Systematic review: malfunction of totally implantable venous access devices in cancer patients
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CRD summary
The review found a broad range of malfunction incidence for totally implantable venous access devices in cancer patients. No firm conclusions could be drawn due to differences in devices used, definitions of malfunction and malfunction measurement. Limitations in the review process and study quality mean that the authors’ conclusions are justified.

Authors’ objectives
To evaluate the safety of totally implantable venous access devices in cancer patients.

Searching
PubMed was searched from January 1993 to February 2011 for publications in English, French, German and Dutch. Search terms were reported. The bibliography of each retrieved article was handsearched.

Study selection
Randomised controlled trials (RCTs), quasi-experimental designs and descriptive studies that assessed the incidence of functional problems (malfunctions) in totally implantable venous access devices (TIVADs) across different types of port and catheter designs in adult cancer patients were eligible for inclusion. At least 95% of the study population had to consist of onco-haematology patients and at least 95% of patients with a newly inserted chest or arm port. TIVAD malfunction was considered to be a loss of patency for injections and/or fluid withdrawal. Relevant definitions used in the studies were summarised. Eligible studies had to report a functional outcome. Follow-up had to start at the time of TIVAD insertion. Studies were excluded if results were reported only for part of the population.

Most studies (91%) were published in English. Studies were performed in Europe (61%), USA (25%), Asia (8.8%), Brazil (3.5%) and Canada (1.8%). Where reported, device insertion was performed by surgeons (44% studies), radiologists (28% studies), gynaecological oncologists (3.5% studies) or in a mixed setting (18%). Most studies (67%) focused on the insertion technique and complications; others compared different TIVADs (21% studies) or compared TIVADs with another type of intravenous catheter (7% studies). There were more participants with chest ports (83.6% including 2.2% double lumen ports) than arm ports. Where reported, most TIVADs were inserted into the right body side. Subclavian and internal jugular veins were most frequently accessed for chest ports and the basilic vein for arm ports. Mean/median patient age ranged from 28 to 70 years. Thirty-three different TIVADs were used: 98.4% had a standard port design, 1.6% had a modified reservoir design, 74.8 had a standard non-valved catheter and 54.9% were made of silicone. Malfunction definitions were given in 29.8% of studies and did not generally cover both aspiration and infusion malfunction.

The authors did not state how many reviewers performed study selection. Authors were contacted for clarification if it was not clear whether a study met the inclusion criteria.

Assessment of study quality
Methodological quality was assessed by two reviewers independently using a modification of the methodological index for non-randomised studies (MINORS) developed by Slim et al. Disagreements were resolved by consensus with two other reviewers. Nine criteria were scored on a three-point scale (0=not reported, 1=reported but inadequate and 2=reported and adequate) with a total possible score of 18. Criteria included a clearly stated aim, inclusion of consecutive patients, prospective data collection, a priori definition of functional problem and appropriate endpoint, accurate functional outcome measure (valid and reliable), blinding of assessors and blind evaluation of endpoint, follow-up at least 130 days, loss to follow-up less than 5% and prospective calculation of study size.

Data extraction
Absolute numbers of malfunctioning TIVADs were extracted to enable calculation of percentage of affected TIVADs,
number of malfunctions per 1,000 catheter days, number of catheter occlusions per 100 treatment cycles and number of malfunction events per TIVAD access attempt and per 100 TIVAD access attempts.

One reviewer performed data extraction.

**Methods of synthesis**
A narrative synthesis was provided due to differences in outcome measurement.

**Results of the review**
Fifty-seven studies were identified (14,311 participants, range 17 to 1,418). Eleven studies were RCTs and eight were observational studies. Where reported, mean or median number of catheter days ranged from 90 to 493 days. Total study quality scores ranged from 4 to 14 and 89.5% studies scored at least 9.

The malfunction incidence of TIVADs ranged from 0% to 47% (all studies) and 21 studies (36.8%) had an incidence of less than 1%. The number of malfunctions per 1,000 catheter days ranged from zero to 2.24 (43 studies). The number of catheter occlusions per 100 treatment cycles ranged from zero to 1.3 (four studies). The number of malfunction events per TIVAD access attempt was reported for one study as 21 withdrawal occlusions per 364 TIVAD accesses. The number of access events per 100 TIVAD access attempts ranged from 0% to 26% (22 studies).

**Authors' conclusions**
No firm conclusions on the true incidence of malfunctions of TIVADs in cancer patients could be drawn due to a lack of standard definitions of malfunction and heterogeneity in definitions of device malfunction and calculation and reporting methods. There was a broad range in the reported incidence of malfunctions.

**CRD commentary**
The review addressed a well-defined question in terms of participants, interventions and study design. One of the aims of the study was to identify and define relevant outcomes. Only one database was searched and unpublished studies were not considered; some relevant studies may have been missed even though studies published in four languages were included. Publication bias was not assessed. Study quality was assessed with suitable criteria. Most of the studies were of poor quality. Validity assessment was carried out with efforts to reduce error and bias; whether or not clear this applied to other aspects of the review process was not clear. Some relevant study details were reported. There were few details of individual study design. Numbers of participants for each study and overall participant numbers were not clear.

A narrative synthesis was provided due to the differences in the outcomes measured. Potential limitations in the review process and the poor quality of included studies mean that the authors’ conclusions are justified.

**Implications of the review for practice and research**

**Practice:** The authors did not state any implications for practice.

**Research:** The authors identified a need for more rigorous research with prospective design and sufficient participants on the functional outcomes of TIVADs; studies should involve TIVAD end users. TIVAD malfunction needed to be described for both aspiration and injection capacities. Objective outcome measurements were needed. Full definitions of suggested malfunction and outcome measurements were given. Malfunction incidence rate should be calculated as a percentage of access attempts adjusted by the mean number of functional problems per patient. Research should document precise malfunction definitions. Future research on predisposing factors required details of all confounding variables, which included device specification, insertion technique, precise catheter tip location, post-insertion care and maintenance, and procedures to salvage device failure. Researchers should take into account that successive problems in the same device were not independent events.

**Funding**
Not stated.

**Bibliographic details**
Goossens GA, Stas M, Jerome M, Moons P. Systematic review: malfunction of totally implantable venous access
devices in cancer patients. Supportive Care in Cancer 2011; 19(7): 883-898

**PubMedID**
21556721

**DOI**
10.1007/s00520-011-1171-3

**Original Paper URL**
http://www.springerlink.com/content/f4431408272362m1/

**Indexing Status**
Subject indexing assigned by NLM

**MeSH**
Catheterization, Central Venous /adverse effects; Catheters, Indwelling /adverse effects; Equipment Failure; Hematology; Humans; Incidence; Medical Oncology; Neoplasms /complications; Risk Factors

**AccessionNumber**
12011005397

**Date bibliographic record published**
12/10/2011

**Date abstract record published**
10/05/2012

**Record Status**
This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.