ASK THE QUESTION

Question: In patients requiring long-term infusion through an implanted vascular access port, what is the effect of placing the port during an inpatient stay on patient safety compared with placing it after discharge as an outpatient?

SEARCH FOR EVIDENCE

Databases: PubMed, Scopus


("Vascular Access Devices”[Majr] OR implanted vascular port OR venous access ports OR port devices) NOT (“Catheterization, Peripheral”[Mesh] OR Peripheral Inserted Central Catheter OR PICC OR PICCs OR peripherally inserted central catheter)

Filters: English, Humans, Published last 10 years

CRITICALLY ANALYZE THE EVIDENCE

There were seven studies (Bamba et al., 2014; Gapany et al., 2011; Ji et al., 2015; Pandey et al., 2013; Shim et al., 2014; Young et al., 2016; Zerati et al., 2016) found addressing the effects of placing an implanted vascular access port during the inpatient stay compared with placing it after discharge as an outpatient. All seven were observational studies, six of which were retrospective designs (Bamba et al., 2014; Ji et al., 2015; Pandey et al., 2013; Shim et al., 2014; Young et al., 2016; Zerati et al., 2016). All six of these retrospective studies were completed in adult populations. One, small prospective study (Gapany et al., 2011) was conducted in pediatric patients.

All of these articles support a trend toward increased infection rates for patients when implanted vascular access ports are placed in the inpatient setting. Ji et al. (2015) reported a 9.5% infection rate in the 1026 patients in their study who all had their vascular access ports placed in the inpatient setting. Bamba et al. (2014) and Shim et al., (2014) both found that patients with bloodstream infections were significantly more likely to have had their port inserted as inpatients. Pandey et al. (2013) found the hazard of inpatients needing port removal being 44% greater than that of outpatients, which remained significant even after accounting for heterogeneity in the indication for port placement between
the two groups. Gapany et al. (2011) reported an 8 times greater odds of infection within 10 days of increased daily access (3+ times per day) in pediatric inpatients (OR 8.43; 95% CI: 2.189601-32.51152; p=0.002). Young et al. (2016) investigated the effects of placement location (inpatient vs outpatient) and accessing the port on day of placement on infection rates. They found a significantly larger number of infection-free catheter days in patients with a port placed as an outpatient, and that significantly more inpatients had their port accessed on the day of placement. Additional analysis showed that patient age and whether or not the port was accessed on the first day did not explain the variation for probability of infection between inpatients and outpatients. Finally, Zerati et al. (2016) found that placement of the port during an inpatient stay was an independent risk fact for infection (OR 3.69, 95% CI 2.56-5.32, p< 0.001) in over 1200 cancer patients.

### PICO Question:
In patients requiring long-term infusion through an implanted vascular access port, what is the effect of placing the port during an inpatient stay on patient safety compared with after placing it discharge as an outpatient?

<table>
<thead>
<tr>
<th>Author/Date/Journal</th>
<th>Purpose of Study</th>
<th>Study Design</th>
<th>Sample &amp; Setting</th>
<th>Outcomes</th>
<th>Design Limitations</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bamba et al., 2014, Journal of Vascular and Interventional Radiology</td>
<td>To identify risk factors for port infections within 30 days of placement</td>
<td>Case-control study</td>
<td>99 patients with vascular access ports placed at a single medical center (2002-09) in the US -CLABSI + patients (n=33) -gender-matched controls (n=66; chosen randomly from patients with ports placed within 1 month of case)</td>
<td>Port infection defined by CDC guidelines for CLABSI</td>
<td>Study Limitations = None Non-Experimental/Observational Studies (case-control, cohort, cross sectional, longitudinal, descriptive, epidemiologic, case study/series, survey)</td>
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<tr>
<td>Gapany et al., 2011, Journal of Vascular Access</td>
<td>To address the relationship between complication rates and the number of accesses for pediatric patients</td>
<td>Prospective cohort</td>
<td>45 consecutive pediatric patients &gt; 1 yr old with totally implanted vascular (TIVA) ports placed at a single medical center in Switzerland (2006-08) -placement due to solid and blood cell</td>
<td>Using 5-day infection period: 1.49% exposed periods are followed by an infection, vs. 0.35% of non-exposed periods (p=0.099) Using 10-day infection period: 2.29% of exposed</td>
<td>Study Limitations = None Non-Experimental/Observational Studies (case-control, cohort, cross sectional, longitudinal, descriptive, epidemiologic, case study/series, survey)</td>
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</tbody>
</table>
with a vascular port

