Topical Arnica and mucopolysaccharide polysulfate (Hirudoid) to decrease bruising and pain associated with haemodialysis cannulation-related infiltration: a pilot study
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Abstract

Background: Topical treatments such as Arnica cream and mucopolysaccharide polysulfuric acid (contained in Hirudoid cream) have been used to treat the bruising and pain arising from dialysis-related infiltrations.

Aim To undertake a randomised controlled pilot study comparing the efficacy of Arnica and Hirudoid creams in treating bruising and pain following post-needling infiltration.

Methods One dialysis centre of 40 patients over a 12-month period. Following infiltration, and at the five subsequent dialysis treatments, pain was measured using the Abbey pain scale and size of the bruise was recorded.

Results Eleven cases of infiltration were recorded consisting of seven males (64%) and four females (36%) who had a mean age of 78 years (SD=9). Access for eight patients was via arteriovenous fistula and for three patients via arteriovenous graft. Eight patients experienced bruising and two patients reported mild pain post-infiltration but there were no differences found between the effect of Arnica or Hirudoid in treating either symptom.

Conclusion This pilot study was unable to detect any differences in the effect of Arnica and Hirudoid on pain or bruising. The study demonstrated that a larger, multicentre trial would be required to power a study and that a non-interventional control group should be added.

Keywords
Extravasation, haemodialysis, cannulation, arnica, mucopolysaccharide polysulfate.

Background

People receiving haemodialysis require access to large blood flows via the use of the native arteriovenous fistula (AVF), arteriovenous graft (AVG) or central venous dialysis catheter (CVDC). A frequent complication when using AVFs and AVGs is infiltration or extravasation (bruising caused by blood leaking into tissues around blood vessels) related to cannulation (needling) (Padberg et al., 2008). This can be minor, such as swelling with fistula usable for the next dialysis, major such as significant bleeding and swelling requiring greater than seven days of recovery, or severe requiring blood transfusion treatment and/or hospital admission (Lee et al., 2011). Although most infiltrations are minor, the resulting bruising and pain can cause discomfort. Treatments ranging from pressure, topical creams and ice are used to minimise swelling and bruising (Lee et al., 2006). There remains, however, limited research informing effective treatment of post-infiltration bruising and pain.

Topical treatments such as Arnica and Hirudoid creams have

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been used in the treatment of bruising and pain associated with dialysis needle infiltration of the AVF or AVG (Niu, 2009; Yang et al., 2008). Arnica is sourced from an organically grown alpine plant and is available without prescription, usually from homeopathic outlets. Arnica has been shown to have anti-inflammatory and analgesic properties (Kouzi & Nuzum, 2007) and has been used for centuries to treat muscle, joint and cartilage pain (Cohen et al., 2000). A small number of positive research findings have been reported (Reddy et al., 2013), including effective reduction of laser-induced bruising (Leu et al., 2010), oedema following rhinoplasty (Totonchi & Guyuron, 2007), and ecchymosis following rhytidectomy (Seeley et al., 2006). Despite these positive findings, the broader literature is equivocal and suggests that Arnica is no more effective than placebo in treating bruising, pain and swelling (Kouzi & Nuzum, 2007).

Hirudoid cream contains mucopolysaccharide polysulphate (MPS), a semi-synthetic glycosaminoglycan with a mean molecular mass of 9700 with multifold actions. MPS has various effects on blood coagulation, fibrinolysis and platelet function (Haas et al., 2001). Creams containing MPS have been used for the topical treatment of superficial thrombophlebitis, haematoma, and sports injuries (Haas et al., 2001) and have been shown to reduce complications and extend the duration of AVFs for dialysis patients (Yang et al., 2008). There has been limited research comparing these two treatments and the success of these creams is unclear.

**Aim**
The aim of this pilot study was to compare the efficacy of Arnica and Hirudoid creams in treating bruising and pain following post-needling infiltration.

**Methods**

**Sample**
The study was conducted at one satellite haemodialysis unit in Melbourne, Australia. Inclusion criteria were: patients aged 18 years and over, a functioning AVF or AVG, able to understand and converse in the English language, able to provide informed consent, receiving nurse-assisted haemodialysis for greater than three months, and experienced an episode of infiltration in the dialysis unit during the study period. Ethics approval was received from Monash Health (#11246Q).

**Procedure**
Patients who provided informed consent to participate in the study were alternately randomised to either the Arnica (n=6) or Hirudoid (n=5) group. Allocation to each treatment group was determined based on the selection of a sealed envelope by the treating nurse. The envelopes were locked in a filing cabinet and accessed when a patient was recruited. Treatment allocation and instructions were enclosed within the blank envelopes. There was an equal number of envelopes for Arnica and Hirudoid creams and the envelopes were shuffled each time a patient was recruited. It was not possible to know which treatment

