Equipment

A Prospective Clinical Comparison of Two Intravenous Polyurethane Cannulae

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SUMMARY

Tissue irritation, as evidenced by phlebitis, associated with Optiva™ (Johnson & Johnson Medical) and Inxye™ (Becton Dickinson) polyurethane cannulae was studied. The integrity of the cannula on removal, the incidence of infection at the cannula site and the factors which influence phlebitis were also examined.

One thousand and eight patients had a polyurethane cannula placed for induction of anaesthesia for cardiac surgery. After surgery, the cannula was examined every 24 hours. If evidence of phlebitis occurred, the cannula was removed and sent for culture. All remaining cannulae were removed at 72 hours and the site examined daily for a further three days.

There were 503 Optiva™ and 505 Inxye™ cannulae studied. The distributions between the two cannulae with respect to patient characteristics, gauge of cannula, number of attempts and difficulty of insertion, cannula site and anaesthetist inserting were similar. The early removal rate for both groups was 47%.

Overall phlebitis rate with Optiva™ was 31% and Inxye™ 33%. This difference is not statistically significant. The cumulative phlebitis rate increased with time but did not differ between the two types of cannula.

Minor tip distortion or shaft kinking of the cannulae occurred in 16.2% of Optiva™ and 23.5% of Inxye™. This difference is statistically significant and may relate to the slightly more acute angle at the Optiva™ cannula tip. Both cannulae were similar in clinical performance.

Key Words: EQUIPMENT: polyurethane cannulae; ANAESTHETIC TECHNIQUES: intravenous cannulation; COMPLICATIONS: phlebitis

Phlebitis is a well recognized complication of intravenous therapy. Several factors have been shown to contribute to phlebitis. Maki and Ringer reported a risk of phlebitis over 50% after four days insertion and identified patient and other factors which contributed to the phlebitis rate. Female patients were found to be 1.9 times more likely to get phlebitis and insertion on the forearm was more likely to result in phlebitis than insertion into the hand or wrist. They also reported that the catheter material affected the incidence of phlebitis. A cannula made from Teflon™ was 1.37 times more likely after a few days to cause phlebitis than one made with polyurethane (Vialon™). Larson and colleagues suggested that this might be explained by chemical leaching from the different cannula materials. A difference in phlebitis rates for the two materials was supported by a study by McKee et al in 199 patients. They found a phlebitis rate at 72 hours of 31% for Vialon™ and a 51% rate for Teflon™. A larger study of 945 cannulae used for induction of anaesthesia by Gaukurger et al but which remained in for up to four days also found that Vialon™ had only 54% of the phlebitis risk of Teflon™. However, a double-blind randomized controlled comparison of both types of cannulae at the Central Middlesex Hospital in London failed to find any difference in phlebitis rate over five days.

The difference in findings is difficult to explain.

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One possible explanation is the difference in treatment of the Teflon™ surface. All the positive studies were comparing the Insize™ made of Vialon™ by Becton Dickinson with the Jelco™ made of Teflon™ by Johnson & Johnson Medical. The negative study used a Teflon™ Vasuol™ cannula made by Viggo Spectramed. The microscopic surface properties of similar material can be different. A study by Fobes et al of polyurethane catheters showed that the smoothness of the surface differed substantially and the smoother surfaces were associated with a lower bacterial colonization after one hour of incubation. Thus even if cannulae are made of the same material, other factors may still create a significant difference in the clinical phlebitis rate. Although the new Optiva™ cannula is made of polyurethane, the cannula is transparent and claimed by the company to be an improvement on the Vialon™ polyurethane. In addition, the inserting needle is of a different profile, being back-sharpened and it is claimed that about a 20-30% smaller force is required for needle and cannula insertion. This could alter the tissue damage on insertion.

As the major concern for most clinicians is how long they can use an intravenous cannula, a trial was designed to prospectively compare the two clinically available polyurethane cannulae, Optiva™ from Johnson & Johnson Medical and Insize™ from Becton Dickinson with particular reference to phlebitis, which is the most common limiting factor for long term use.

**METHODS**

Patients undergoing cardiac surgery were randomly allocated to have their induction through either an Optiva™ or Insize™ polyurethane cannula. Randomization was determined by a table of random numbers. All patients were greater than 18 years old and gave informed consent as approved by the Royal Adelaide Hospital Ethics Committee.

Patients were excluded if informed consent was not possible or the patient refused. They were also excluded if there was evidence of infection, or the cannula was not suitable for the patient.

