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Nationwide Provision of Radiologically-guided Interventional Measures for the Supportive Treatment of Tumor Diseases in Germany – An Analysis of the DeGIR Registry Data

Flächendeckende Versorgung mit radiologisch-interventionellen supportiven Maßnahmen bei Tumorerkrankungen und anderen Erkrankungen (DeGIR-Modul C) in Deutschland – Eine Analyse der DeGIR-Registerdaten

Authors

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Key words

Oncology, Interventional radiology, DeGIR-registry, nationwide availability, supportive therapy

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ABSTRACT

Purpose In addition to direct oncologic therapy, interventional radiology plays an important supportive role in oncologic therapy primarily guided by other disciplines. These supporting measures include diagnostic punctures, drainages, biliary interventions, central venous access including port implantations, osteoplasties, pain therapies etc.). This study investigated the extent to which these radiologically guided supportive measures are available in Germany.

Material and Methods All interventional procedures documented in the DeGIR-registry (excluding transhepatic portosystemic shunts) of the years 2018 and 2019 were recorded (DeGIR-module C). A breakdown of the documented interventions was performed based on federal states as well as 40 individual regions (administrative districts and former administrative districts).

Results A total of 136,328 procedures were recorded at 216 centers in DeGIR Module C in 2018 and 2019. On average, 389 cases were documented per hospital in 2018 and 394 cases in 2019; the increase per hospital from 2019 is not statistically significant but is relevant in the aggregate when new participating centers are included, with an overall increase of 10 %

(6,554 more cases than the previous year). Normalized to one million inhabitants, an average of 781 procedures took place across Germany in 2018 and 860 in 2019. Districts with no registered procedures are not found for Module C.
Indications for Module C interventions were mostly interdisciplinary in 2018 and 2019. In this context, the quality of outcome was very high; for the procedures drain placement, marking and biopsy the technical success was 99 %, while the complication rate was lower than 1 %.
Conclusion The structural analysis of this work concludes that in Germany there is good nationwide availability of radiologically guided supportive measures in oncological therapy. Accordingly, the training situation for prospective interventional radiologists is good, as the distribution to centers with high experience is excellent. In addition, the overall outcome quality of radiology-guided interventions is very high.

Key Points:

- In Germany, there is good nationwide coverage of radiologically guided supportive interventions in oncological therapy.
- The training situation for prospective interventional radiologists is good, as the distribution to centers with high experience is excellent.
- The overall outcome quality of radiology-guided interventions is very high.

Citation Format

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ZUSAMMENFASSUNG

Ziel Die interventionelle Radiologie spielt neben der direkten onkologischen Therapie auch eine wichtige unterstützende Rolle in der primär von anderen Disziplinen geführten onkologischen Therapie. Diese unterstützenden Maßnahmen umfassen diagnostische Punktionen, Drainagen, PTCD, Portimplantationen, Osteoplastien, Schmerztherapien etc. In der vorliegenden Arbeit wurde untersucht, inwiefern in Deutschland eine flächendeckende Verfügbarkeit dieser Eingriffe vorliegt.
Material und Methoden Erfasst wurden alle im DeGIR-Register dokumentierten interventionellen Eingriffe (exklusive der Anlage des transhepatischen portosystemischen Shunts) der Jahre 2018 und 2019 (DeGIR-Modul C). Es erfolgte eine Aufschlüsselung der dokumentieren Eingriffe anhand von Bundesländern sowie 40 Einzelregionen (Regierungsbezirke und ehemalige Regierungsbezirke).
Ergebnisse Insgesamt wurden in den Jahren 2018 und 2019 im DeGIR-Modul C 136.328 Eingriffe an 216 Zentren erfasst. Im Durchschnitt wurden 2018 pro Klinik 389 Fälle dokumentiert und 2019 394 Fälle; der Anstieg pro Klinik zu 2019 ist nicht statistisch signifikant, jedoch in der Summe unter Einbeziehung neuer teilnehmender Zentren relevant mit einem Gesamtzuwachs von 10 % (6.554 Fälle mehr als im Vorjahr). Normiert auf 1 Million Einwohner fanden deutschlandweit 2018 im Durchschnitt 781 und 2019 860 Eingriffe statt.
Bezirke ohne registrierte Eingriffe finden sich für das Modul C nicht. Die Indikationsstellung für Modul-C-Eingriffe erfolgte 2018 und 2019 zumeist interdisziplinär. Dabei war die Ergebnisqualität sehr hoch; für die Verfahren Drainagenanlage, Markierung und Biopsie betrug der technische Erfolg 99 %, während die Komplikationsrate deutlich kleiner als 1 % war.
Schlussfolgerung Die Strukturanalyse dieser Arbeit kommt zu dem Schluss, dass in Deutschland eine gute flächendeckende Versorgung mit radiologisch geführten, supportiven Maßnahmen in der onkologischen Therapie vorliegt. Entsprechend ist die Ausbildungssituation für angehende interventionelle Radiologen gut, da die Verteilung an Zentren mit großer Erfahrung hoch ist. Zudem ist die Ergebnisqualität der radiologisch geführten Maßnahmen insgesamt sehr hoch.