<table>
<thead>
<tr>
<th>Patient</th>
<th>Time 1</th>
<th>Time 2</th>
<th>Time 3</th>
<th>Time 4</th>
<th>Time 5</th>
<th>Time 6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Arnica 1</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
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<tr>
<td>Arnica 2</td>
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<td>0</td>
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<td>0</td>
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<td>Arnica 3</td>
<td>4</td>
<td>4</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
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<tr>
<td>Arnica 4</td>
<td>36</td>
<td>25</td>
<td>49</td>
<td>49</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Arnica 5</td>
<td>12</td>
<td>12</td>
<td>16</td>
<td>24</td>
<td>14</td>
<td>12</td>
</tr>
<tr>
<td>Arnica 6</td>
<td>104</td>
<td>100</td>
<td>100</td>
<td>100</td>
<td>-</td>
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</tr>
<tr>
<td>Hirudoid 1</td>
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<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Hirudoid 2</td>
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<td>50</td>
<td>140</td>
<td>91</td>
<td>22</td>
<td>0</td>
</tr>
<tr>
<td>Hirudoid 3</td>
<td>20</td>
<td>16</td>
<td>16</td>
<td>16</td>
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<td>0</td>
</tr>
<tr>
<td>Hirudoid 4</td>
<td>4</td>
<td>2</td>
<td>2</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Hirudoid 5</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

Table 1: Size of post-extravasation bruising (area mm²)
condition was selected until the envelope was opened. Before commencing any treatment, the size of any resultant bruising was measured and the level of patient pain was recorded. For both treatment conditions, the treatment was applied in the dialysis unit soon after infiltration occurred and the patient was provided with a tube of cream to apply twice per day to the affected area.

Data collection
Data collection commenced in July 2012 and continued for 12 months. In the event of infiltration, data were collected that day and at the five subsequent haemodialysis treatments over a two-week period (that is, six data points). Patient pain/discomfort was measured using the Abbey pain scale (Abbey et al., 2004). This scale contains six indicators of pain (for example, vocalisation, physiological change), rated on a four-point scale from 0 (absent) to 3 (severe). Scores for the six items are summed to produce a total pain score that can be classified as no pain (0–2), mild (3–7), moderate (8–13), or severe (14+). The size of the bruise (area mm²) was also recorded at each appointment over two weeks.

Data analysis
Data were entered into IBM SPSS Statistics, Version 22 (IBM Corp, Armonk, NY, USA). Comparative analyses were not feasible due to the unanticipated small sample sizes. Analysis was, therefore, limited to descriptive statistics (for example, frequencies, mean, SD).

Results
Over the 12 months of data collection, only 11 cases of post-cannulation infiltration were recorded and all of these patients consented to participate in the study. This included seven males (64%) and four females (36%) who had a mean age of 78 years (SD=9, range=64–90 years). Access for six patients was via left AVF, for two patients via right AVF, and for three patients via right AVG.

Pain
On the day of the infiltration (Time 1), four patients in the Arnica group scored between 0 and 2 points (no pain) on the Abbey pain scale, and the remaining two patients scored between 3 and 7 points (mild pain). At all subsequent data collection points, participants in the Arnica group received a score of zero. All patients in the Hirudoid group received a score of zero on the day of the infiltration (Time 1) and at all subsequent data collection points.

Bruising
Three patients (Arnica n=1; Hirudoid n=2) experienced infiltration without any bruising. Of the remaining eight patients who experienced a bruise, the size on the day of infiltration ranged from 4–104 mm² (Mean=28.00, SD=32.55) (Table 1). The bruises for two participants in the Arnica group had disappeared completely by Time 3 but one patient had a bruise that was still evident by Time 6. Data for the remaining two participants were incomplete beyond Time 4. The bruise of one participant in the Hirudoid group had disappeared by Time 4, and one disappeared by Time 5; however, the bruise for the third participant increased to over five times its original size by Time 3 before reducing back to its original size by Time 5.

Discussion
People receiving dialysis may experience unpleasant bruising and pain following cannulation-related infiltration (Dinwiddie et al., 2013) and this was clearly demonstrated in this study. Both Arnica and Hirudoid were associated with decreased bruising and pain; however, whether the creams made any difference than normal healing could not be confirmed. This pilot study was unable to detect any difference in the effect on pain and bruising of Arnica or Hirudoid.

Studies measuring the effects of Arnica and Hirudoid provide mixed results. Although Arnica has been shown to reduce bruising and swelling in small clinical trials (Levy & Emer, 2012) other studies suggest only limited effects on bleeding, inflammation, pain or myocardial ischaemia (Cornu et al., 2010), postoperative pain, bruising and swelling (Stevinson et al., 2003) and no better than placebo for post eye surgery bruising (Perry, 2011). Hirudoid has been shown to be effective in reducing bleeding-related complications (Yang et al., 2008) but the evidence is limited.

In this study only minor infiltrations occurred with no access losses recorded. Severe infiltrations can lead to access loss (Brouwer, 2011) and can delay access usage (Dinwiddie et al., 2013). If Arnica and Hirudoid are effective in reducing pain and bruising, there may be clinical implications for these topical treatments in major or severe infiltrations.

The main function of a pilot study is to inform the methods and design for a future larger study. Over a 12-month period in a 40 patient dialysis unit there were only 11 episodes of cannulation-related infiltration that met the inclusion study criteria. Clearly an increased participant group from a greater number of dialysis centres would need to be included in order to power a larger study.
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Study limitations
The major limitations were the small number of recruited participants and the lack of a non-intervention control group.

Conclusion
This pilot study was unable to demonstrate any differences between the effect of Arnica or Hirudoid creams in reducing pain and bruising post-cannulation infiltration. The study highlighted the challenges in recruiting for this type of study. Over a period of 12 months in one 10-chair dialysis unit only 11 occasions of infiltration were recruited into the study. A much greater population of more than one dialysis centre would be required to power a larger study. Results from a larger study may have relevance to other areas of cannulation (for example, oncology, haematology, emergency) and surgery.

References


