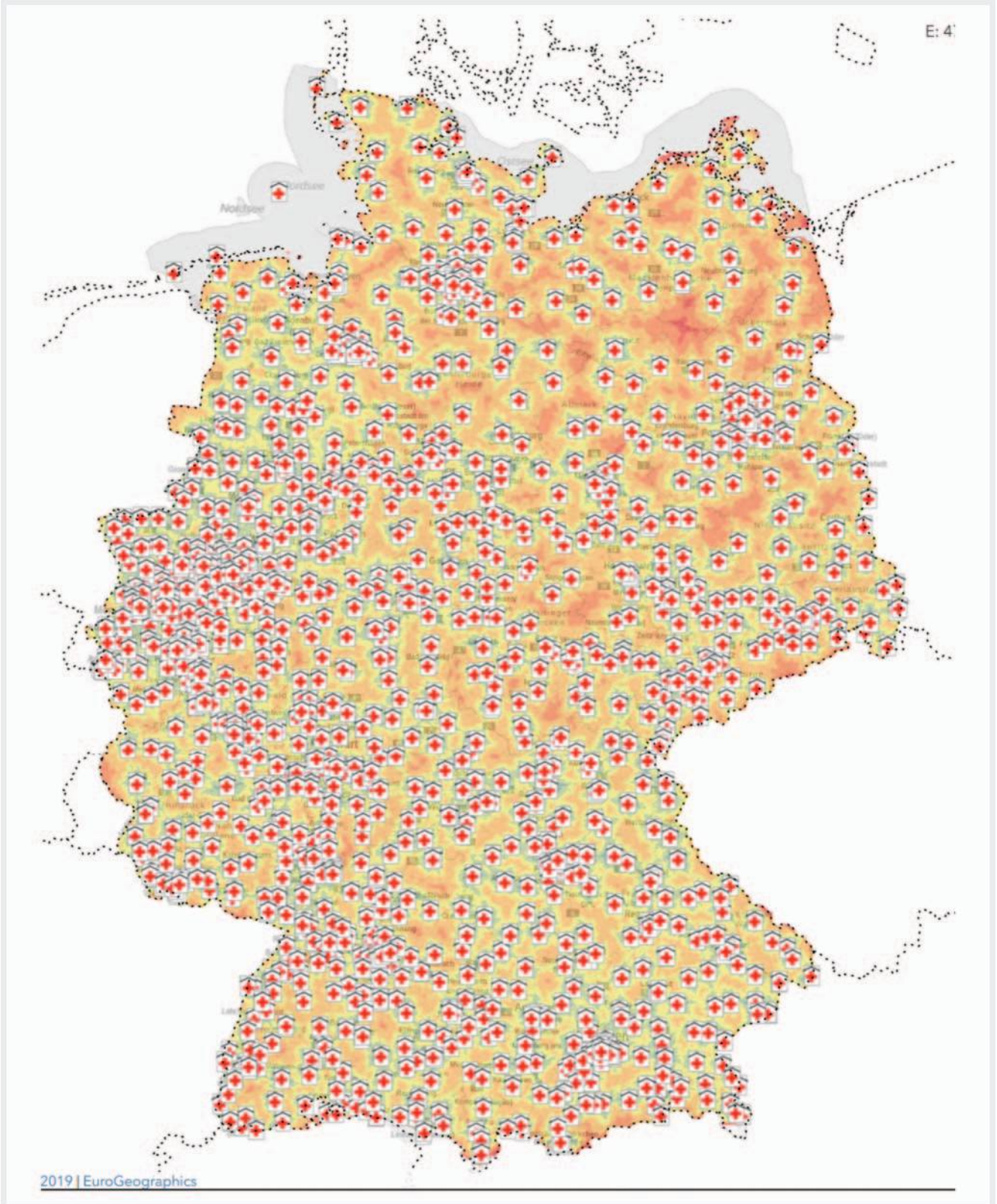
In addition to the effectiveness and level of risk of a method, its availability plays a major role in the practical situation and especially in patient care in general. The DeGIR registry data shows high nationwide availability on the state level. The radiologists performing interventional radiological procedures to treat acute bleeding also have the necessary experience. The results coincide with the neuroradiology results regarding DeGIR module E data [10]. The large number of centers that are suitable for certification as a DeGIR training center or are already certified and also the large number of high-volume centers indicate that the conditions are good for training young radiologists interested in interventional radiology. There are no comparable numbers for surgical or endoscopic methods of hemostasis in the literature. Therefore, we were not able to compare various techniques. It is also not possible to make a statement about the percentage distribution of the use of different hemostasis techniques. However, this was also not the goal of the present study. Instead, the aim was to examine whether nationwide availability of interventional radiological techniques for treating acute bleeding is ensured in Germany. Based on the current data, the answer is yes even though there are limitations regarding the interpretation of the voluntarily recorded registry data as discussed in the following.