- insertion technique and care of device were standardized
- late complications = over 2 years of F/U

Every TIVA manipulation, type of manipulation and any problems encountered were prospectively recorded by specialized nurses in the patient's file.

Infection = positive blood culture in the presence of fever with neutropenia or fever alone with clinical signs of bacteremia.

Infection period = 5-10 day period preceding a documented port infection.

Exposed period = mean of 3+ daily accesses.

**periods are followed by an infection vs. 0.24% of non-exposed periods (OR 8.43; 95% CI: 2.189601-32.51152; p=0.002)**

- Sample not representative of patients in the population as a whole
- Variables (confounders, exposures, predictors) were not described and accounted for
- Outcome criteria not objective or were not applied in blind fashion
- Insufficient follow-up, if applicable
- For prognostic study, sample not defined at common point in course of disease/condition
- For diagnostic study, gold standard not applied to all patients
- For diagnostic study, no independent, blind comparison between index test and gold standard

_Ji et al., 2015, Cell Biochemistry and Biophysics_

To investigate the incidence and risk factors of infections associated with totally implantable venous access ports.

**Retrospective cohort**

1026 patients with totally implantable vascular access ports placed at a single medical center (2007-13) in China - all placed while undergoing inpatient management of cancer - infection occurred in 97 patients (9.5%).

Port infections defined by ISDA guidelines for exit-site infection, tunnel infection, pocket infection, bloodstream infection.

Patients with nonsolid tumor had a significantly higher infection rate when compared with patients with solid tumors (p < 0.05).

Incidence rate of infection was significantly higher in patients younger than 40 years old (p < 0.05).

Patients using chemotherapy for palliative purposes had a significantly higher infection rate than those with a curative intent (p < 0.05).

There was no difference for infection rates between males and females (p = 0.17).

**Study Limitations =**
- None
- _Non-Experimental/Observational Studies (case-control, cohort, cross sectional, longitudinal, descriptive, epidemiologic, case study/series, survey)_
- Insufficient sample size
- Sample not representative of patients in the population as a whole
- Variables (confounders, exposures, predictors) were not described and accounted for
- Outcome criteria not objective or were not applied in blind fashion
- Insufficient follow-up, if applicable
- For prognostic study, sample not defined at common point in course of disease/condition

