

ewimed

ewimed report

24

Data collection 2023





Foreword

This third edition of the ewimed report was produced for the first time in a cross-national collaboration. This international focus provides an additional perspective on the treatment options for pleural effusion and ascites and shows that the subcutaneously tunnelled pleural or peritoneal indwelling catheter is used internationally for this treatment.

To improve readability, the subcutaneous tunnelled pleural or peritoneal catheter will be abbreviated as IPC.

The ewimed report 2024 publishes the latest data from the internal ewimed patient survey based on data collected in 2023. This data has been gathered from all ewimed patients nationwide in Germany and evaluated for the past 14 years. The ewimed team has picked out relevant clinical studies and articles during 2023 on the subjects of pleural effusion and ascites and shared their reviews. The chapter and topic “Quality of life of patients with IPC” offer insights from a medical perspective presenting an interview with Univ.-Prof. Dr Clemens Aigner from the Universitätsklinikum / AKH Vienna in Austria and from a patient’s case report from Sweden. Another section in this year’s ewimed report is IPC during ongoing chemotherapy. The oncologist Dr Yannick Buccella from Stadtspital Zurich in Switzerland gives an interesting interview on this subject, also highlighting the possibilities and advantages of IPCs during chemotherapy.

ewimed GmbH

ewimed GmbH is an expanding medical technology company based in Medical Valley Hechingen that has specialised in the drainage of pleural effusion and ascites for over 30 years. As the developer, manufacturer and distributor of catheters and drainage accessories, ewimed offers a wide range of products for symptom relief in recurrent malignant and non-malignant pleural effusion and ascites. The products are designed for both clinical use and home care. ewimed offers a number of services related to its products and offers care for all patients under its ewimed care concept, from the implantation of the catheter to patient self-drainage at home and beyond. With subsidiaries, sales and service units in Germany, Sweden, Switzerland, Austria, Hungary, Denmark, Norway, Belgium and the Netherlands, ewimed is one of the largest providers of drainage systems in Europe and is continuously working on the development of innovations in this area. Since the company was established in 1991, the patient has always been the focus of ewimed’s activities. The aim is to improve and maintain the quality of life for patients through the carefully developed patient-centred care concept.



Lotta and Egon Wiest, managing directors and founders of ewimed GmbH



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1. A closer look at the ewimed patient survey

The ewimed patient survey is filled out by a member of the ewimed training team during the home care training. The data from the survey, which has now been collected for more than 10 years, provides ewimed with important insights for the further development of the treatment of pleural effusion and ascites based on first-hand patient experience and knowledge of the market needs.

ewimed is continuously working on refining and expanding the survey to improve the quality of the data obtained. Besides annually recurring questions like those for the patient's age and cause of illness it is now also possible to address new topics over a specific period of time. ewimed also offers medical professionals the opportunity to raise clinical questions that fit into the context of training for home drainage.

Below you can see the last 5 years of data (2019–2023) from the ewimed patient survey.

It should be noted that the following data refers to the surveys analysed by ewimed in Germany. The data does not represent the overall European market for pleural effusion and ascites. An internationalisation of the ewimed patient survey is planned.

1.1 Average patient age

The average patient age has not changed much in the last five years (see Fig. 1). We can see that the average age for pleural effusion is approximately 5.3 years higher than the average age for ascites. A slight increase in age can be seen in both cases over the last 5 years.

1.2 Gender distribution

The gender distribution is similar for both conditions and has remained almost unchanged. Over the last 5 years, the average gender distribution of pleural effusion and ascites is 53% male patients and 47% female patients.

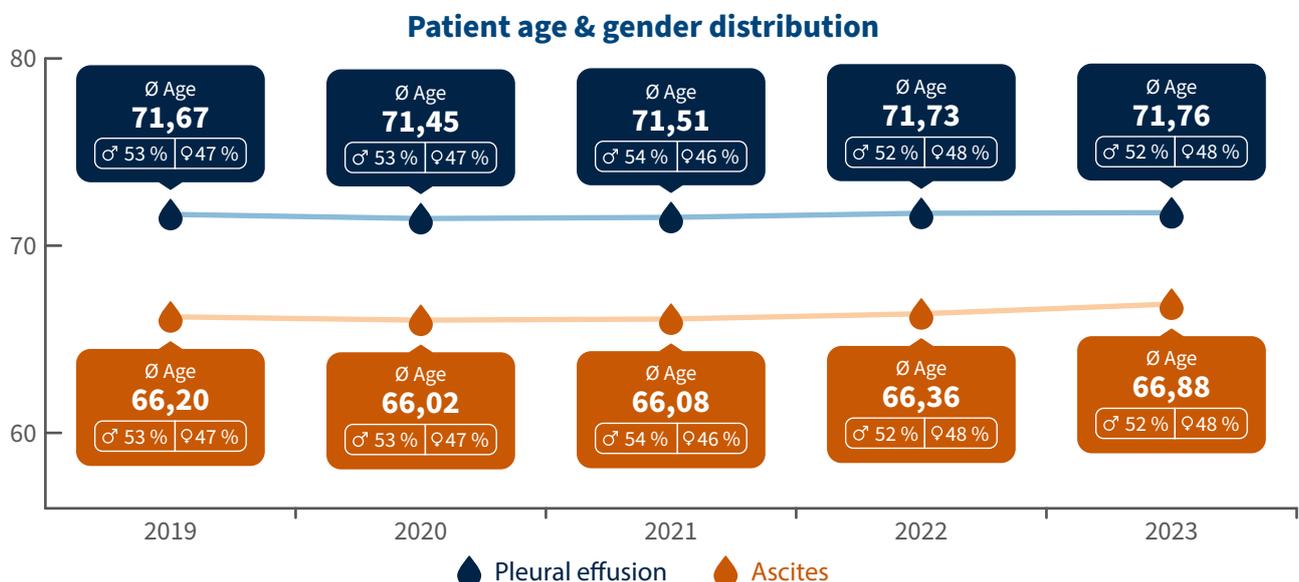


Fig. 1: Average patient age and gender distribution



1.3 Causes of illness and underlying diseases

In the next section of the survey, the cause of the disease is broken down into malignant and non-malignant causes and the underlying disease that led to the pleural effusion or ascites is also analysed.

