Clinical Study

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# Initial Experience with Healthport miniMax® and Other Peripheral Arm Ports in Patients with Advanced Gastrointestinal Malignancy

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**Key Words**
Peripheral ports · Port infection · Catheter-related thrombosis · Color-coded duplex sonography · Gastrointestinal malignancy

**Abstract**
While central ports are located at the chest, peripheral ports (PP) are inserted at the patients' forearms. Two new PPs (Healthport miniMax® and Bard Titan Low Profile Port) and two well-established types (Port-A-Cath® P.A.S. Port and PeriPort™ peripheral access system) were tested. 125 patients were given the choice between PP and chest ports, and 100 of them chose PP. PP were inserted in patients suffering from gastrointestinal malignancies (n = 95), AIDS (n = 3) or Crohn's disease (n = 2). The first 30 patients were prospectively monitored by repeated color-coded duplex sonography examinations in order to evaluate clinically inapparent thromboses. Easy percutaneous needle puncture as early as 1 day after surgery was possible using innovative ports with large septa. The following complications arose during 12,688 catheter placement days: difficult implantation (n = 5), intolerable pain at the insertion site (n = 1), port erosion of the skin (n = 1), catheter leaks (n = 4), disconnection of the catheter from the port (n = 1), systemic infections (n = 4), local infections (n = 6) and symptomatic deep vein thrombosis (n = 8) despite anticoagulation in 1 of these. Only systemic infections and intolerable pain resulted in PP explantation (n = 5); other complications were easily dealt with. No serious or life-threatening complications occurred.



## Introduction

Central venous access devices are needed for repeated access to the venous system in seriously ill patients. In the United States more than half a million were inserted in 1994 [1]. Central venous catheters were first described by Aubaniac [2]. Niederhuber and colleagues [3] implanted port systems subcutaneously for chemotherapy to replace external catheters. These devices consist of a port with a self-sealing septum, accessible by percutaneous needle puncture, and a catheter for the parenteral delivery of

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**Table 1.** Advantages and disadvantages of peripheral ports as compared to chest ports

| Advantages | Disadvantages |
|---|---|
| Fewer serious complications (hemothorax, pneumothorax, chylothorax, nerve injury, subclavian artery injury) | Higher thrombosis rate |
| | Higher rate of phlebitis |
| Easier insertion of the systems | |
| Cosmesis | |
| Comfortable access by rolling up sleeve | |
| Cost saving | |
| Simple monitoring of thromboses by Doppler ultrasound | |

**Table 2.** Patients suffering from gastrointestinal malignancies

| Tumor localization | Number of patients |
|---|---|
| Pancreas | 40 |
| Stomach | 11 |
| Bile ducts | 13 |
| Colorectal | 8 |
| Esophagus | 6 |
| Other | 17 |

**Table 3.** PP implanted

| PP | Number |
|---|---|
| Healthport miniMax | 76 |
| Port-A-Cath P.A.S. Port | 22 |
| PeriPort peripheral access system | 1 |
| Bard Titan Low Profile Port | 1 |

medications, fluids and nutritional solutions. Implantation of chest ports can sometimes be very difficult and time-consuming because of anatomic irregularities of the subclavian veins. Venous access devices for peripheral placement in the arm, peripheral ports (PP), have therefore been developed. Implantation of such devices is easier and generally quicker. Operating room facilities are not necessary. Final x-ray control of the tip position is required. Arguments against such PPs are presumed higher rates of thromboses and a possible handicap for patients. The risk of local and systemic infections is supposed to be the same as with chest ports.

The present study was undertaken to evaluate the advantages and complications of different PPs, two of which have recently been developed (Healthport miniMax® and Bard Titan Low Profile Port). The main advantage of the recent PPs are the larger septa as compared to the older ones. The main objectives were to investigate the incidence of catheter-related thrombosis and infection, patient compliance, and acceptance by the medical staff.

## Patients, Material and Methods

Patients (n = 125) with indications for repeated venous access were offered a choice between PPs and conventional central chest ports after detailed information about the advantages and disadvantages of PP (table 1). One hundred patients (80%) opted for a PP mostly because of better cosmetic results and smaller surgical trauma. These represent the study population of this communication. Ninety-five of the patients suffered from gastrointestinal malignancies (62 males, 33 females; table 2), 3 from AIDS (2 female, 1 male) and 2 from Crohn's disease. They received PPs for chemotherapy, parenteral nutrition and analgesia. The mean age was 62 years (range 22–87). PPs were not implanted in the presence of known or suspected infection or in patients with unsuitable veins. No patient was denied a chest or arm port due to local factors such as skin condition or radiation.

