FINDING THE EVIDENCE FOR KEEPING THE PATENCY IN PERIPHERAL INTERMITTENT INTRAVENOUS DEVICES

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Abstract

Background: There is a controversial aspect concerning the method of choice for maintaining the patency of peripheral intermittent intravenous catheters. Some institutes use a dilution of heparin for this purpose, whereas many others use a small amount of normal saline flush. So, it would be worthwhile to look for the best available evidence for this.
Methods: A thorough search was performed in different nursing and medical databases, in order to find the available evidence. All relevant information has been obtained from papers written in English and published during the last twenty years.
Results: Many research papers were examined and appraised for their level of evidence. The available evidence suggests the same degree of effectiveness of normal saline versus heparin solution for maintenance of patency of peripheral intermittent intravenous catheters.
Conclusion: Since the use of heparin is considered the cause for many side effects and complications, normal saline should be the solution of choice as it contributes to patients' safety, patients' satisfaction and cost savings.

Keywords: Evidence-based practice, peripheral intermittent intravenous device, patency, heparin solution, saline solution

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Introduction

The term "evidence-based healthcare" was primarily introduced in the United Kingdom in the 1970's and since then it has been widely used (Hammer, 1999). Thereby, since nursing knowledge used to be based on anecdote and tradition up to that time, many efforts have been made in order to introduce nursing practice based on research, resulting in the espousal of evidence-based practice in the early 1990's (Le May, 1999, Johnson and Griffiths, 2001).

Many contributing factors were acknowledged for the eruptive development of evidence-based practice. The introduction of new technology and new knowledge during the last 20 years contributed much in the advancement of health sciences, which have been used to support clinical practice, resulting the need for clinical decision making to be based on information generating from research (Muir-Gray, 2001). On the other hand, there is increased competition as health care practice is supported by new technologies,

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procedures, products and pharmaceutical elements; all of them postulate evidence in order to prove their effectiveness (Evans and Pearson, 2001). Moreover, increased requisition for evidence-based practice is related to changing demographic profile (population ageing), to patients' expectations for quality health service, accessibility for health services and accountability of health care professionals and to professionals' expectations as they are influenced by patients' expectations and developments in technology (Muir Gray, 2001). Other factors driving application of evidence-based practice are cost pressures and value for money movement, consumer awareness, availability of information (Hamer, 1999, Geyman, 2000), political and international consensus, increase in management-led decision, and authority granted to non-clinicians to question effectiveness (Hamer, 1999).

Evidence-based practice in patients' care

Evidence-based practice is perceived as the process for making reasonable decisions (Hamer, 1999) and the ultimate to clinical effectiveness that needs to be multilateral in order to reflect the different needs of practice and patients (Le May, 1999). Thus, as most professionals need their patients' care to be characterised by effectiveness and meeting of their needs (Mulhall, 1998) they could be reinforced by evidence-based practice as its goal is "to support professionals in their decision making in order to eliminate ineffective, inappropriate, too expensive and potentially dangerous practice" (Hamer, 1999:7). Furthermore, Johnson and Griffiths (2001) state that evidence-based practice inducts evidence arising from research into the clinical decision making whilst Muir-Gray (2001) suggests that research evidence could be used to improve patients' choice, clinical practice and health service management. However, the magnitude of evidence-based practice is reflected in that it is the determinant in "doing the right things right" (Muir-Gray, 2001:45). Thus, evidence-based practice could be the key for the provision of the best possible quality patients' care.

The use of heparin for maintaining patency of peripheral intermitted intravenous devices

Most of the patients being admitted to the hospital need some time of their hospitalisation to receive fluids, medications or nutrition intravenously (Hamilton et al, 1988, Randolph et al, 1998). In our days, a widely used method for administration of medications is through peripheral intermittent intravenous devices (PIID) and use of intravenous locks. PIID's became very popular since 1970 as they can maintain intravenous access without continuous fluid infusion (Ashton et al, 1990, Krueger-Paisley et al, 1997). PIID's could also be used for blood withdrawal in order to avoid recurrent venipunctures (Lombardi et al, 1988). They allow patients freedom to move (Goode et al, 1993, Reineck and Reineck, 1996) and provide health organisations many advantages such as cost savings related to tubes and fluids administered for keeping vein open, and prevention of incompatibility between fluids infused and medications administered (Meyer et al, 1995). Maintenance of the patency of these catheters is essential as resiting a catheter may produce discomfort to patients and increased cost (Randolph et al, 1998).