Causes of illness – malignant and non-malignant

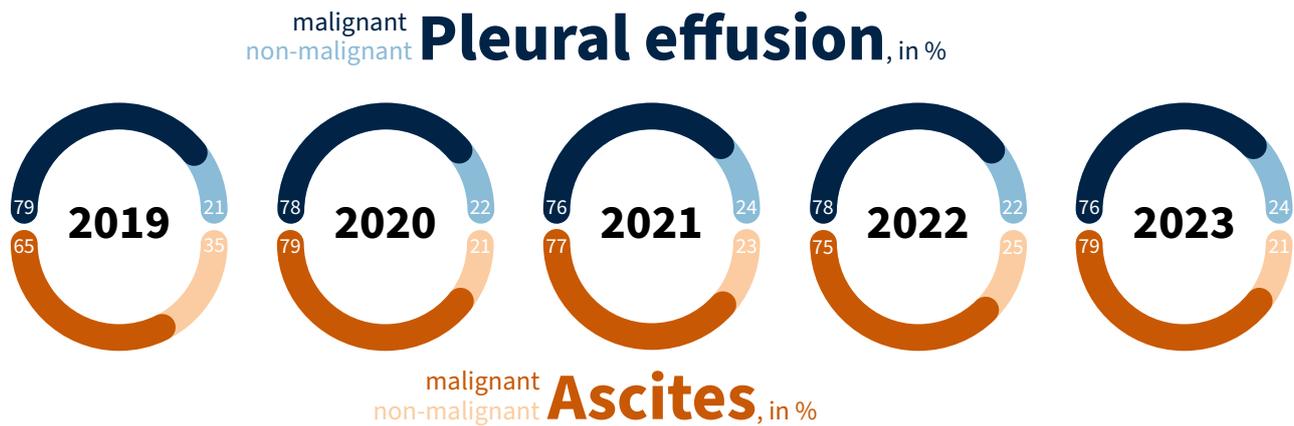


Fig. 2: Causes of illness – malignant and non-malignant

The changes in the underlying disease between malignant and non-malignant groups is different for pleural effusion and ascites. In the last 5 years, the proportion of malignant causes of pleural effusion has decreased and the proportion of non-malignant causes has increased. In ascites, however, the proportion of malignant causes increased relatively sharply, whereas the non-malignant proportion decreased.

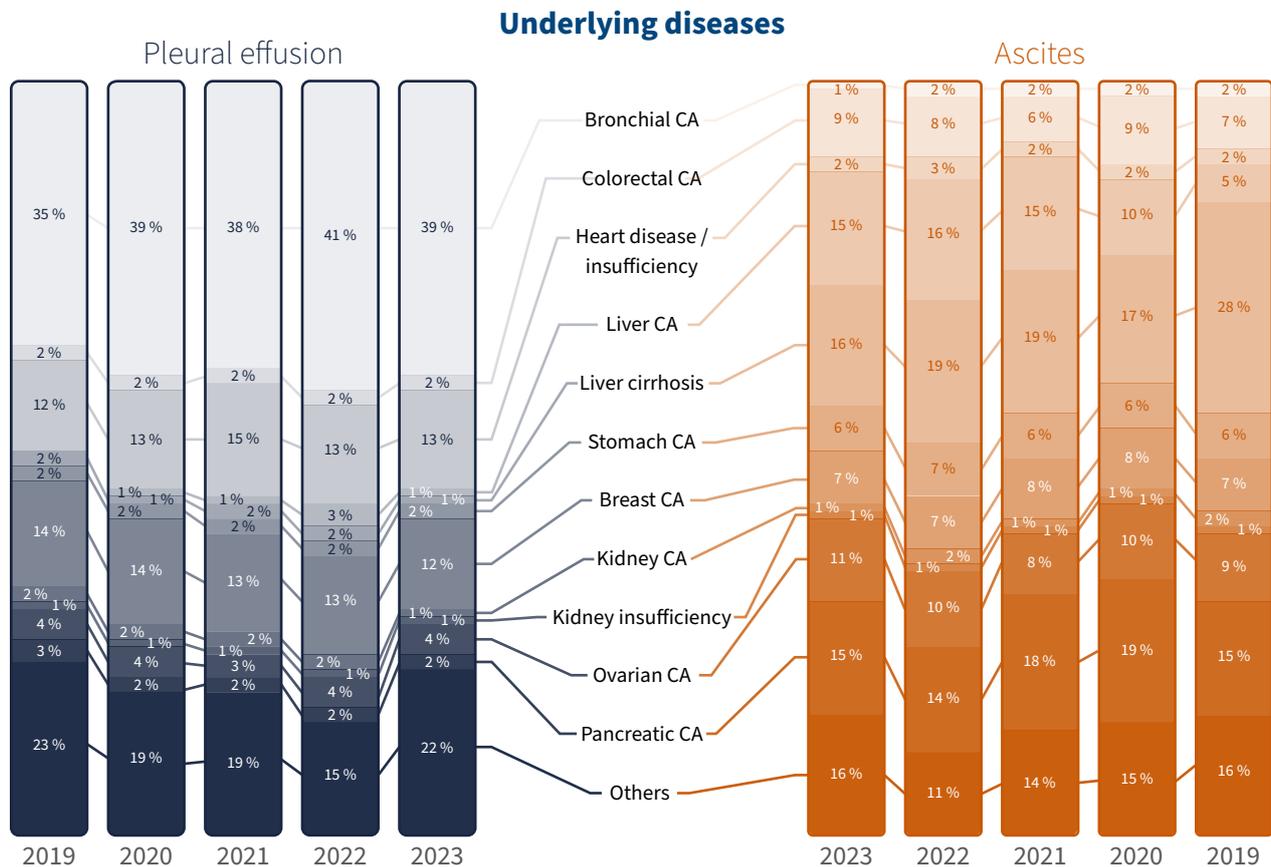


Fig. 3: Underlying diseases



There have only been a few shifts in the underlying diseases over the documented years. With regard to pleural effusion, Bronchial CA has clearly been the leading underlying disease in the last 5 years in the range of 35–41%. It is followed by Breast CA and Heart disease/insufficiency, both in the same 12–15% range.

Turning to the ascites, Liver cirrhosis has fallen from 28% to 16% in the last 5 years but is still the leading underlying disease. This is followed by liver CA with a significant increase from 5% to 15%. Pancreatic CA, which is quite stable at an average of 16% over the last 5 years, is an equally common underlying disease.

The other underlying diseases are in the single-digit range for both causes of the disease. ewimed is continuously working to analyse the “Other” category more closely in order to obtain even better insights.

1.4 Proposing vs. implanting medical specialty

This part of the survey is designed to determine which medical specialty proposes treatment with an IPC and which specialty actually carries out the implantation of an IPC.