Introduction

In addition to vascular image-guided procedures, non-vascular minimally invasive interventional radiology procedures are an indispensable part of modern medicine. These include image-guided biopsies and drainage, port catheter implantation, pain management and osteoplastic procedures. The spectrum of diseases treated is very heterogeneous and includes mainly malignant diseases but also benign diseases such as osteoporosis or inflammatory bile duct stenosis. These procedures are classified as Module C by the German Society for Interventional Radiology and Minimally Invasive Therapy (DeGIR). There are numerous clinical cooperation partners for this type of surgery, such as visceral surgery, gastroenterology, gynecology, orthopedics, trauma surgery, neurosurgery, urology and many others.

Current oncological treatment concepts include not only causal therapy of the underlying disease, such as chemotherapy, ablation or surgical therapy, but also increasingly complex supportive measures in order to achieve an optimal outcome and improve the patient's quality of life. Interventional radiology plays an incrementally important role in these supportive interventions pre-therapeutically, post-therapeutically, as well as the management of complications, and is therefore represented in various national (e. g., S3 guidelines) and international guidelines [1–5]. Supportive pre-therapeutic interventions of interventional radiology in the treatment of tumor diseases include, for example, biopsy of suspicious masses to confirm a diagnosis or marking of confirmed malignant tumors in preparation for therapy, such as prior to radiation, ablation or surgical removal. Pretherapeutic, bioptic intervention makes malignancy diagnosis and the resulting individualized therapy possible in the first place, as knowledge of tumor biology based on obtained tissue samples is critical. Benign findings can be detected early on in a minimally invasive and safe manner to avoid unnecessary treatments or major invasive diagnostic procedures. Bile duct interventions are another im-

portant pillar of supportive, peritherapeutic measures in modern oncology. For example, stenoses and occlusions of the bile ducts in central liver tumors, bile duct malignancies, and pancreatic head carcinomas can be treated interventionally. The lower morbidity and mortality of interventional procedures compared with open operative procedures is of high importance in mostly palliative situations [6]. Likewise, the implantation of port catheters is one of the important supportive measures in modern tumor therapy [7, 8]. Furthermore, pain that is difficult to control with medication can occur in the course of advanced tumor diseases. This can be successfully and safely treated by interventional, targeted deactivation of nerves, so that the quality of life of tumor patients can be enhanced [8]. These techniques are also used for pain patients with benign conditions (e. g., degenerative spine disease). In addition, osteolysis can occur during tumor diseases and eventually lead to fractures, which increases the morbidity as well as mortality of tumor patients. These osteolyses can be stabilized by radiologically-guided osteoplasty before a fracture occurs to improve patients' quality of life [5].

Even in the case of oncologically successful treatment of a tumor, the underlying tumor tissue can become infected, allowing abscesses to develop, arising not only in the area of the treated tumor, but may also be triggered by certain therapeutic approaches, e. g., the risk of an intrahepatic abscess is increased by the placement of a biliodigestive anastomosis after pancreatic head resection [9–11]. In addition to malignancies, benign diseases also lead to abscesses or other fluid accumulation, thus interventional drainage techniques are also used in these cases. Abscesses can be treated minimally invasively by percutaneous drainage with very high level of patient safety [12]. In addition to abscess drainage, percutaneous creation of a nephrostoma as a complement to endoscopic retrograde procedures is also an important tool of interventional radiology [13]. In addition to the aforementioned techniques and indications, numerous other non-vascular interventions using similar techniques with image guidance have been established and often represent individually important clinical solutions for patients. All of the above procedures can be performed under local sedation and usually do not require general anesthesia, thus these therapies can be offered to a wide range of patients.

The German Society for Interventional Radiology and Minimally Invasive Therapy (DeGIR) has been recording vascular and non-vascular interventions for over 25 years as part of a quality assurance program based on a registry operated jointly with the German Society for Neuroradiology (DGNR). This Registry comprises the following modules: Module A (vasodilator and vascular reconstructive procedures); Module B (vaso-occlusive procedures); Module C (diagnostic punctures, drains, PTCD, TIPS, port implantations, osteoplasty, pain therapy, etc.). Module D (oncological procedures including primarily tumor-specific embolizations and ablations); Module E (vascular neuro-interventions), and Module F (neurovascular embolization treatments) [14].