Heparin sodium used to be the traditionally used medication as anticoagulant in those catheters in order to prevent clotting, minimise the incidence of phlebitis (Garrelts et al, 1989) as it enhances antithrombin III activity and compensates coagulation factors XII, and X (Kulkarni et al, 1994). However, although health caregivers believe that small doses of heparin used in flushing of PIID's are harmless (Goode et al, 1991), heparin could cause many side effects like hemorrhage, allergic reactions, thrombocytopenia and pain at the injection site (Hamilton et al, 1988, Walenga and Bick, 1998, Sideris and Michalis, 2000). Heparin could also have interaction with many other frequently used medications, like acetylosalic acid, antihistamines, digoxin etc (Sideris and Michalis, 2000), so its use premises good knowledge of incompatibility between drugs (Goode et al, 1991).

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The policy used for administration of medications through an intravenous lock recommends irrigation of 2-3 mls of normal saline, administration of the medication, a second irrigation with another 2-3 mls of normal saline and finally flush with 2 mls of heparin solution. Consequently, nurses need two different syringes for flushing, one containing normal saline and the other heparin solution, three syringes' insertions to the lock and much nursing time to dilute heparin. Potential for contamination of the lock is increased when it is flushed with heparin solution (three syringes' insertion instead of two if catheter would be flushed with normal saline only) and moreover the cost of treatment is also increased because of more nursing time required and the cost of the additional syringe containing diluted heparin (Kotter, 1996).

Finding the evidence

Twenty-three studies were thoroughly examined among all the studies retrieved through different databases (such as Ovid, Medline, Chochrane Database of Systematic Reviews). Nine of these, were addressed to adult population (Holford et al, 1977, Cyganski et al, 1987, Dunn and Lenihan, 1987, Hamilton et al, 1988, Garrelts et al, 1989, Ashton et al, 1990, Shoaf and Oliver, 1992, Meyer et al, 1995, Reineck and Reineck, 1996), 10 studies were addressed to paediatric population (Lombardi et al, 1988, Danek and Norris, 1992, Kleiber et al, 1993, Hanrahan et al, 1994, Gyr et al, 1995, Kotter, 1996, Krueger-Paisley et al, 1997, LeDuc, 1997, Heilksov et al, 1998, Mudge et al, 1998), three were meta-analyses (Goode et al, 1991, Peterson and Kirchoff, 1991, Randolph et al, 1998,) and one was conducted in rabbits (Kyle and Turner, 1999).

Appraising the evidence

Findings of research on the efficacy of normal saline versus heparin solution for maintaining patency of PIID's are ambiguous (Goode et al, 1991, Shoaf and Oliver, 1992). Many researchers state that normal saline is as effective as heparin solution (Dunn and Lenihan, 1987, Hamilton et al, 1988, Lombardi et al, 1988, Garrelts et al, 1989, Ashton et al, 1990, Peterson and Kirchoff, 1991, Goode et al, 1991, Shoaf and Oliver, 1992, Danek and Norris, 1992, Kleiber et al, 1993, Hanrahan et al, 1994, Reineck and Reineck, 1996, Kotter, 1996, Krueger-Paisley et al, 1997, LeDuc, 1997, Randolph et al, 1998, Heilskov et al, 1998, Kyle and Turner, 1999), whereas many others suggest that heparin provides the catheter longer patency and reduces potential incidence of associated phlebitis (Holford et al, 1977, Cyganski et al, 1987, Gyr et al, 1995, Meyer et al, 1995, Mudge et al, 1998).

In order to appraise available evidence, papers related to paediatric population were not taken into consideration, therefore only adult population was examined. Additionally, relative research, which has been performed in children or in neonates used either as a part or as the whole sample, 24 gauge intravenous catheters, which are rarely or never used in adults. Kyle and Turner's (1999) study was conducted in rabbits and not in human beings. Meyer et al's (1995) study was excluded as it was conducted in a sample of pregnant women at 26-34 weeks of gestation, hospitalised for spontaneous preterm labor. Results of such a study could not be generalised in the whole population as pregnancy is characterised as a "hypercoagulable" state (Meyer et al, 1995:435) since during pregnancy clotting factors are normally increased (Nettina, 1996).