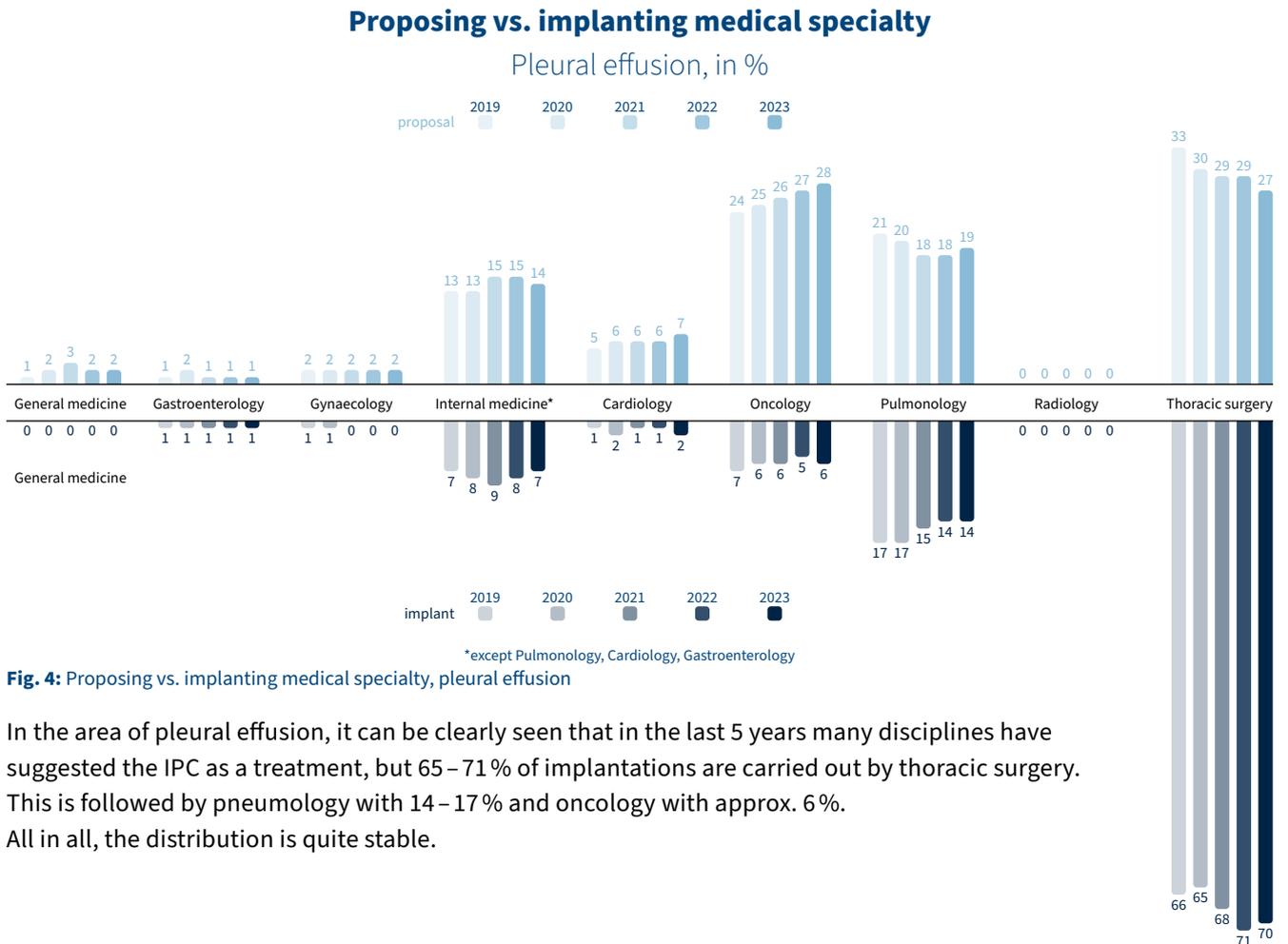


Fig. 4: Proposing vs. implanting medical specialty, pleural effusion

In the area of pleural effusion, it can be clearly seen that in the last 5 years many disciplines have suggested the IPC as a treatment, but 65–71% of implantations are carried out by thoracic surgery. This is followed by pneumology with 14–17% and oncology with approx. 6%. All in all, the distribution is quite stable.



Proposing vs. implanting medical specialty



Fig. 5: Proposing vs. implanting medical specialty, ascites

In the 5-year course of ascites, the leading disciplines for the indication of implantation of an IPC are oncology (37–41%), internal medicine (21–24%) and gastroenterology (17–21%). IPC implantations are mainly distributed among surgery, which has risen from 32% to 45% in the last 5 years, followed by Gastroenterology (19–23%), Internal Medicine (18–20%) and Oncology (12–14%).

1.5 Puncture before IPC Implantation

This section shows the number of punctures performed before implantation of an IPC for both pleural effusion and ascites.

Puncture before IPC Implantation

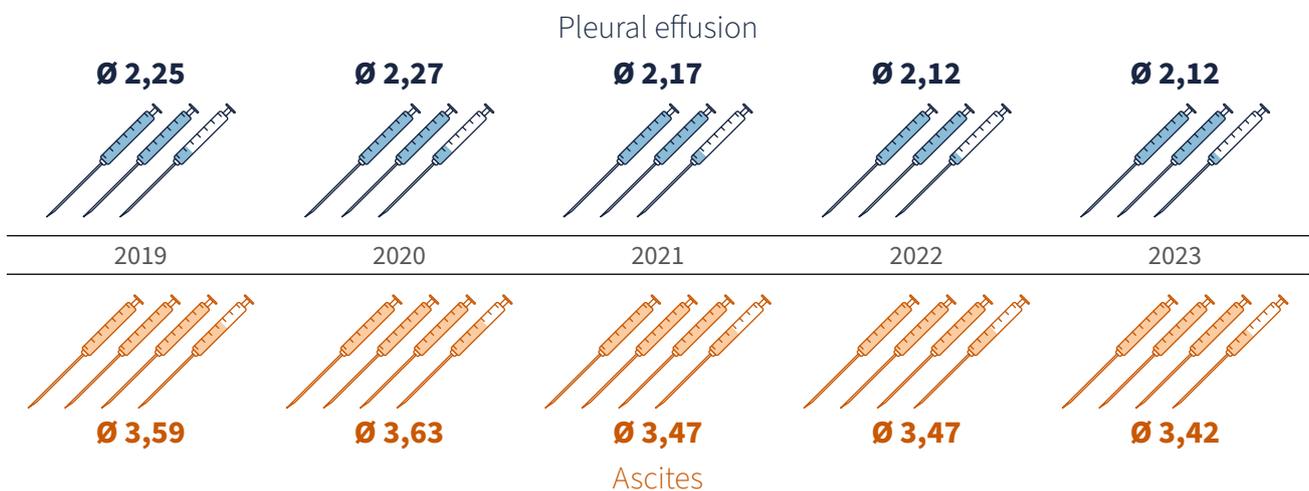


Fig. 6: Puncture before IPC Implantation



A slight decrease in average pre-implantation punctures can be seen in both pleural effusion and ascites. This may be an indication that IPCs are implanted earlier.

1.6 Pleurodesis attempt (only pleural effusion)

Whether medical or surgical (VATS/talc) pleurodesis was used as therapy for pleural effusion before the implantation of an IPC is examined in the last part of the ewimed patient survey analysis. This specifically does not include pleurodesis that can be achieved by daily drainage via the catheter.

In the last 5 years, the proportion of pleurodesis attempts prior to implantation has fallen slightly from 11% to just 9%. This might also be due to the catheters being implanted at an earlier stage, also as first-line treatment.