Four different systems were evaluated: the innovative Healthport miniMax® (November 1995; Baxter Deutschland, Unterschleissheim, Germany), the Port-A-Cath® P.A.S. Port (SIMS Deltec, St. Paul, Mo., USA), the PeriPort™ peripheral access system (Strato/Infusaid, Pfizer Hospital Products Group, Norwood, Mass., USA) and the innovative Bard Titan Low Profile Port (March 1997; Bard, Karlsruhe, Germany; table 3). All ports were single-lumen. Ports were implanted according to the availability from hospital stocks without any particular selection or random assignment of particular types of PP. The Healthport miniMax® is a newly developed system designed according to the authors' own clinical needs. Deltec CathFinder™ catheter/sensor assembly to facilitate catheter positioning was not used since x-ray seemed to be more reliable.

Ports of the Healthport miniMax®, the Port-A-Cath® P.A.S. Port and the Bard Low Profile Port are made of titanium. The PeriPort™ peripheral access system is made of polysulfone. Radiopaque polyurethane catheters of all four systems were similarly introduced by the Seldinger technique. All catheters have markings with 5-cm increments to facilitate their positioning. Data on the ports and catheters tested are summarized in table 4.

Before implantation the patient's arm was placed in an abducted, externally rotated position. The arm vein was localized for the puncture by painstaking palpation. The puncture site was prepared using a standard surgical technique. The insertion site was anesthetized. The catheter reaches the central venous circulation via the basilic

**Table 4.** Data of ports and catheters tested in the present study

| | Ports | | | Catheters (polyurethane) | | |
|---|---|---|---|---|---|---|
| | septum diameter mm | height mm | weight g | inside diameter mm | outside diameter mm | length cm |
| Healthport miniMax | 9.0 | 9.5 | 5.0 | 1.1 | 2.1 | 78 |
| Port-A-Cath P.A.S. Port | 6.6 | 10.0 | 5.6 | 1 | 1.9 | 76 |
| PeriPort peripheral access system | 5.7 | 10.2 | 1.3 | 1 | 1.7 | 76 |
| Bard Titan Low Profile Port | 9.0 | 9.4 | 7.7 | 1 | 2.1 | 76 |

(n = 83) or cephalic vein (n = 17) after vein puncture by introducer needle (Venflon® 2 i.v. cannula, 17 gauge, 45 mm; Ohmeda, Erlangen, Germany) at the forearm (58 right side, 42 left side), insertion of the guidewire (PLAN 1 HEALTH, Casiacco, Italy) and dilatation of the catheter track. Correct positioning of the catheter tip at the junction of the superior vena cava and right atrium was verified by fluoroscopy. The catheter was flushed with heparinized saline (2,500 IU heparin in 5 ml of saline) and clamped close to the end. Then it was tunneled from the insertion site to the port pocket. After cutting the catheter to the required length it was attached to the port by a connector. The port was placed in an offset position adjacent to the vein entry site in the inner forearm area. After preparation of a subcutaneous pocket the port was sutured to the underlying muscle fascia using resorbable sutures (Ethilon 3/0, vicryl suture; Ethicon Norderstedt, Germany) as is recommended by the manufacturer. Finally, the system was flushed again with heparinized saline before the port pocket was closed (Ethilon 3/0, polyamide suture; Ethicon).

Each access to the ports was obtained using aseptic techniques. The port septum was located by palpation and the skin punctured directly over the septum. The needles (winged infusion set, 0.5 inch, 20 gauge, Arrow International, Walpole, Mass., USA) were advanced slowly through the septum until they made contact with the bottom of the port. Finally, injections were given, blood was drawn or infusion initiated. After each injection or infusion a heparin lock was established by flushing the PPs with heparinized saline, i.e. 2,500 IU of heparin in 5 ml of saline. A prospective study was performed involving the first 30 patients (mean age 59 years, range 38–81, 18 men) in order to evaluate small, asymptomatic thromboses by repeated color-coded duplex sonography examinations. In 21 of these patients PPs were implanted in the right forearm, in 9 in the left one. In 23 of them catheters were inserted via the basilic vein, in 7 via the cephalic vein. The prospective study was stopped after the first 30 patients because of the low incidence of symptomatic thromboses and patients' annoyance by time-consuming color-coded duplex sonography examination. Low molecular weight heparin (dalteparin sodium 5,000 IU s.c. once daily) was indefinitely given to the last 52 patients of the study population.