Many studies were excluded from appraisal. Holford et al's (1977) study was published in a correspondence letter without data on study design or statistical analysis and Reineck and Reineck's (1996) work was a pilot study in a very small sample of geriatric patients (20 subjects).

Knowing that, evidence concerns comparison of two different solutions for flushing PIID's, a randomised controlled trial (RCT) is considered to be the most appropriate research design for extracting the best form of evidence as RCT's are considered as the "gold standard" in research evidence in order to compare different interventions (Humphris, 1999,), or to determine the effectiveness of an intervention (Miser, 2000a, Muir-Gray, 2001). Besides that, RCT's

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provide the best research evidence (Evans and Pearson, 2001). So, Cyganski et al's (1987) study was excluded as there was a non-random study and there was no statistical analysis. Moreover, nor Dunn and Lenihan's (1987) study was randomised and statistical analysis of the data was limited. Ashton et al's (1990) research was excluded as it was conducted in a small sample (32 volunteer subjects).

In the study carried out by Garrelts et al (1989) the study's sample was recruited from two 35-bed general medical-surgical units whilst in Shoaf and Oliver's study (1992) it was recruited from a cardiovascular surgery unit. So randomisation was not perfect (Greenhalgh, 2001), as subjects were randomised according to the hospital units and not individually. This way of subject's selection could rise bias as many patients, like patients with neurologic disorders or patients receiving chemotherapy did not have any chance to participate in the study [taking into account that lots of chemotherapeutic agents or many medications administered for the treatment of seizures are extremely irritant for the veins (Nettina, 1996)]

Many strengths were noticed in Hamilton et al's (1988) double blind RCT. The hypothesis of the study was clearly stated. The population studied, the interventions given and the outcomes considered were clearly addressed in this trial. All patients admitted to the hospital having a PIID were eligible to enter the study. Only patients hospitalised in Intensive Care Units were excluded from this study but authors did not mention the reason for exclusion of those patients. Patients were appropriately randomised into the heparin solution or the normal saline group using a computer-generated assignment sheet. One hundred sixty patients from the 241 enrolled completed the study resulting in a total sample of 307 subjects (PIID's observed) for analysis. Thus, follow-up was completed for 66% of the sample but reasons for this were clearly stated. However, there were more observations in the heparin group (170 versus 137 in the saline group) as analysis was applied to the subjects (catheters) rather to patients. Subjects were analysed in both heparin and normal saline groups. Subgroup analysis was also included (concerning gender and age of patients, nursing units where patients were hospitalised, intravenous medications used and type of the PIID). This study was double blind as the assigned solutions were supplied in a cartridge labeled with a lot number and a solution letter and there were distributed to the different hospital's units as "flush solution". Patients remained to the same assigned solution throughout the whole course of their therapy through PIID's. Patients in either group, excepting the flush solution, were equally treated. Moreover, all catheters sites were evaluated daily by five registered nurses who were also blinded to the group assignment.

Authors stated a priori that the sample should include 250 observations, 125 for each group. This study sample consisted of a total sample of 307 subjects. So it could be considered that this trial has a good degree of power (Muir-Gray, 2001) but confidence interval was not mentioned in this paper. In this paper, the statistical methods used were appropriate. The only significant difference between the two groups concerned distribution between subjects in males and females (67 versus 103 in the heparin group and 75 versus 62 in the saline group respectively) as females seemed to have shorter duration of catheter patency than males resulting in more intravenous lines restarts in females. The overall means concerning duration of catheter patency was 44.3 ± 18.6 in heparin group and 45.4 ± 17.7 in the saline group. Results of the study confirmed the study's hypothesis that, using either solution (100 IU/ml diluted heparin or normal saline) there are no differences in the patency of PIID's. This RCT having a good design could be considered as level II of evidence (National Health and Medical Research Council, 2000) or as level I quality of evidence as well (Pinsky and Deyo, 2000).

Dickson (1999) and Muir-Gray (2001) suggest that systematic review is the most suitable type of research for evidence-based decision making about intervention treatments whilst meta-analysis is a systematic review that using quantitative approach synthesises evidence from different studies (Hunink et

al, 2001, Muir-Gray, 2001). So appraisal was engaged in meta-analyses too.