The description of good, nationwide interventional radiological care for cerebral thrombectomy (Module E), revascularizing interventions (Module A) and emergency care for acute bleeding utilizing catheter embolization (Module B) has already been published based on DeGIR quality assurance data [14–17]. This current study presents the interventional supportive procedures of DeGIR Module C (excluding the placement of a transjugular intrahepatic portosystemic shunt [TIPS]).

The purpose of this study is to investigate whether interventional radiological therapy in Module C (excluding the installation of a TIPS) is available to patients in Germany on a nationwide basis. The interventions in DeGIR Module C are particularly challenging, as many different techniques are required to cover the sometimes very diverse approaches.

Materials and Methods

Data Collection

The study results of the current work are based on DeGIR Registry data from 2018 and 2019. The data was collected using software from Samedi (samedi GmbH). Module C (excluding the placement of a TIPS) was recorded as a proxy for those supportive interventions for tumor disease.

The number of centers meeting the criteria for DeGIR certification as a training center (at least 50 procedures per year) or already certified was recorded. Centers with more than 500 interventions per year were defined as "high volume".

Analysis of Coverage

As described in the preliminary work on Modules B and E, the data breakdown was organized by German federal state. For a more detailed analysis of the area coverage, without making the data of individual clinics visible, the recorded Module C interventions were broken down into 40 smaller regions (government districts, former government districts and federal states [if there was never a division into government districts]: Arnsberg, Berlin, Brandenburg, Braunschweig, Bremen, Chemnitz, Darmstadt, Dessau, Detmold, Dresden, Düsseldorf, Freiburg, Gießen, Halle, Hamburg, Hanover, Karlsruhe, Kassel, Koblenz, Cologne, Leipzig, Lüneburg, Magdeburg, Mecklenburg-Vorpommern, Middle Franconia, Münster, Lower Bavaria, Upper Bavaria, Upper Franconia, Upper Palatinate, Rhine-Hesse-Palatinate, Saarland, Schleswig-Holstein, Swabia, Stuttgart, Thuringia, Trier, Tübingen, Lower Franconia, Weser-Ems) [14, 18].

Analysis of selected Quality Parameters

As an example, as proxy parameters for a high quality of results from the register database, quality parameters for diagnostic puncture, drainage and marking were analyzed, such as the indication in an interdisciplinary board, technical success and complications in the first 24 hours.

Statistics

A descriptive statistical analysis employed the R Statistics program (R version 3.5.3 (2019–03–11) – "Great Truth") [19]. The accepted significance level was $p = 0.05$.

Creation of Graphics

Creation of the graphics was as previously described [14].
The following software was employed:

▶ **Table 1** Listing of the various services and performance figures of the DeGIR Module C without TIPS.

Type of intervention	2018 (n = 68 971)	2019 (n = 75 890)	Year-on-year change (n = + 7183)
Biospy	23 116 (34 %)	25 112 (33 %)	1996 (+ 8,6 %)
Drainage	8075 (12 %)	8958 (12 %)	883 (+ 10,9 %)
Marking	3367 (5 %)	4207 (6 %)	840 (+ 24,9 %)
Osteoplasty	874 (1 %)	819 (1 %)	–55 (–6,3 %)
Recanalization/reconstruction non-vascular	1516 (2 %)	1578 (2 %)	62 (+ 4,1 %)
Pain/infiltration treatment/neurolysis	20 866 (30 %)	22 327 (29 %)	1461 (+ 7,0 %)
Other procedures: ▪ Port, PICC ▪ Cava filter ▪ Foreign body removal ▪ Position correction ▪ PRG	11 103 (16 %)	12 889 (17 %)	1996 (+ 18,0 %)

Note: The sum of interventions in this table is larger than the study population for the geographic region analysis, as it also includes data from interventions without region assignment.

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Technical data:
© German Federal Office of Statistics data according to Section 21 of the Hospital Remuneration Act, 2016.
© Federal Statistical Offices and state census data: 2011 census
Basic data:
© EuroGeographics (2013) European Boundary Map 2013 at 1:3000 000 scale
© GeoBasis-DE/BKG (2018) Germany administrative boundaries 2017 at 1:250 000 scale
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Genesis-Online; Data license dl-de/by-2–0), Openstreetmap (https://www.openstreetmap.org/copyright © OpenStreetMap contributors), Folium/Geopandas/Shapely/Python (map creation).

Results

In 2018 and 2019, a total of 136 328 procedures at 216 centers were recorded in DeGIR Module C. In 2018, the number of documented procedures was 64 887 at 205 centers; 164 centers met certification requirements; 41 centers were considered high-volume centers with more than 500 documented procedures per year.