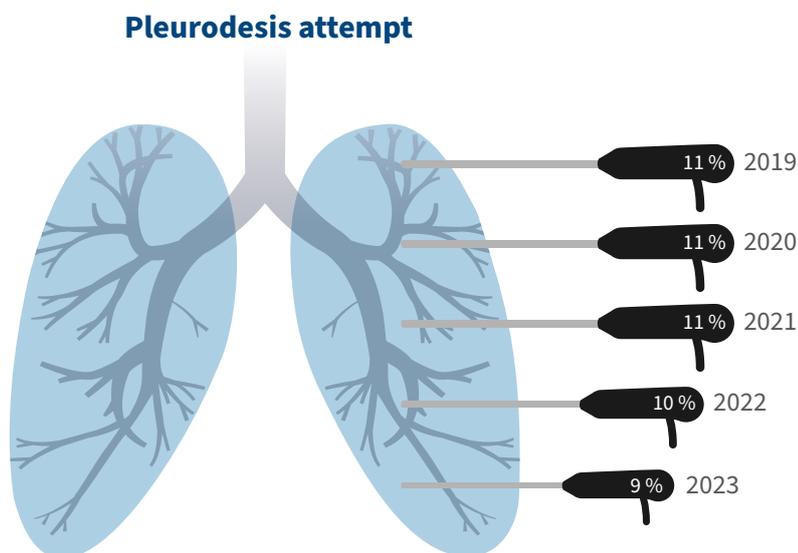


Fig. 7: Pleurodesis attempt



2. Relevant literature 2023

The chapter relevant literature, which forms an integral part of the ewimed report, explores the current status of studies relating to the treatment options for pleural effusion and ascites. Literature searches and analysis of new publications are carried out continuously at ewimed. This year we present two studies published in 2023 that, in our opinion, are very important. One study in the area of pleural effusion and one study in the area of ascites.

2.1 Pleural effusion

Efficacy and Safety of Indwelling Catheter for Malignant Pleural Effusions Related to Timing of Cancer Therapy: A Systematic Review (Porcel et al. 2023)¹

This review – published in Spain in 2023 – compares the efficacy and safety of implanted subcutaneous tunnelled pleural catheters (IPC) in relation to the timing of the systemic cancer therapy (i.e. before, during or after the therapy) in patients with malignant pleural effusion. It examines reviews of randomised controlled trials, quasi-controlled trials, prospective and retrospective cohort studies, and case series of more than 20 patients in which the time of IPC implantation was placed in temporal relation to the initiation of systemic cancer therapy. In the end, a total of 10 studies were included in the review.

Malignant pleural effusion is an indication of advanced disease. Many patients are initially asymptomatic, but later develop symptoms such as dyspnoea. The focus of treatment in this patient group should be minimally invasive therapy with the aim of improving the patients' quality of life.

Porcel et al. state that for a long time, talc pleurodesis was considered the standard treatment. In recent years, the IPC has become established as a treatment option for patients with trapped lungs (non-expandable lungs) or in the case of failed pleurodesis attempts, as well as in patients with re-expandable lungs. According to Porcel et al., one advantage of the IPC is the shorter duration of hospitalisation and a reduction in follow-up pleural procedures. There is also the option of combining the IPC with a talc pleurodesis to induce the pleurodesis.

However, in patients who are undergoing ongoing systemic cancer therapy, the use of an IPC is still viewed as controversial according to Porcel et al. There are different opinions, especially regarding the timing of an implantation. While improved symptom management and quality of life are arguments in favour of early implantation, there is concern about the risks associated with implantation. The risk of infection in immunocompromised patients in particular is often viewed as a contraindication.

The primary tumour in the included studies was usually lung or breast cancer, but there were also mesotheliomas, lymphomas, liver carcinomas, bile duct carcinomas, and ovarian carcinomas. Results on the effect of an IPC on survival, indications for explantation, catheter time in situ, possible reinterventions and catheter related infections were evaluated.

All included studies showed a prolonged lifespan in those patients who received an IPCs during or shortly after systemic cancer therapy. Patients who received chemotherapy before or after catheter implantation had a longer median survival (106 vs. 41 days; $p = 0.004$). In addition, 6-month mortality was lower in patients with both IPC and systemic cancer therapy than in patients without systemic cancer therapy (35% vs. 59%; $p = 0.007$) and (57% vs. 68%) respectively. One study also reported improved quality of life with chemotherapy combined with IPC.



The catheter in situ time varied greatly with the median time being between 28 and 68 days. The most common reason for explantation was the patient's death or a spontaneous pleurodesis. The rate of spontaneous pleurodesis was relatively high at 23–50%. Other reasons, such as infections, were given as the reason for explantation in only 4–7.9% of all cases.

No pleural re-interventions were recorded in any of the included studies. In general, however, there were very few re-interventions.

The overall prevalence of infections varied greatly between studies, which is probably due to the different methods. However, none of the studies found a significant increase in the risk of infection with catheter implantation in connection with the timing of initiation of systemic cancer therapy (despite the presence of neutropenia). Furthermore, one study showed a significant reduction in infections in patients who received home training. In summary, Porcel et al. therefore conclude that the timing of systemic cancer therapy has no effect on the risk of catheter related complications, including infections. This also applies to immunocompromised patients with treatment-induced neutropenia. In relation to palliative treatment plans, the authors advocate that all patients with malignant pleural effusion should be offered early definitive pleural interventions (such as an IPC), regardless of the oncological treatment plan.

2.2 Ascites

Daily Low-Volume Paracentesis and Clinical Complications in Patients With Refractory Ascites: Retrospective cohort study (Tergast et al. 2023)²

In patients with refractory ascites and a contraindication for treatment with a TIPS (transjugular intrahepatic porto-systemic shunt), the standard treatment is often large-volume paracentesis with corresponding albumin substitution. However, this approach is associated with risks such as bleeding or infections. In addition, it is time-consuming for patients and is often poorly accepted by them. Instead of costly, recurring paracenteses and to improve their quality of life, patients can be implanted with a subcutaneous tunnelled peritoneal catheter (IPC).

The aim of this retrospective cohort study published in 2023 was to investigate whether the daily drained volume has an influence on clinical outcome in patients with end-stage liver disease and refractory ascites who perform drainage at home via an IPC or an Alfapump.

A total of 250 patients with refractory ascites were included in the study, 152 patients were treated with an IPC, 27 with an Alfapump and 71 with large-volume paracentesis and the corresponding SoC (standard of care). The patients with implants received training on how to carry out the regular drainages at home and had a follow-up appointment at the clinic one month after the implantation. Regular albumin substitution was not performed in patients with an IPC. However, for new indications such as spontaneous bacterial peritonitis (SBP), acute renal failure or hyponatremia, albumin infusion was possible according to the current guidelines.

The primary endpoints of the study were 90-day incidence of hyponatremia (i.e. serum sodium level less than 130 mmol/L), acute renal failure and severe acute renal failure. The secondary endpoint was 90-day survival without liver transplantation or rehospitalisation within 90 days.

The patients with an IPC or Alfapump were divided into two patient groups: one group in which 1.5 L or more ascites was drained daily and a second group in which less than 1.5 L ascites was drained daily. The outcome of these two



groups was again compared with two matching patient groups who received large-volume paracentesis with SoC in the hospital over the 90 days.

The result of this cohort comparison study is that a higher incidence of hyponatremia or acute renal failure is to be expected with a drainage of $\geq 1.5\text{L/day}$ than with a drainage of less than 1.5L of ascites per day. However, compared to the standard of care of repeated large-volume paracentesis and corresponding albumin infusion, the frequency of complications in the patient group with daily drainage via the catheter of less than 1.5L were not increased.