Peterson and Kirchoff (1991) conducted a systematic review using 20 studies concerning effectiveness of normal saline versus heparin solution in maintenance of intravenous and intra-arterial catheters. Meta-analysis was performed for 13 of those studies. Unfortunately, this meta-analysis could not be used as evidence as evaluation was addressed to a combination of studies carried out in both continuously infused and locked catheters. Further to this, many non-randomised studies were included in this meta-analysis as only 3 were truly RCT's.
Another meta-analysis was carried out by Goode et al (1991). In this meta-analysis, although methods and methodology were well structured and presented, the 17 studies included were of different levels of quality and only 7 were truly RCT's.
Randolph et al (1998) accomplished a systematic review and meta-analysis of RCT's carried out for comparing effectiveness of normal saline versus heparin for maintenance of PIID's. Validity of this systematic review and meta-analysis was determined following many of the steps suggested by Miser (2000b). Thus, this study answered a well-defined question. A good effort to search all available, published and unpublished, randomised control trials was done. The search strategy was explicitly described. Limitations of the search strategy could be considered that there is no information if the authors searched "Cochrane database of Systematic Reviews" or unpublished Master or Doctorate theses or conference proceedings as well. In addition to this, there is no information addressed on material in languages other than English. Inclusion and exclusion criteria were clearly reported. Inclusion criteria were appropriate but although the authors state that studies, in which 40% of patients were excluded from analysis after randomisation were excluded, they do not mention the rationale for their decision. However, inter-rater reliability was established between two investigators. Evaluation of agreement was calculated by quadratic weighted k for all the items, found to be 0.72-1.00. Validity of included studies was adequately addressed and there were sufficient details about the primary studies. A structured statistical analysis was performed. This study was funded from the Agency for Health Care Policy and Research and had no conflict of interest.
From the 26 RCT's who met the inclusion criteria, only 13 RCT's addressed to the PIID's entered in the meta-analysis. The reasons for excluding the half of those trials were appropriate and clearly declared. Although this meta-analysis was addressed to arterial and venous catheters and to intermitted peripheral catheters or catheters used for continuous infusion as well, analysis of the results was conducted separately for each subgroup. So, meta-analysis concerning PIID's was carried out in three RCT's whilst primary studies were summarised and combined appropriately.
Results of this meta-analysis are in accordance with Peterson and Kirchoff's (1991) and Goode et al's (1991) meta-analyses' findings which addressed to controlled and uncontrolled studies (Randolph et al, 1998). Thus, sections described analysis concerning PIID's could be used for appraising evidence concerning the effectiveness of normal saline versus heparin solution for maintenance of patency in PIID's. Considering a level I of evidence (National Health and Medical Research Council, 2000), this meta-analysis could serve as the evidence for changing the policy, following the authors suggestions that the current use of 10 U/ml heparin as an intermittent flush is no more effective than normal saline flush (Randolph et al, 1998:974).

Conclusion

Evidence suggests the same degree of effectiveness of normal saline versus heparin solution for maintenance of patency of peripheral intermittent intravenous catheters (Hamilton et al, 1988, Randolph et al, 1998). Thus, normal saline should be the solution of choice as it provides many advantages summarised in patients' safety, patients' satisfaction and cost savings. Patients' safety is improved as much as by using heparin, even in a small concentration. There is a potential risk for allergic

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reactions, iatrogenic hemorrhage, incompatibility and heparin induced thrombocytopenia (Hamilton et al, 1988, Lombardi et al, 1988, Garrelts et al, 1989, Goode et al, 1991, Shoaf and Oliver, 1992, Krueger-Paisley et al, 1997, Reineck and Reineck, 1996, LeDuc, 1997, Randolph et al, 1998). Moreover, using saline, the number of entries in the three-way-stop-cock is decreased, decreasing the potential for contamination (Kotter, 1996).

Use of saline results not only in reduction of costs (related to supplies and to that heparin is more expensive that normal saline) but also in securing valuable nursing time as well (Hamilton et al, 1988, Garrelts et al, 1989, Goode et al, 1991, Shoaf and Oliver, 1992, Krueger-Paisley et al, 1997, LeDuc, 1997, Mudge et al, 1998). Patients' satisfaction could be also improved as patients would avoid burning and pain experienced sometimes when using heparin (Goode et al, 1993, Kleiber et al, 1993). Thus, use of saline for maintaining patency of PIID's could improve quality of care since it is a safe and cost-effective procedure (Muir-Gray, 1997) contributing to patients' satisfaction, which is an important indicator for improvement of quality care (Cleary and McNeil, 1988, Donabedian, 1988).

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