**Level of evidence for studies as a whole:**
- High
- Moderate
- Low
- Very Low

(e.g. pharmaceutical company sponsors study on effectiveness of drug)
<table>
<thead>
<tr>
<th>Study</th>
<th>Objective</th>
<th>Study Design</th>
<th>Patients and Methods</th>
<th>Results</th>
<th>Study Limitations</th>
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</thead>
<tbody>
<tr>
<td>Pandey et al., 2013, Journal of Vascular and Interventional Radiology</td>
<td>To determine whether the inpatient versus outpatient status of patients at the time of port placement affects the infection rate</td>
<td>Retrospective cohort</td>
<td>2112 patients with vascular access ports placed at a single medical center (2001-10) in the US -1030 patients with a known reason for port removal (infection, n=160; inpatient placement, n=45; outpatient placement, n=115) -all ports were same design (LifePort) -majority placed for solid organ (n=672) and hematologic (n=289) malignancy Excluded patients with incomplete placement and removal documentation All given prophylactic dose of antibiotics (pre-SIR guidelines recommending against their use) Infection defined using SIR guidelines</td>
<td>There was a significant difference between inpatients and outpatients in time to catheter removal as a result of infection -the hazard of inpatients needing port removal being 44% greater than that of outpatients (p = 0.04) -when dehiscence was included with infection, there was a 45% greater hazard of inpatients needing port removal (p = 0.03) The increased hazard of inpatients needing port removal was significant even after accounting for heterogeneity in the indication for port placement between inpatient and outpatient groups (p = 0.02)</td>
<td>Non-Experimental/Observational Studies (case-control, cohort, cross sectional, longitudinal, descriptive, epidemiologic, case study/series, survey) ☑ Insufficient sample size ☑ Sample not representative of patients in the population as a whole ☑ Variables (confounders, exposures, predictors) were not described and accounted for ☑ Outcome criteria not objective or were not applied in blind fashion ☑ Insufficient follow-up, if applicable ☑ For diagnostic study, sample not defined at common point in course of disease/condition ☑ For diagnostic study, gold standard not applied to all patients ☑ For diagnostic study, no independent, blind comparison between index test and gold standard</td>
</tr>
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<td>Shim et al., 2014,</td>
<td>To determine the incidence rate of IVAP-related events among patients with IVAC placement</td>
<td>Retrospective</td>
<td>1747 patients with IVAC placement in the US</td>
<td>Incidence rate of IVAP-related events among patients with IVAC placement</td>
<td>Study Limitations =</td>
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<tr>
<td>Korean Society of Radiology</td>
<td>incidence and risk factors of infections associated with implantable venous access ports (IVAP)</td>
<td>cohort with nested case-control study</td>
<td>vascular access ports placed at a single medical center (2003-11) in Korea -during inpatient stay (n=1203) -as an outpatient procedure (n=544) -placed by 1 of 2 interventional radiologists -considerable loss-to-follow-up noted</td>
<td>infection was 0.067 events/1000 catheter days -31 with systemic illness -8 with local infection -1 with both -6 with immediate infections -34 with delayed infection</td>
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| | | | | Infection was more common in patients with IVAP placed during inpatient stay instead of as an outpatient procedure (85% vs 15%, p=0.016)

Adjusted odds ratio (OR) of infectious complication for hematologic malignancy versus solid organ malignancy was 7.769 (95% CI, 2.356-25.615)

Adjusted OR for palliative chemotherapy versus adjuvant, neoadjuvant, and curative chemotherapy was 4.863 (95% CI, 1.726-13.700)

Overall infection rate was 7.5% (0.27 per 1000 catheter days) -infection rate 9.8% for inpatients and 6.7% for outpatients -30.8% occurred within 30 days of placement

Study Limitations = None

Non-Experimental/Observational Studies (case-control, cohort, cross sectional, longitudinal, descriptive, epidemiologic, case study/series, survey)

- Insufficient sample size
- Sample not representative of patients in the population as a whole
- Variables (confounders, exposures, predictors) were not described and accounted for
- Outcome criteria not objective or were not applied in blind fashion
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Young et al., 2016, Journal of Vascular Access | To study the effect of accessing the port on day of placement with regard to infection rates | Retrospective cohort | 1378 patients with vascular access ports placed at a single medical center (2008-13) in the US -during inpatient stay (n=367) -as an outpatient procedure (n=1011) -age adjustment due to fact that inpatients were significantly younger than outpatients | Excluded patients without complete placement and |
| --- | --- | --- | --- | --- |
| | | | | Overall infection rate was 7.5% (0.27 per 1000 catheter days) -infection rate 9.8% for inpatients and 6.7% for outpatients -30.8% occurred within 30 days of placement

Outpatients had a significantly larger number of infection-free catheter days when compared to inpatients (p = 0.027)

Study Limitations = None

Non-Experimental/Observational Studies (case-control, cohort, cross sectional, longitudinal, descriptive, epidemiologic, case study/series, survey)