## Results

PPs were in place from 0 to 597 days (mean 90 days) resulting in a total of 12,688 catheter placement days. Introduction of the catheters was very difficult in 5 patients and impossible in 4, because Seldinger wires could not be pushed forward in the punctured veins. In the latter patients PPs had to be implanted on the contralateral side. All wounds healed without complications.

One PP had to be explanted 1 week after implantation because of intolerable pain at the site of port fixation. Four PPs had to be removed because of systemic infections. One port (P.A.S. port) erosion through skin was successfully treated by reimplantation next to the first chamber. Two other PPs were removed because of treatment cessation or at the patient's request. Seventy patients died of progression of their disease without removal of the system, the other systems are still in use.

Catheter leaks near the ports were diagnosed 1–9 weeks postoperatively in 4 patients. It was possible to cut the catheters proximal to the damage and reconnect them to the ports in all cases. Microscopic analysis of removed catheter particles showed that intraoperative manipulation by instruments with teeth or sharp edges was responsible for the leaks. The catheter disconnected from the port in one case (P.A.S. port). Reattachment was easily achieved with standard surgical techniques.

Patients did not report postoperative pain or PP-induced handicaps in everyday use. Percutaneous needle puncture was easy in ports with large septa such as the Healthport miniMax® and Bard Titan Low Profile Port. They can be well located by palpation. On the other hand, it was nearly impossible to puncture the smaller septa of the other PPs immediately because of postoperative wound hematoma and swelling at the implant side. In 4 patients (2 patients with AIDS) PPs had to be explanted

**Table 5.** Symptomatic thromboses induced by PP (n = 100)

| Veins | Implanted PP | Thromboses |
|---|---|---|
| Cephalic | 17 | 4 (24) |
| Basilic | 83 | 4 (5) |

Figures in parenthese represent percentage.

because of systemic infection 21, 30, 55 and 96 days after port implantation. The incidence of systemic infection was 0.315/1,000 catheter placement days. *Klebsiella pneumoniae* was isolated from the blood of 1 female patient suffering from duodenal cancer. In 2 patients suffering from AIDS no bacteria could be grown from the catheters extracted. The PP of the 4th patient was explanted in another hospital. The pathogenic agent is not known. Minor temporary local infections were observed in 6 patients. These were treated by local antiseptics combined with oral antibiotics. One patient had local thrombophlebitis. He daily received 1 × 5,000 IU of Calciparine s.c. Thrombosis was found in 15 of the first 30 patients monitored by weekly color duplex sonography examinations, predominantly 0–3 days after insertion (5 × subclavian vein, 1 × brachial vein, 3 × basilic vein, 2 × axillary vein, 4 × fibrin sleeves). The incidence of thrombosis was higher after insertion into the cephalic vein (6 of 7) as compared to the basilic vein (9 of 23; $p < 0.05$). Five patients were symptomatic (2 × thromboses of the subclavian vein, 1 × of the brachial vein, 2 × of the axillary vein) with swelling of the arm, cyanosis or pain; the remaining 10 patients were asymptomatic. Symptomatic deep vein thrombosis of the upper extremity (5 on the right side) was diagnosed in 8 of the 100 (8%) patients in the entire study population (table 5) from 2 to 90 days after PP implantation. Therefore, the incidence of clinically manifest thrombosis was 0.7/1,000 catheter placement days. Four of the thromboses occurred after implantation of the Healthport miniMax® (5.3%) and 4 in patients with the Port-A-Cath® P.A.S. Port (18.2%). Fifty-two patients were on prophylactic anticoagulants, and one of them developed deep vein thrombosis; 48 patients were not on anticoagulant therapy, and 7 of them had a thrombosis. The PPs were not removed after a diagnosis of symptomatic thrombosis and they were in further use in all 8 patients. Patients with manifest deep vein thromboses were put on therapeutic doses of heparin, i.e. doubling of the partial thromboplastin time for at least 6 months. Symptoms disappeared in all patients 3–4 weeks later. In 2 patients (2%), blood samples could not be aspirated, starting from the 3rd week after implantation. Infusions posed no problems, however. There was no clinical evidence of pulmonary embolism.