According to Tergast et al., the treatment must be adjusted or an albumin substitution procedure must be considered in patients with an IPC who perform daily drainage of $\geq 1.5\text{L}$ of ascites.

One suggestion from Tergast et al. is to limit daily drainage to less than 1.5 litres per day and to do an additional large-volume paracentesis via the catheter every few weeks in the context of an outpatient appointment. An albumin infusion should then be administered in association with this LVP.

An alternative approach could be to perform drainage of $\geq 1.5\text{L/d}$ combined with albumin infusions with the support of an outpatient nursing service.



3. Quality of life in patients with IPC

WHO³ defines Quality of Life as an individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns.

The subcutaneous tunnelled pleura peritoneal catheter (IPC) is an effective solution for treating the symptoms of pleural effusion and ascites and has been shown to improve the quality of life of patients.

This chapter is intended to provide a more comprehensive understanding of the effects of the therapy on changes in quality of life. It explores this aspect of IPC therapy in more detail, including studies and two interviews. In the first interview, Univ.-Prof. Dr Clemens Aigner, head of the department of thoracic surgery at Universitätsklinikum/AKH Vienna, assesses the extent to which implantation and symptom management improve quality of life from a medical perspective. The second interview was conducted with a patient in Sweden who has been living with an IPC for almost a year.

3.1 Overview of literature

No explicit studies regarding IPC with a primary focus on their impact on quality of life are available. But there are several studies which have investigated the extent to which quality of life is improved by IPC treatment as a secondary aspect. The results of two studies are presented below.

In the year 2021 Petzold et al.⁴ studied the most severely ill patients with malignant ascites and obtained clear results that an indwelling catheter improved their quality of life despite their short life expectancy. The study showed that an IPC significantly reduces hospitalisations and symptoms, such as dyspnoea. There was no necessity to readmit majority of patients with very short life expectancy (<1 month) to hospital.

In 2023 Peddle-McIntyre et al.⁵ studied the mobility of patients with malignant pleural effusion and IPC. A patient group with daily drainage was compared with a patient group with symptom-guided drainage. The authors suggest that a main goal of treating patients with malignant pleural effusion is to manage symptoms so that patients can participate in normal physical activities of daily life (not exercise but being able to move about and perform light activities). Patients with daily drainage were significantly more mobile than patients with symptom-guided drainage. A quality-of-life questionnaire also showed better results. In general, most patients at this stage of the disease are quite sedentary, so any increased activity represents an improvement in quality of life (coping with their condition).

Guidelines from The National Care Programme for Palliative Care⁶ in Sweden states "Patients with lung cancer report that shortness of breath, along with pain and fatigue, are the most unpleasant symptoms, even when the shortness of breath was not so severe. Factors outside the lung itself can cause shortness of breath, such as pleural effusion and/or ascites. If the patient's shortness of breath is due to pleural effusion, a pleural drainage can facilitate breathing. In ascites, abdominal drainage offer relief".

Palliative care nurse Marie Lidén talks about her personal experiences and reflects on quality of life for patients in advanced home care with IPC. Palliative Care has been her specialty for 15 years.

"There are many advantages. To connect a gravity reservoir or vacuum bottle so easily and get an immediate effect has really made a difference in quality of life for the vast majority of patients. No venous ports, no needle-sticks, no drugs with delayed effects or side effects. No waiting several days for a thora-/paracentesis, when it's already difficult enough to move about or breathe due to large amounts of fluid. For the patient to be able to decide for him-/herself when it's time for drainage before the symptoms are unbearable. The possibility to be active, mobile and flexible again is a huge improvement in quality of life."



3.2 Interview with Univ.-Prof. Dr Clemens Aigner

In July 2023, Univ.-Prof. Dr Clemens Aigner became the head of the University Clinic for Thoracic Surgery at MedUni Vienna and the Vienna General Hospital and he is also a Professor of Thoracic Surgery at MedUni Vienna. Before his current appointment, he was Professor of Thoracic Surgery and Director of the Clinic for Thoracic Surgery at University Hospital Essen – Ruhrland Clinic in Germany and, most recently, since October 2022, Head of the Department of Thoracic Surgery at the Floridsdorf Clinic, Vienna. Prof. Aigner has contributed to more than 200 scientific papers and received numerous awards for his outstanding work and achievements. We had the opportunity to talk to Prof. Aigner about the quality of life in this area from a clinical perspective.



When you think about the patient's quality of life, what aspects are most important to you as a physician?

In fact, the definition of health is fairly comprehensive: physical, mental and social well-being combined with the simultaneous absence of illness. Quality of life is maintained when as many aspects of health as possible are preserved. This also applies to the course of an underlying disease.

Is the quality of life a factor in the decision whether to implant an IPC?

Yes, that's always a factor in the decision. When treating patients with recurrent pleural effusion, in many cases the decision to intervene or perform surgery is not about treating the underlying disease as such, but rather about maintaining or improving quality of life. And so it's a relevant factor which technique is used to treat the patient, how the patient is limited by it and how his or her everyday life is affected by hospital stays. Of course, quality of life is a highly relevant point in the decision on whether to implant an IPC or not.

In addition to the palliative situation of the patient, are there any other indications for which IPC therapy makes sense?

Of course, there are also situations where IPC therapy forms part of a curative treatment regimen. If, for example, a patient develops a pleural effusion due to an underlying disease, where it is possible to curatively treat this underlying disease with surgery and the catheter is implanted

in the neoadjuvant therapy phase. Here, too, it is partly a question of quality of life but above all of obtaining the best possible starting point for the subsequent surgery.

What are the advantages of implanting an IPC compared to other treatment methods, in relation to the quality of life of the patients?

There are several advantages. It can be used comprehensively in every situation with pleural effusion, regardless of whether the lung can still expand or not, even in the case of a trapped lung. It is a therapeutic procedure that, in contrast to talc pleurodesis, does not lead to any immediate and expected severe interpleural scarring. This means that it is also highly suitable for bilateral effusions. It is a therapeutic procedure that is safe and has few complications. It can also be potentially offered entirely on an outpatient basis, so it does not necessarily require an inpatient stay. Of course, there are situations when it is all implanted under video thoracoscopy because diagnostics are required or other accompanying measures are required, in which case an inpatient stay is of course required.

Do you also see an advantage for your team and for you as a physician? Does this approach save hospital resources?

Of course, catheter implantation has its advantages, but there are also other therapeutic procedures for recurrent effusions that need to be compared to it. This is the relevant aspect for us (from a surgical perspective). Conserving



hospital resources is of course important, but it's really more a question of providing the best possible care for patients than of cost aspects.

To what extent does the implantation of an IPC improve the quality of life of patients?

Basically, the treatment of chronic effusion is a good way to relieve dyspnoea. This is the primary goal of the therapy from a medical perspective. And because the implantation can be carried out in an outpatient setting and the drainage can be carried out at home, the duration and frequency of hospitalisation is of course minimised. This improves key aspects of quality of life from a physical, psychological and social perspective and this is the objective of catheter implantation.