▶ **Fig. 2** Widespread distribution of interventions and changes. Fig. 2 shows the number of interventions in 2016 and 2017 for the states and regions. In **A–C** the absolute numbers are shown in increasing shades of green and the changes from 2016 and 2017 in increasing shades of blue (**D**). **A** shows the absolute number of interventions in 2016 for each state and **B** shows the numbers from 2017. **C** illustrates the summarized numbers for each region from 2016 and 2017. **D** shows percentage changes in interventions between 2016 and 2017 on the state level; small changes and negative tendencies were encoded as white areas.



▶ **Fig. 3** Performance of the different states per one million citizens. Nationwide distribution of transcatheter vessel occlusion (2016 and 2017) on the state level per one million citizens in Germany.



▶ **Fig. 4** Distribution of clinics in Germany https://www.destatis.de/DE/Service/Impressum/copyright-genesis-online.html (Statistisches Bundesamt (Destatis), https://krankenhausatlas.statistikportal.de/; Datenlizenz dl-de/by-2-0, https://www.govdata.de/dl-de/by-2-0.

Interpretation of the registry data

DeGIR module B data was used in the present analysis as a surrogate for experience and performance distribution for interventional radiological emergency care in Germany. It is important to note that performance data is recorded on a voluntary basis. Therefore, it can be concluded that the number of interventions and experience with the corresponding treatments are significantly higher than the present numbers indicate. The significant fluctuation in the number of recorded interventions in some regions in the years 2016 and 2017 with a constant Germany-wide total number of interventions is a result of multiple parallel effects. In numerous cases, the fluctuations exceed the variance of incidence of the indications for interventional radiological treatment to be assumed. The reason for the local fluctuations of up to approx. +-90 % is ultimately unclear and can possibly be explained by inconsistent recording of performance data in individual clinics. Since the recording of performance data in the DeGIR registry is currently performed on a voluntary basis and also entails a certain time requirement, the recorded number of interventions can vary greatly. However, in individual cases, the availability of the technique could have changed thus explaining the significant local fluctuations. The switch of an experienced interventional radiologist to another clinic would be a further possible explanation for the fluctuation. The acceptance of the minimally invasive technique by referring physicians and a change among these colleagues could also be responsible for the fluctuation.

Over the years more and more radiology clinics have entered data in the DeGIR registry. Only after a longer stagnation it will be possible to evaluate the development of the interventional treatment of acute bleeding based on the absolute number of module B interventions.

Availability of care

On the whole, the analysis shows good nationwide availability on the state level in Germany of transcatheter vessel occlusion performed by interventional radiologists. However, given an average of approximately 200 in both 2016 and 2017, the number of interventions in every state per one million inhabitants varies greatly in some cases (see ▶ **Fig. 3**). In individual regions, e. g. Mecklenburg-West Pomerania, Bremen and Saarland, Hamburg and Thuringia, the deviation from the average is more than a standard deviation. As discussed above, this is due to fluctuations in registry data. Status as a city state must also be considered as a reason for the deviation in performance data. Large city states can recruit patients from neighboring states while smaller city states or even states can be subject to greater statistical fluctuations due to the consequently smaller amount of data in this regard and individual centers have a major influence on registry data. Based on the current data, the availability of individual interventionalists at a particular center cannot be ruled out as a factor since the individual interventions in the registry cannot be broken down by physician for reasons of privacy. Differences in established clinical processes must also be considered as a further cause of local fluctuations. In some clinics, cases of active bleeding tend to be referred to surgery so that these cases are treated but do not undergo interventional therapy and are thus not entered in the registry.

Some regions have a lower density of hospitals offering interventional radiological treatment in cases of acute bleeding. In individual cases, this means longer transport times and routes for patients requiring interventional radiological treatment for acute bleeding. Therefore, in the reverse conclusion, the high number of certified vascular centers in Saarland could be responsible for the unusually high number of interventions in the nationwide comparison.

Due to the good training conditions in Germany, it might be possible to further improve the situation in smaller regions by training more interventional radiologists and employing them in regions with less coverage.

The future of DeGIR/DGNR quality registry data

The DeGIR has been continually improving and revising web-based recording of performance data since 1994 to simplify data entry and to reduce the time needed to enter data while maintaining suitability for quality assurance. In 2018, the web-based solution provided by Samedi was implemented. In addition to structural data, indication data, procedural data, and parameters regarding result quality, the registry includes data regarding patient radiation exposure as a result of the particular intervention. Therefore, the registry data could also be used for mandatory dose reporting. Moreover, § 137 of the Social Code states that quality assurance is mandatory. This requirement could be satisfied at the same time when entering data in the registry. Furthermore, the recorded data provides the foundation for multi-level personal and institutional DeGIR/DGNR certification in the various treatment modules of interventional radiology. Mandatory nationwide data entry in the future would increase the value of results from analyses regarding various issues.

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