## Discussion

No patients suffered from any serious life-threatening complications in the present study. Several complications which may occur during placement of conventional subclavian approaches – such as hemothorax, pneumothorax, chylothorax, lesion of the phrenic nerve or brachial plexus, lesions of left thoracic duct, and subclavian artery injury [4–6] – are eliminated by the use of PPs.

Symptomatic catheter thromboses occurred in 8% of the oncologic patients in this study during 12,688 catheter placement days after PP implantation. A review of the literature revealed a lower mean thrombosis rate of 4.1% (0–26%) in a total of 1,247 patients (table 6). This minor difference between our own data and those cited in the literature is most probably attributable to differences between the study populations. Patients with cancers of the abdomen have a much higher risk of thrombosis than those with extra-abdominal malignancies [7] and other diseases. In addition, nearly half of the patients in the present study suffered from advanced pancreatic cancer with a particularly high thrombosis rate [8]. Another reason for the differences in quoted incidences might be the use of different diagnostic tests and/or minor awareness of clinical symptoms. This is endorsed by the monitoring of 30 of the authors' own patients by color-coded duplex sonography. This procedure disclosed thrombosis in 50% of the patients examined, only 5 of whom had symptoms. Since seven of the eight thromboses were found in the first 48 of the authors' own patients, the experience of the medical staff with implanting PPs might be an additional factor beside insufficient prophylactic anticoagulation. Technique and localization of PP insertion was not changed in the following 52 patients. It is well recognized that traumatization of the venous endothelium by catheters will induce thrombosis [9]. Foley et al. [10], who had reported on only 2% of symptomatic venous thromboses in the patients' axillary/subclavian vein region, believe that it may be useful to at least visually evaluate the size of cephalic and basilic veins before the placement of the P.A.S. port catheter with its outer diameter of nearly

**Table 6.** Data in the literature on symptomatic thromboses observed in patients with PP

| Authors | Ref. No. | Patient number[1] | Thrombosis rate[2] %/1,000 days | Systemic infection rate[3] %/1,000 days |
|---|---|---|---|---|
| Starkhammar et al. | 20 | 61 | 5/NA | 4.9/NA |
| Winters et al. | 16 | 32 | 6.2/0.4 | 3/0.2 |
| Morris et al. | 22 | 22 | 0 | 4.5/0.37 |
| Pearl et al. | 23 | 60 | NA/NA | 5/0.99 |
| Nanninga et al. | 11 | 170 | 5.9/NA | 0.6/NA |
| Finney et al. | 21 | 79 | 0 | 9/NA |
| Kahn et al. | 24 | 40 | 0 | 2.5/0.24 |
| Starkhammar et al. | 15 | 16 | 6.3/NA | 0 |
| Salem et al. | 25 | 47 | 6.4/0.21 | 0 |
| Carey et al. | 26 | 51 | 0 | NA/0.29 |
| Johnson and Didlake | 27 | 61 | 6.5/NA | 6.6/NA |
| Schuman and Ragsdale | 12 | 140 | 2.9/0.08 | 10/0.32 |
| Foley | 10 | 150 | 2/0.12 | 3.3/0.21 |
| Cunningham et al. | 28 | 18 | 26/NA | 5.5/NA |
| Kaufman et al. | 29 | 41 | 17.1/0.54 | 0.1/0.34 |
| Deppe et al. | 19 | 154 | 3.2/NA | 1.2/NA |
| Hata et al. | 17 | 105 | 5.8/0.66 | 0 |

NA = Not available.
[1] Total: 1,247 patients.
[2] Average: 4.1/0.20.
[3] Average: 2.9/0.27.

2 mm. This was not sufficiently observed in the first 48 patients described.

Clinically manifest pulmonary embolism has been observed by other authors [11].