In 2019, the number of documented procedures was 71 441 at 216 centers; 179 centers met certification requirements; 44 centers identified as high-volume centers with more than 500 documented procedures per year.

On average, 389 cases were documented per hospital in 2018 and 394 cases in 2019; the increase per hospital in 2019 is not statistically significant but is relevant in the aggregate when new participating centers are included, with an overall increase of 10 % (6554 more cases than the previous year). ▶ **Table 1** shows a breakdown of the registered services for the years 2018 and 2019. ▶ **Table 2** shows the anatomical regions of biopsies.

Coverage of Care

Normalized to one million inhabitants, an average of 781 interventions were performed across Germany in 2018 and 860 in 2019. Based on the calculations of the individual federal states from 2018 and 2019 together, this results in a mean of 1579 per million inhabitants (standard deviation = 943). The interquartile range (IRQ) is 1224–1784 interventions per million inhabitants; the minimum value is 7 in Bremen and the maximum value of 4,062 in Saarland. The median is 1500. ▶ **Fig. 1** provides an overview of the registered services per million inhabitants for each federal state.

An analysis of the administrative districts or former administrative districts results in an average of 3408 interventions per year (calculated from 2018 and 2019) in 40 regions; the standard deviation is 2627. The median is 2892 procedures per year. There were no districts without procedures registered in Module C. ▶ **Fig. 2** illustrates the absolute number of interventions by federal state and region as well as the related trend. ▶ **Fig. 3** shows the combined number from 2018 and 2019 of interventions per million inhabitants for each federal state.

Trend between the Years 2018 and 2019.

There were no statistically significant changes in registered cases between 2018 and 2019, but there was an overall increase of just over 10 %. Similar to Module B, some significant variations between individual districts and individual states occurred for Module C as well. ▶ **Fig. 2 D** illustrates the trend between 2018 and 2019

▶ **Table 2** Listing of the anatomical regions including the absolute intervention numbers in DeGIR Module C in 2018 and 2019.

Anatomical region	2018	%	2019	%
Autonomic nervous system	60	0,3	37	0,1
Gall bladder	12	0,1	18	0,1
Gastrointestinal tract	46	0,2	67	0,3
Heart	6	0,0	1	0,0
Pelvis	1133	4,9	429	1,7
Head/neck	342	1,5	347	1,4
Liver	2743	11,9	3067	12,2
Lung	3938	17,0	4002	15,9
Lymph nodes	1392	6,0	1532	6,1
Mamma	6508	28,2	7148	28,5
Male genitals	426	1,8	596	2,4
Mediastinum	295	1,3	342	1,4
Spleen	43	0,2	46	0,2
Muscle tissue/subcutis	861	3,7	996	4,0
Adrenal gland	139	0,6	165	0,7
Kidney	592	2,6	707	2,8
Ovaries	13	0,1	21	0,1
Pancreas	155	0,7	201	0,8
Peritoneum/mesentery	522	2,3	1204	4,8
Pleura	259	1,1	272	1,1
Retroperitoneum/extraperitoneal space	943	4,1	407	1,6
Thorax/peripheral skeletal system	1460	6,3	2931	11,7
Uterus	5	0,0	7	0,0
Spine/Ilio sacral joint	1207	5,2	569	2,3

Note: The total number of procedures in this table is larger than the study population for the geographic region analysis, as it also includes data from procedures without region assignment.

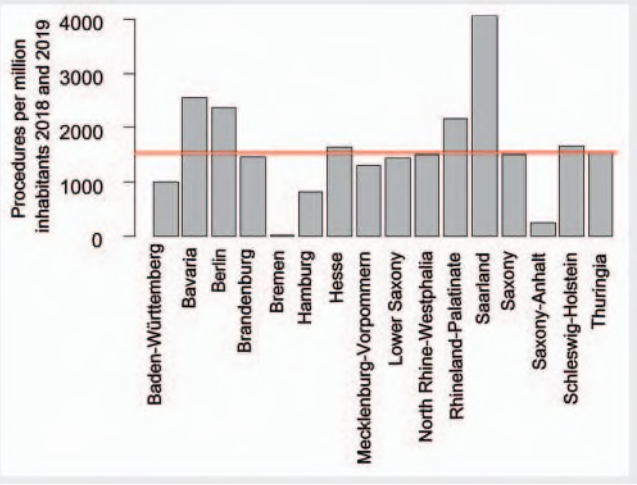
for each state. The increase at the state level averaged 13 % (IRQ: 0–19 %).