- Insufficient sample size
- Sample not representative of patients in the population as a whole
- Variables (confounders, exposures, predictors) were not described and accounted for
- Outcome criteria not objective or were not applied in blind fashion
- Insufficient follow-up, if applicable
| Zerati et al., 2016, Journal of Vascular Surgery: Venous and Lymphatic Disorders | To investigate risk factors for complications of totally implantable catheters in a referral cancer center | Retrospective cohort | 1230 cancer patients with non-valved implanted port catheters placed at a single medical center in Brazil (2008-12) -during inpatient stay (n=257) -as an outpatient procedure (n=998) All implantation procedures performed by residents in the surgical suite using standard procedures F/U conducted 1 week after implantation and | Infectious complication rate was 13% (0.35 per 1000 catheter days) -late infections more frequent (66%), with most being bloodstream infections (81%) **Infection was significantly more common in hospitalized patients compared with outpatients (29% vs 9%, p< 0.001)** -in multivariate analysis, placement of the port during an inpatient stay was an independent risk fact for infection (OR 3.69, 95% CI 2.56-5.32, p< 0.001) Study Limitations = None Non-Experimental/Observational Studies (case-control, cohort, cross sectional, longitudinal, descriptive, epidemiologic, case study/series, survey) ☑ Insufficient sample size ☑ Sample not representative of patients in the population as a whole ☑ Variables (confounders, exposures, predictors) were not described and accounted for ☑ Outcome criteria not objective or were not applied in blind fashion ☑ Insufficient follow-up, if applicable ☑ For prognostic study, sample not | removal data All ports placed in 1 of 6 interventional radiology suites | Significantly more inpatients had their port accessed on the day of placement compared with outpatients (91.6% vs 6%, p < 0.0001) -controlling for age (p=0.4885) and whether or not the port was accessed on the first day (p=0.1656) does not explain a significant amount of the variation in probability of infection when also controlling for location [inpatient/outpatient] Mean # days after placement when port is first accessed (DAP) -controlling for age, DAP does not explain a significant amount of the variation either in time until infection (p = 0.6647) or in the probability of infection (p = 0.2029) -controlling for location in addition to age, both the time until infection and the probability of infection remain statistically non-significant (p = 0.9725 and p = 0.9990, respectively) applicable |
every 6 months after that; also in the case of complications (infection or malfunction)
- early complications = first 30 days after implantation
- late complications = after 30 days

In hospitalized patients, venous access choice had no effect on rate of infection (33.3% FEV vs 26.5% IJV vs 39.5% SCV, p = 0.218)

defined at common point in course of disease/condition

For diagnostic study, gold standard not applied to all patients
For diagnostic study, no independent, blind comparison between index test and gold standard

Young et al. (2016)

 REFERENCES


### Appendix A: GRADE criteria for rating a body of evidence on an intervention

Developed by the GRADE Working Group

**Grades and interpretations:**

<table>
<thead>
<tr>
<th>Grade</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>High</td>
<td>Further research is very unlikely to change our confidence in the estimate of effect.</td>
</tr>
<tr>
<td>Moderate</td>
<td>Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate.</td>
</tr>
<tr>
<td>Low</td>
<td>Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate.</td>
</tr>
<tr>
<td>Very low</td>
<td>Any estimate of effect is very uncertain.</td>
</tr>
</tbody>
</table>

**Type of evidence and starting level**

<table>
<thead>
<tr>
<th>Evidence Type</th>
<th>Grade</th>
</tr>
</thead>
<tbody>
<tr>
<td>Randomized trial</td>
<td>High</td>
</tr>
<tr>
<td>Observational study</td>
<td>Low</td>
</tr>
<tr>
<td>Any other evidence</td>
<td>Very low</td>
</tr>
</tbody>
</table>

**Criteria for increasing or decreasing level**

**Reductions**

- Study quality has serious (−1) or very serious (−2) problems
- Important inconsistency in evidence (−1)
- Directness is somewhat (−1) or seriously (−2) uncertain
- Sparse or imprecise data (−1)
- Reporting bias highly probable (−1)

**Increases**

- Evidence of association† strong (+1) or very strong (+2)
- Dose-response gradient evident (+1)
- All plausible confounders would reduce the effect (+1)

†Strong association defined as significant relative risk (RR 2-5 or 0.5-0.2) based on consistent evidence from two or more studies with no plausible confounders; Very strong association defined as significant relative risk (RR >5 or <0.2) based on direct evidence with no threats to validity.