As a physician, do you get the opportunity to assess the patient's quality of life even after the implantation?

In our clinical routine it is rather unusual that we would follow-up patients because that would simply exceed our capacities.

There are indeed a number of different standardised surveys to assess quality of life, for example from the EORTC and QLQ-C 30.

However, such direct feedback happens relatively rarely in the clinical routine of thoracic surgeons. This is more something that is done in studies.

Published studies do show that the catheter definitely improves the quality of life of patients. In daily clinical routine, the most important symptom that we look at is dyspnoea. This is probably the most relevant thing for patients; everything else is a consequence of the improvement in dyspnoea.

In addition, the frequency of hospitalisation is lower and patients can spend more time at home.

There are currently plans to reform outpatient care in Germany. What is your opinion on this? Is IPC therapy part of this? What are the pros and cons for patients?

IPC therapy absolutely contributes to outpatientisation and of course it is something that is beneficial and its wide acceptance is ultimately inevitable. If you compare the European healthcare systems, you can see that in Scandinavia historically a lot of outpatient care has been offered, while in Germany and Austria the bed density compared to the population is relatively high. Accordingly, the expectation of patients and sometimes also

physicians is that certain things should be done in an inpatient setting, whereas in reality this is simply not necessary. Also, with the shortage of trained medical personnel, which is actually spreading throughout Europe, it will be impossible to avoid cutting back on certain things and instead we will have to do much as possible on an outpatient basis. And the catheters are absolutely essential for treating these patients in an outpatient setting.

Do you think that enough scientific research has been done on quality of life in relation to IPC therapy? Should more research be done? Would it support the therapy if there were more scientific data?

In principle, the more data, the better. The question is in what form it is presented. Quality of life is of course a relevant point, but I'm not sure whether it would do anything to change the basic indications for the various procedures. In principle, the different dimensions of quality of life can certainly be explored in more detail. But I don't think that the most urgent issue is to set up large prospective studies focused on quality of life. Ultimately, it's always a decision that is made in consultation with the patient. "Shared decision making" is very important in this regard. The question is always which procedures are actually appropriate for the respective patient and which form of treatment the individual patient prefers. Quality of life is certainly one variable that plays a role in this consideration.

You are a professor at the MedUni in Vienna. Are young doctors already familiar with the topic of IPC or do they first encounter it in the course of their medical activities?

Definitely in the field of thoracic surgery, everyone knows about IPC. It's also known to the same extent in other specialties, such as pulmonology and in the field of ascites treatment, in abdominal surgery and gastroenterology. And knowledge of IPCs is also increasingly imparted during their training. Since it is a therapeutic procedure that is also used on a routine basis and, fortunately, it is technically so straightforward that young junior doctors can perform it easily.

We would like to warmly thank Univ.-Prof. Dr Aigner for his willingness to do this interview.



3.3 Case report

To demonstrate the improvement in quality of life, we present the following case report featuring a Swedish patient who has been living with an IPC for almost a year. It provides insight into life with a catheter. After implantation, the patient's life has changed significantly, which he says has led to an enormous improvement in his quality of life.

Introduction – The patient's situation

Lars Johansson had an IPC implanted in May 2023. He and his wife Anita have been performing the drainage at home ever since. He now wants to share his experience of how his quality of life has improved and the general benefits that come with IPC therapy. So that more people take this decision earlier.

The patient who is 76 years old has a big family and has always been active with many hobbies such as a football coach for kids. He and his wife have a caravan and travelling around the country with it is a very important part of their life.

Diagnosis

In 2020, the patient was diagnosed with liver cirrhosis due to alcohol consumption and an associated ascites, after which he was treated with diuretics. The patient also has various comorbidities such as cardiac insufficiency, which did not make his situation any easier.

Symptoms, first therapy and shared decision making

Between 2020 and 2023, the patient needed to drain ascites every 4-5 weeks. This meant going to the hospital and undergoing what he describes as the "painful paracentesis procedure". By 2023 the interval between punctures was reduced to every 2 weeks. The patient found it difficult to breathe, was not able to move around and had no energy. He lost his appetite and the swelling in his legs caused big problems. Everyday life became very difficult.

"It was toughest in the days just before drainage" he says, "and it was a big relief to get it done despite the painful procedure." He found the subcutaneous injection of an anaesthetic prior to the paracentesis itself to be the most painful part. The first time an attending gastroenterologist mentioned the option of getting an IPC implanted was at a paracentesis treatment in February 2023. The gastroenterologist observed how the repeated procedures affected him, and the negative impact the worsening symptoms had on the patient's quality of life.

The catheter sounded like a good solution, however the patient and his wife had some reservations and there was a fear of losing regular contact with the attending physicians and the hospital. A supporting factor for the decision was their daughter-in-law, who was familiar with the system from her experience of working with lung patients. She was positive about the IPC therapy since she had seen the clear benefits of it.

Implantation and adjustment period

The patient made his decision, and he was scheduled to get the catheter implanted in May 2023.

"The procedure was nothing strange, it felt safe and by this stage you are used to it", Lars Johansson.

A few days after the implantation, an instruction nurse of ewimed visited the patient and his wife at home for the drainage training and they drained 2 litres of fluid together. The target was to drain a maximum of 2000 ml 3 times a week. The severity of ascites decreased and by the end of October his prescription was changed to drainage every 3 days.

In connection with this year's ewimed report quality of life assessment, an ewimed employee visited the patient in December 2023. The patient and his wife were able to drain 1800 ml within 10 to 15 minutes and the whole procedure was finished in less than 30 minutes.



Benefits of the implanted catheter

The patient's initial symptoms improved over time and together with his wife they have the flexibility to travel with their caravan throughout the summer and autumn. They are able to maintain regular contact with the hospital as well.

"The immediate benefits are of course - no need for hospital visits, less fluid per drainage, and continuous symptom relief. Getting the catheter implanted was a very good decision" – Lars Johansson.

The patient and his wife find the drainage system easy to use and his wife is reassured to see the improvement in her husband's symptoms. "He is more independent and feels better" she says.

Conclusion

"You should take the decision without reservations if it suits you! You can be at home in peace and spend time with family instead of being at the hospital," the patient says. The benefits far outweigh any drawbacks, and they would have made the decision earlier if they had heard other patient stories.

This chapter demonstrates the effectiveness of an IPC in alleviating patients' symptoms and improving their quality of life. In conclusion, IPC is beneficial for patients with recurrent pleural effusion or ascites.

"You can be at home in peace and spend time with family instead of being at the hospital"

– Lars Johansson –





4. IPC during ongoing chemotherapy

Many patients develop pleural effusion or ascites during the course of an oncological disease. Therapy for oncological patients is complex and requires good interdisciplinary cooperation. As can be seen in the first section of the ewimed patient survey, the indication for the implantation of a tunnelled pleural or peritoneal catheter (IPC) is often determined by oncology. However, uncertainties continue to arise as to when a tunnelled catheter can be considered as an alternative treatment. Concern about infections and complications is still widespread, especially with immunocompromised patients. This section aims to help refute these uncertainties and show that an IPC can also be implanted while chemotherapy is ongoing.