Analysis of selected Quality Parameters

The indication for Module C procedures was generally interdisciplinary. This was the case for drain placement in 84 %, marking in 75 %, and biopsy in 80 %. The quality of outcome was very high; for all three procedures; the technical success rate was 99 %, while the complication rate was significantly less than 1 %. ▶ **Table 3** provides a detailed breakdown of selected quality characteristics.

Discussion

Analysis from 2018 and 2019 DeGIR Registry data regarding nationwide coverage of interventional radiological procedures in



▶ **Fig. 1** Procedure documentation according to 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 2018 and 2019 and normalized on one million citizens. The red line illustrates the median of 1500.

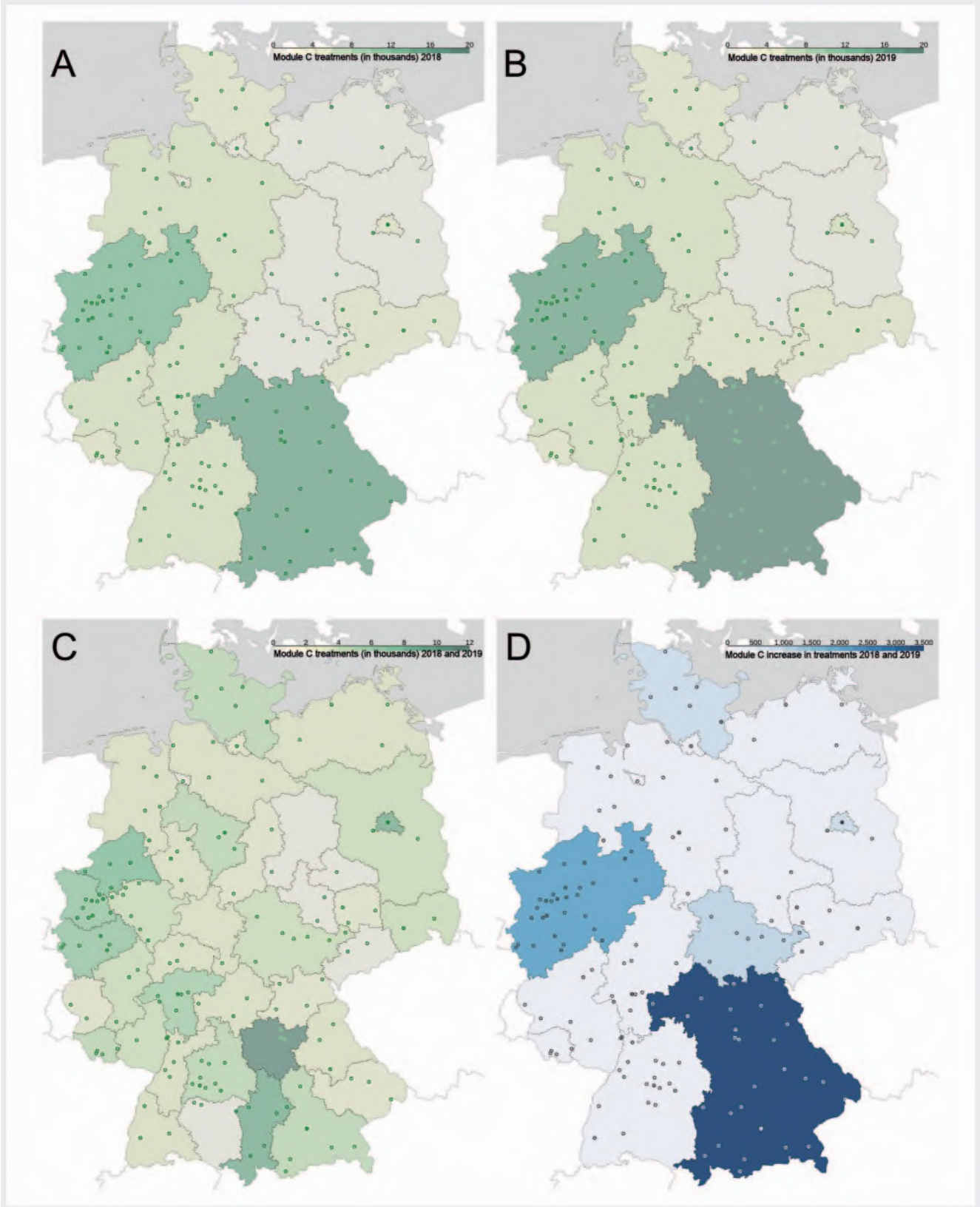
DeGIR Module C (excluding TIPS) shows suffieicnt availability exists for these procedures on a state-wide level; in addition, professional qualifications and experience regarding the required procedures are well distributed across the individual regions. Regions with comparatively lower numbers of procedures correspond to regions that have a low density of hospitals, see ▶ **Fig. 4**. At the district level, there is no region where this type of interventional radiology procedure is not available. The present results document not only the good availability of the above-mentioned interventions, but also a very high intervention quality.