Catheter thromboses of implantable chest ports reportedly occurred in 3% (0.17/1,000 catheter placement days) of 1,500 patients suffering from solid tumors or systemic hematologic diseases [6]. This incidence is lower than with PPs. However, small catheter thromboses are not diagnosed to the same extent as in patients with PPs. Intrathoracic veins cannot be monitored reliably by color-coded duplex sonography as peripheral veins can. Therefore the real thrombosis rate might be nearly the same with both systems, as was also concluded by Schuman and Ragsdale [12] on the basis of a review of their venous access database, and Foley et al. [10] who summarized the literature.

Anticoagulation obviously prevented catheter-induced thromboses in the patients in the present study, since the thrombosis rate was 7 times higher in patients without prophylaxis. This confirms observations from an open, prospective former study by Monreal et al. [13], who reported an overwhelming decrease in the thrombosis rate through the use of low molecular weight heparin in cancer patients (n = 29) with subclavian venous catheters (6 vs. 62%). On the recommendation of the ethics committee, patient recruitment was terminated earlier than planned. Of course, subclavian central venous access devices should not be compared with PP. But the latter study was the basis for recommending heparin prophylaxis as state of the art [14]. Superficial phlebitis occurred in a single patient. Former studies reported a rate of 8% [15] to 12.5% [16].

The systemic infection rate was 4%. PPs wer explanted in these patients, but pathogenic agents were isolated from only one catheter. This incidence is higher than that reported in the literature (table 6), but it must be emphasized that the PPs were not the septic starting point in the patients affected. Antibiotic prophylaxis was not administered to any of the patients in the present study, which might be an additional reason for the higher rate of systemic infections. Since some of the authors cited [12, 17] gave antibiotics intravenously prior to and after port implantation, the infection rate in these studies was lower. However, infections did not occur before at least 21 days after port implantation. Therefore, insufficient antisepsis before system access might be the more important cause in the present study. It is not yet clear when 'the

infected subcutaneous infusion reservoir should be removed' [18], because it is often difficult to make this determination without actually removing the catheter. Only 40 out of 63 catheters removed for suspected infection were infected in the latter study. Local erythema, tenderness or swelling correlated significantly with catheter infection. This was the case in only 1 out of the 4 patients in the present study. *K. pneumoniae* was isolated from that patient's catheter. Therefore, catheter removal was not really necessary in three cases. We now belive that antibiotic therapy should precede removal except in the presence of the above-cited clinical signs. Otherwise catheters are removed although the sepsis results from a distant point of the body and can successfully be treated. On the other hand, bacteria in the bloodstream might secondarily colonize the catheter. Fungal sepsis as was formerly reported by Deppe et al. [19] was not found in the present study.

Port erosion of the skin [20] catheter-port disconnection, and an inability to aspirate blood samples [16] have also been reported by other authors. These are typical complications the patient has to be informed about. Drip insufficiency as reported by Hata et al. [17] when the patients bent the elbow on the catheter insertion side – ports were located distal to the elbow – was not observed in the present study. Needle dislodgment did not occur in patients with Healthport miniMax® and Bard Titan Low Profile Port, but there were two such cases in patients with the P.A.S. port. Other authors [17] observed this complication in 1.9% of patients in association with the Port-A-Cath® P.A.S. Port. The most striking differences between the well-established ports (Port-A-Cath® P.A.S. Port and PeriPort peripheral access system) and the more recent ones (Healthport miniMax® and Bard Titan Low Profile Port) are predominantly the larger septa of the latter. Percutaneous needle puncture is therefore much easier early after port implantation. In addition, catheters can more reliably be attached to the recently developed ports by optimized connectors.

Overall cost savings are considerable when PPs rather than chest ports are implanted, as already stated by Foley et al. [10] and Finney et al. [21]. Although costs of the port systems (400–1,200 DM) are very similar, costs of operating room facilities (3,500 DM/h) can be saved.

In conclusion, PPs can easily be inserted without serious complications. Thromboses and infections can be mostly controlled by heparin and antibiotics and rarely require PP removal. There are good reasons for patients to prefer PP, including cosmesis, comfortable access by rolling up the sleeve, and fewer serious problems. Innovative devices enable doctors and nurses to easily puncture the port membranes as early as 1 day after insertion. Cost savings are substantial as less equipment is needed for PP implantation than for chest ports.

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