4.1 Overview of literature

Many studies have dealt with this topic in recent years. In the following section we would like to offer a brief overview of some interesting research findings from recent years.

Wilshire et al.⁷ (2021) examined the association between the use of an implanted subcutaneous tunnelled pleural catheter (IPC) and infections in 1,318 patients with malignant pleural effusion in an international multi-centre study in patients with immunosuppression due to chemotherapy. Of the patients included, 828 (63%) were receiving chemotherapy and 157 (12%) were immunocompromised (76 (6%) with moderate neutropenia, 81 (6%) with severe neutropenia). Only 7% developed a catheter-associated infection during the course of treatment. The frequency of infections did not differ between patients with moderate or severe neutropenia and, in 72% of the patients, the IPC could remain in situ despite the infection. These findings are supported by a review by Porcel et al.¹ (2023). None of the studies included in this review found a significant increase in the risk of infection with IPC implantation associated with the timing of the systemic oncological therapy. There was also a high rate of spontaneous pleurodesis (from 23% to up to 50%), which could lead to the removal of the catheter. There was also a trend to improved quality of life.

Similar findings can also be found in the literature regarding patients with malignant ascites.

A large 2015 study by Wong et al.⁸ examined the safety and effectiveness of IPC as an alternative to repeated large-volume paracentesis in 386 patients. Surgery was performed in 42% of the patients and one or more adjuvant therapies, such as chemotherapy, radiotherapy or hormone therapy, were administered in 82% of them. 54% of the patients had a tunnelled peritoneal catheter implanted in an outpatient setting and in 49% of patients this was without prior therapeutic paracentesis. Within 12 weeks, 255 patients (66%) had died. The median time that the IPC remained in situ was 31 days and in 4.05% of patients the catheter could be explanted again because ascites no longer formed. In 305 patients the catheter remained in situ until death. Very few complications were reported and these could largely be treated without explantation. Lungren et al.⁹ (2013) also found no significant differences in complication rates in the context of ongoing, adequate cancer therapy for malignant ascites.

All of these research results suggest that the IPC is an appropriate therapeutic option for the relief of malignant effusions, even in immunosuppressed patients with planned or ongoing chemotherapy, and planned or ongoing chemotherapy or radiotherapy is not a contraindication for IPC implantation. The risk of infection is not increased in this patient group either. In addition, the implantation of an IPC and the associated individual drainage of the effusion in the home setting can relieve a burden for patients and increase their quality of life.

Following on from this literature, we would also like to give you an insight into practice. In the next section we present an interview with the oncologist Dr Yannick Buccella who talks about his experience with IPC during chemotherapy.



4.2 Interview with Dr. Yannick Buccella

Dr Yannick Buccella studied medicine at the University of Duisburg/Essen and Ulm, among others between 2011 and 2017. During his time as a junior doctor, he worked in various areas of oncology and palliative medicine and since 2022 has been a senior physician at the Clinic for Medical Oncology and Haematology at Stadtspital Zurich, Switzerland.



What burdensome symptoms associated with oncological diseases do you often encounter in your practice?

I work primarily in gastrointestinal oncology. Consequently, the most common symptoms I encounter are cachexia, nausea, vomiting, or ascites in peritoneal cancer. The ascites in turn is conducive to a variety of massive symptoms, such as constipation, nausea, pain, etc.

Which patients do you consider for treatment with an IPC?

I consider an IPC in patients in whom rapid accumulation (≤ 1 month) of ascites recurs after a standardised first puncture. Especially in pancreatic carcinoma, cholangio carcinoma and peritoneal carcinoma, effusion almost always recurs over time, which is why a permanent solution is recommended in such cases.

An exceptional case in terms of ascites is ovarian cancer. In treatment-naïve ovarian cancer patients, chemotherapy often has a very quick effect and therefore, in my opinion, it is advisable to wait a bit with the IPC and punctures in general. Intervention is often unnecessary because the ascites resolves itself after just 1–2 chemotherapy treatments. For more severe cases and in second-line treatments, IPC is of course also an option.

As an oncologist, at what stage do you first think about IPC as a treatment option? At what point do you discuss this option with your patients and how do you then proceed at your hospital?

We now have an established practice in our hospital. We start with an initial puncture and then see when the next puncture would be necessary.

For intervals of less than a month, the sooner the better as far as I am concerned. Then I actively recommend the catheter to the patient, also using the patient information brochure from ewimed. If the patients agree, I then refer

them to the gastroenterologists for the implantation. In our hospital, we have a very constructive collaboration with gastroenterology, as they also consider the IPC to be a good alternative and are happy when patients are referred to them at an early stage.

At Stadtspital Triemli, the patients undergoing an implantation for ascites are admitted as inpatients for an overnight stay, in our branch Affoltern it is also possible as outpatient procedure. Both are possible and it is a question of philosophy and the condition of the patient.

Are there concerns from patients with pleural effusion or ascites who also have ongoing chemotherapy when you recommend implanting an IPC?

Patients receiving intensive chemotherapy that involves long-term immunosuppression sometimes express concerns about the infection risk. However, I have to say that these patients often have a large number of indwelling catheters (in some cases also a catheter port). Notwithstanding this, infections occur quite rarely. Of course, the risk associated with indwelling catheters cannot be ignored, but single punctures also lead to an increased risk of infections, bleeding and injuries to internal organs as a result of repeated invasive interventions. In my opinion the risk of infection is low. I have also rarely encountered spontaneous bacterial peritonitis in my work, which is the biggest concern.

In fact, a more common concern among patients is the issue of their own body image and the implantation of a foreign object. There are patients who therefore decide against an indwelling catheter despite the indication. However, I have yet to experience a patient who regretted the insert afterwards. Especially because it gives patients a lot of freedom and independence and they don't have to constantly go back to hospital for punctures.

**What is your experience with IPCs during to chemotherapy, what advantages does this procedure offer?**

My practical experience with IPCs during ongoing chemotherapy has been consistently positive.

Patients often do not report ascites until it is already causing a lot of distress and there is a lot of effusion. The desire for permanent relief or a long-term solution is already there. And of course the IPC is ideal for this.

In addition, patients undergoing chemotherapy often have thrombocytopenia and a resultant risk of bleeding. Many are also anticoagulated regardless of the chemotherapy. If repeated punctures are performed, coagulation must always be checked. This is where the IPC offers a clear advantage.

What advantages does treatment with an IPC offer compared to other therapeutic methods?

The benefits differ for pleural effusions and for ascites. For pleural effusion pleurodesis is a good alternative to a catheter. There are few satisfactory alternatives for ascites. Medication-based approaches in particular are mostly not very promising. On the other hand, the big disadvantage of repeated large-volume paracentesis is that invasive surgery is always necessary. As mentioned, this always carries with it a risk of infection, a risk of bleeding and a potential risk of injury to the abdomen. Also with punctures, it is frequently not possible to drain the entire effusion at once. Regular drainage with an indwelling catheter enables drainage adapted to the specific situation and is less stressful for the patient.