Nonvascular interventional radiological procedures have an assured and increasing place in modern oncological concepts [20]. Interventional radiology performs both pre-therapeutic and post-therapeutic procedures under imaging guidance less radically than with surgical procedures. These include, for example, marking or biopsy as the basis for planning tumor therapy. Likewise, one of the modern pillars of tumor therapy is the placement of port catheters, as these allow safe administration of chemotherapy and other drugs; these catheters are also installed using interventional radiology. However, peri- and post-therapeutic measures are likewise offered, such as drainage placement or interventional pain therapy/neurolysis for affected nerves.

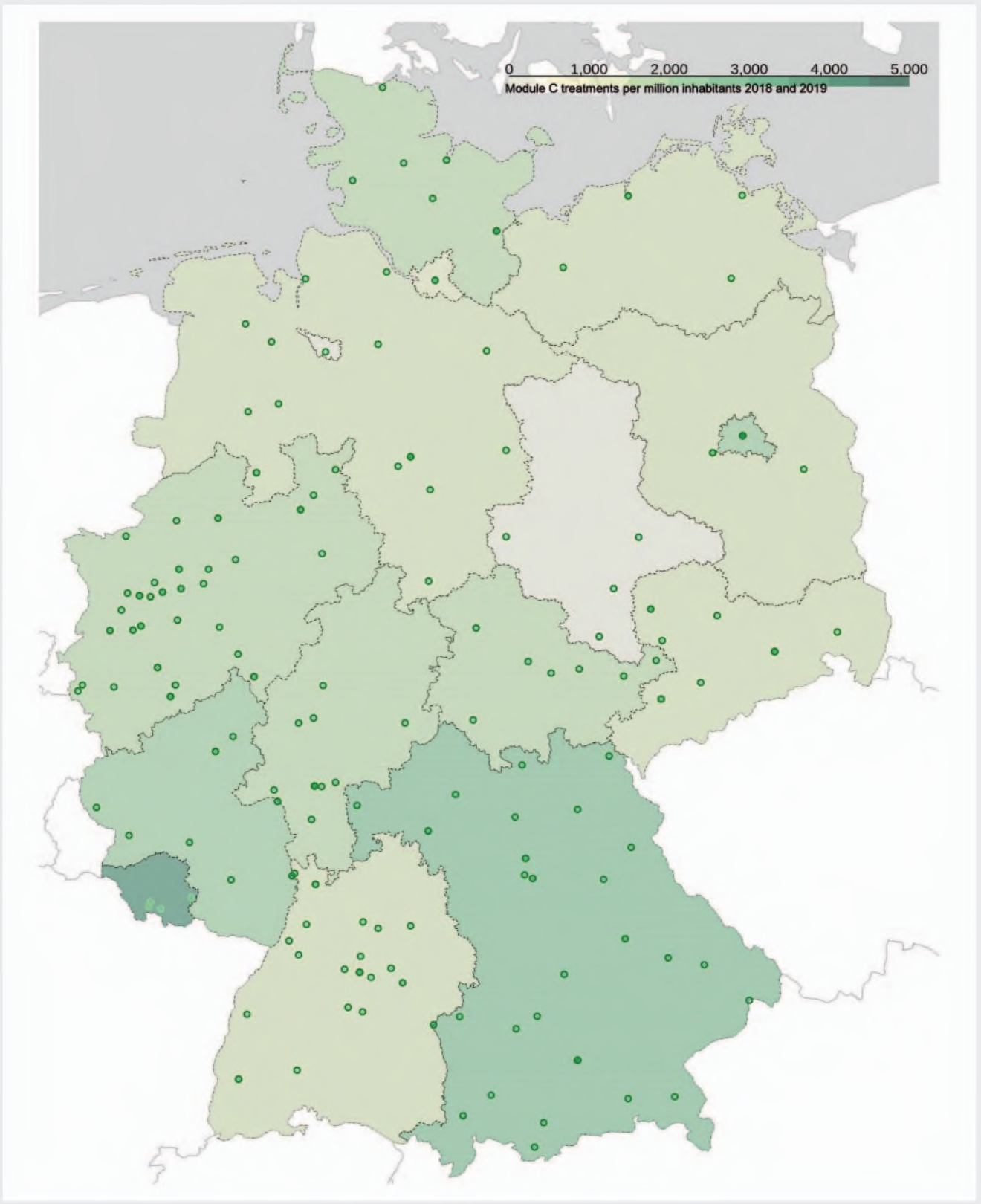
The above-mentioned procedures can contribute in various ways to enable and facilitate oncological therapy and to reduce the mortality and morbidity of patients, especially in palliative situations, and thus improve the overall outcome [21].

In addition to the quality and safety of therapies, ubiquitous availability plays the most important role in practical patient care. Therefore, this study investigated the availability of different supportive oncology and interventional radiology-guided nonvascular interventions in Germany.

DeGIR Registry data from 2018 and 2019 demonstrate a high level of nationwide availability at the state level, similar to the analysis for hemorrhage or stroke care. Numerous hospitals suitable for DeGIR training center certification or currently with certi-



► **Fig. 2** Comprehensive distribution and evolution of interventions. In ► **Fig. 2** the numbers of interventions of 2018 and 2019 are illustrated for the states and regions. In **A–C** the absolute numbers are encoded in increasing green and the changes from 2018 and 2019 in increasing blue **D**. In **A** the absolute numbers of interventions in 2018 are shown for each state and in **B** those from 2019. **C** illustrates the summarized region associated numbers from 2018 and 2019. In **D** percentual changes of interventions between 2018 and 2019 on state level are illustrated; small changes and negative tendencies were encoded as white areas.



▶ **Fig. 3** Procedures in the different states per million inhabitants. Areal coverage of interventional supportive oncologic therapy (2018 and 2019) on state level per one million citizens in Germany.

▶ **Table 3** Summary of selected quality parameters for biopsy, drainage and marking.

Type of intervention	2018	%	2019	%	Total	%
Drainage	**8075**		**8958**		**17033**	
Interdisciplinary indication	6388	79,1	7952	88,8	14340	84,2
Technically successful (target volume recorded or macroscopically representative or positive microbiology)	7957	98,5	8863	98,9	16820	98,7
Occurrence of a complication in the first 24 h	21	0,3	16	0,2	37	0,2
Marking	**3367**		**4207**		**7574**	
Interdisciplinary indication	1996	59,3	3654	86,9	5650	74,6
Technically successful (target area successfully marked)	3344	99,3	4188	99,5	7532	99,4
Occurrence of a complication in the first 24 h	0	0,0	0	0,0	0	0,0
Biopsie	**23116**		**25112**		**48228**	
Interdisciplinary indication	17085	73,9	21242	84,6	38327	79,5
Technically successful (target volume recorded or macroscopically representative)	22837	98,8	24808	98,8	47645	98,8
Occurrence of a complication in the first 24 h	29	0,1	24	0,1	53	0,1

fication are available in Germany for the training of young radiologists interested in interventional radiology. Although individual procedures from Module C are also provided by other disciplines, there is currently no published data on the exact number and area-wide distribution. Corresponding registry data from other professional societies are not currently available for these interventions. Due to the specialty definition of radiology as well as the special expertise in imaging procedures, many diagnostic and therapeutic measures from DeGIR Module C can only be provided by interventional radiologists, including, for example, CT-guided biopsy or marking. Of other supportive measures, only individual types of intervention are also covered by other specialist disciplines, e. g. ultrasound-guided breast biopsies in gynecology. The costs of an interventional radiological procedure are often lower with the same effectiveness; port implantation in the angiography unit, for example, is more cost-effective than surgical implantation with the same complication rate [22]. In addition, the interventional radiologist can be an important clinical partner in the overall treatment approach.