The IPC also offers patients a certain degree of flexibility, as the drainage can be done at home, with the help of a relative, for example.

All in all, the IPC is effective, safe and increases patient comfort.

What is your procedure in patients with indwelling catheters when the chemotherapy is successful?

In gastrointestinal oncology, it is rare for symptomatic peritoneal carcinoma for therapy to be completely successful. These patients usually have to live with the ascites over time because the tumour is already well advanced by the time the ascites develops. However, if it is successful, for example, if ascites occurs in treatment-naive patients, then the catheter can be explanted easily and without any problems. And in my opinion, this is also what should be done.

How do you see the future of this treatment method in oncology?

I think it is a very individual decision. In patients with a slower disease progression or if a very prompt response to systemic oncological therapy is to be expected, it may be possible to wait a bit before implantation while monitoring the progression.

However, in patients who already have an unfavourable prognosis, such as pancreatic CA, bile duct CA and peritoneal carcinoma, for example colon carcinoma, it may well be worth considering not doing punctures and implanting a catheter directly, possibly even without previous punctures. Especially with the above tumours, the remaining life time for patients is often short and the priority is to make the patient as comfortable as possible. Every day without ascites is valuable for the patient.

Many thanks to Dr. Buccella for agreeing to do this interview.





5. Outlook – Healthcare markets

The healthcare system in its entirety plays a very important role. Here you can read short reports about the current state of the healthcare market in the individual countries and how this is likely to change in the next few years.

5.1 Germany

The German healthcare market has many more hospitals compared to other countries such as Denmark. Nevertheless, Denmark does not perform worse in a comparison of healthcare systems (e.g. higher life expectancy in Denmark, lower infant mortality in Denmark). The pressure on the German hospital system is great. The high density of hospital beds leads to high costs and a strain on staff. The Ministry of Health is planning a hospital reform to tackle these problems, among others.

In addition, many procedures in German hospitals are carried out on an inpatient basis, even though they could be performed on an outpatient basis. This places a burden on patients and hospital staff and leads to high costs for health insurance companies. Here too, the Ministry of Health is planning to shift more inpatient operations to the outpatient sector.

Due to the federal structure in Germany, such legislative projects take a long time. It remains to be seen how much of the plans can be implemented and in what time frame.

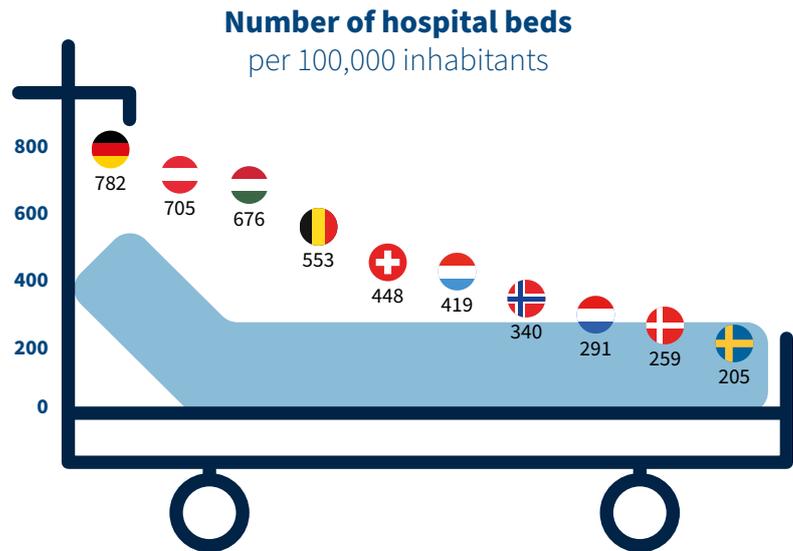


Fig. 8: Number of hospital beds

5.2 Austria

The Austrian healthcare market looks very similar to the German healthcare market.

Due to the severe shortage of medical personnel, individual departments are being merged and even entire departments are being closed. To counteract this personnel shortage and make the healthcare market more attractive again, remuneration in this sector has been increased.

The healthcare reform, which has been in effect since 1 January 2024, aims to guarantee long-term, effective and efficient care for all patients. However, funding for this must be guaranteed. The so-called financial equalisation is intended to govern the distribution of tax revenue between the central government, the federal states and municipalities. By 2028, the Austrian federal government is projected to invest an additional EUR 2 billion annually in healthcare and nursing. The “Scandinavian model” is also to be introduced. This means that patients first go to their primary care physician and are then referred to a hospital. Work is also planned to expand day clinics so that, for example, an implantation can be carried out in the morning and the patient is able to go home again at lunchtime.

There should also be easier approval for group practices and outpatient clinics.



5.3 Switzerland

A lot has also happened in Switzerland in recent years.

The “Electronic Patient Dossier” has been gradually introduced in Switzerland since March 2020. The aim of the EPD is to strengthen the quality of medical treatment, increase patient safety and increase the efficiency of the healthcare system. Service providers are obliged to use this.

Since November 2021, the Swiss federal government and the cantons have been obliged to recognise and promote nursing as an important part of healthcare. Measures to achieve this include the federal government contributing to the training costs until at least 2027 and nursing staff being given more responsibility.

In 2025 there will also be changes in the billing rates for doctors in private practice and billing for outpatient procedures. The change from the “Tarmed” to the “Tardoc” system is intended to improve the standing of primary care physicians relative to specialists and also to take into account improved methods and treatments that are no longer as complex as they used to be.

In December 2019, the Federal Council adopted the “Health 2030” vision for Switzerland. The strategy is intended to set new priorities in health policy. By defining 4 challenges, 8 objectives and 16 lines of action, a health policy framework for action is created within which all players must orient themselves.

“People in Switzerland live in an environment that is conducive to health, regardless of their state of health and socioeconomic status. They benefit from a modern, high-quality and financially viable healthcare system.”

5.4 Sweden

The Swedish healthcare market is currently in a dynamic state, characterised by ongoing developments in healthcare, digital innovations and the desire to ensure high quality services for the population.

One of these changes is “Good and Close Care”. This concept is based on patient-centred care and a close care approach. The aim is to provide high quality, compassionate and individually tailored care that focuses on patient needs and preferences. “Good and Close Care” has been implemented in Sweden for several years and has proven to be successful. Additionally, patient safety has become a key issue. For this purpose, the “National Board of Health and Welfare” has developed a national action plan for greater patient safety. It was published at the beginning of 2020 and contains guidelines and measures for the period up to 2024.

Furthermore, some projects are investigating the extent to which artificial intelligence can help in healthcare.

In summary, it can be said that the shortage of specialist workers is a cross-border problem. Some countries are looking at different approaches to solving this problem. It remains to be seen in the future which approach is most suitable for solving this fundamental problem. Further challenges for the future are the financial situation and digital solutions.

If you are interested in participating in the ewimed Report 2025 or contributing topics, please contact us. The aim is to write the ewimed report annually in close contact with the healthcare system, physicians and other medical professionals.



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