Interpretation of Registry Data

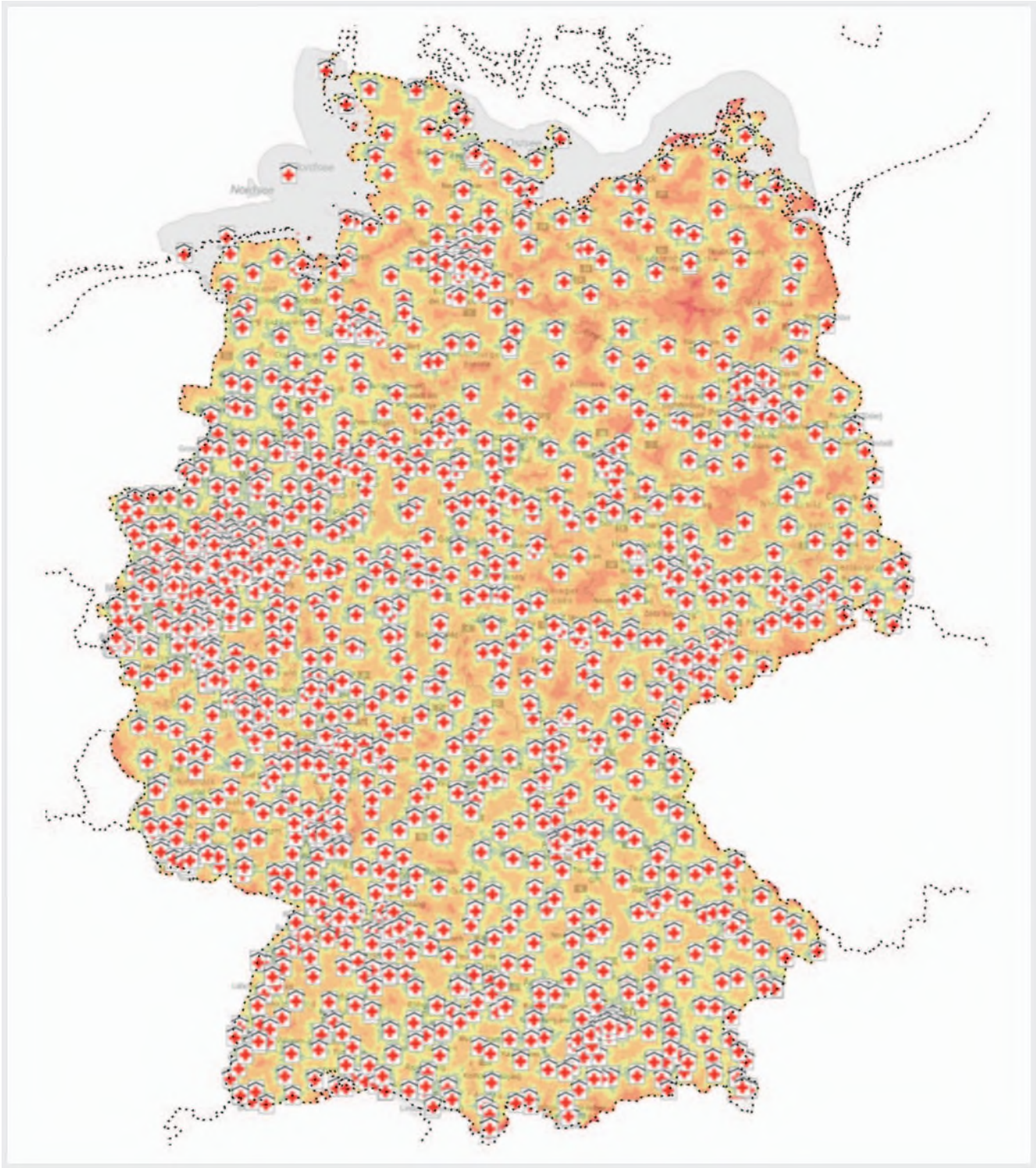
Similar to prior studies, this analysis selected DeGIR data from Module C as a proxy for procedure distribution and experience for interventional radiology-guided, nonvascular procedures with a focus on diagnosis and treatment of tumor disease. Likewise, data provision was voluntary for the study years 2018 and 2019. There are also great regional fluctuations for Module C as previously shown in publications regarding the other individual modules B and E. Similarly, due to the voluntary nature of the registry documentation, a relevant but ultimately unknown number of missing entries (unreported numbers) can be assumed. As already discussed in the publications on Modules B and E, the scope and quality of the reported data are influenced by the motivation and activity of individuals in the clinics. City-states in particular are more affected by statistical fluctuations and the above-mentioned influences.

Coverage of Care

The analysis of the DeGIR Module C (excluding TIPS) shows, analogous to the other modules, overall good nationwide coverage at federal state level with interventional-radiologically guided, nonvascular interventional measures. The normalized, mean average number of interventions at the federal state level from 2018 and 2019 corresponds to the value of the normalized total interventions in relation to the Federal Republic of Germany (1579 vs. 1641). Nevertheless, the number of interventions in each federal state varies significantly per million inhabitants (see ▶ **Fig. 3**). Individual regions such as Saxony-Anhalt, Bremen or Saarland deviate by more than one standard deviation from the mean. As discussed above and in previous studies, fluctuations in the scope of the documentation of the register data are responsible for this.

The above-mentioned favorable training situation in Germany could support the further training of more interventional radiologists and a more even distribution of these radiologists to less well-provided regions, thus allowing greater homogeneous area coverage in Germany in the future.

Overall, the data allow the statement that a comprehensive supply of radiologically-guided interventional measures for the supportive treatment of tumor diseases is assured in Germany; in addition, the training situation for prospective interventional radiologists is favorable.



▶ **Fig. 4** Distribution of hospitals in Germany. Distribution of hospitals throughout 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.

Conflict of Interest

The authors declare that they have no conflict of interest.

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