The chosen cannula was inserted by an experienced anaesthetist and then connected to an infusion set running a balanced electrolyte solution. This set was used for the induction of anaesthesia and the administration of drugs and fluids during the operation. After the patient was in the cardiac intensive care and stable so that this IV line was no longer required, the cannula was capped and flushed with heparin saline. This cannula then remained in for a total of three days, after which it was removed and the site observed daily for a further three days for evidence of phlebitis or infection. After capping, an injection through the cannula of heparin saline flushing solution (50 units in 5 ml) was ordered every four hours.

Daily monitoring of the cannula site was performed by one of the three study nurses. The cannula site was assessed for any signs of phlebitis such as erythema, oedema, pain or tenderness, streak formation, a palpable venous cord or any exudate. If this occurred within the three days, the cannula was removed. If evidence of phlebitis occurred at any time during the six days observation, the site was swabbed and the swab sent for culture. In addition, the degree of phlebitis was graded as mild (pain and/or erythema), moderate (oedema and/or streaking along vein) or severe (a palpable venous cord and/or exudate at cannula site). If a patient had more than one symptom or sign, then the highest appropriate category was used. This scoring was done at the time the cannula was removed or during the subsequent post-decanulation observation and the maximum reaction scored.

Immediately after removal, the cannula was examined macroscopically and any damage or deformation recorded.

Demographic data was collected on the patients and a record was kept of all drugs administered during the three days the cannula was in. In addition, data about the insertion was also recorded. This included the anaesthetists, the size of the cannula, the site of insertion, and the ease of insertion.

Statistical analysis of the cannula duration was by survival analysis using a Kaplan-Meier estimation and multivariate modelling was done using a Cox proportional hazards model with co-variates. The initial variables for the stepwise regression were chosen by a t-test, Chi square, or Wilcoxon as appropriate with a threshold P-value of 0.2.

**RESULTS**

One thousand and eight patients had cannulae inserted for more than 12 hours. Five hundred and three received Optiva™ cannulae and 505 received Insize™ cannulae. These two groups are well matched with respect to age, sex, weight, diabetes, preoperative white cell count and preoperative blood sugar (Table 1). Similarly the two groups were well matched for factors relating to the insertion of the cannula (Table 2).
COMPARISON OF POLYURETHANE CANNULAE

One possible explanation is the difference in treatment of the Teflon™ surface. All the positive studies were comparing the Insite™ made of Vixion™ by Becton Dickinson with the Jelco™ made of Teflon™ by Johnson & Johnson Medical. The negative study used a Teflon™ Vascu™ cannula made by Vigo-Spectramed. The microscopic surface properties of similar materials carried by the study by Bebbins et al. of polyurethane catheters showed that the smoothness of the surface differed substantially and the smoother surfaces were associated with a lower bacterial colonization after one hour of incubation. Thus even if cannules are made of the same material, other factors may still create a significant difference in the clinical phlebitis rate. Although the new Optiva™ cannula is made of polyurethane, the cannula is transparent and claimed by the company to be an improvement on the Vixion™ polyurethane. In addition, the inserting needle is of a different profile, being back-barbed and it is claimed that about a 20-30% smaller force is required for needle and cannula insertion. This could alter the tissue damage on insertion.

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METHODS

Patients undergoing cardiac surgery were randomly allocated on the basis of their indication through either an Optiva™ or Insite™ polyurethane cannula. Randomisation was determined by a table of random numbers. All patients were greater than 18 years old and gave informed consent as approved by the Royal Adelaide Hospital Ethics Committee. Patients were excluded if informed consent was not possible or the patient refused. They were also excluded if there was evidence of infection, or the cannule were not suitable for the patient.

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RESULTS

One thousand and eight patients had cannula inserted for more than 12 hours. Fifty and three received Optiva™ cannulae and 503 received Insite™ cannulae. These two groups are well matched with respect to age, sex, weight, diabetes, preoperative white cell count and preoperative blood sugar (Table 1). Similarly the two groups were well matched for factors relating to the insertion of the cannula (Table 2).

<table>
<thead>
<tr>
<th>TABLE 1</th>
<th>All Patients (n=1008)</th>
<th>Optiva™ (n=503)</th>
<th>Insite™ (n=505)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>Mean</td>
<td>65.5 (75%)</td>
<td>65.2 (75%)</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>Mean</td>
<td>77.0</td>
<td>75.9</td>
</tr>
<tr>
<td>History of diabetes</td>
<td>Yes</td>
<td>58 (12%)</td>
<td>60 (12%)</td>
</tr>
<tr>
<td>White cell count</td>
<td>10(9)</td>
<td>7.4</td>
<td>7.5</td>
</tr>
<tr>
<td>Blood sugar level</td>
<td>18(18)</td>
<td>6.3</td>
<td>6.5</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>TABLE 2</th>
<th>All Patients (n=1008)</th>
<th>Optiva™ (n=503)</th>
<th>Insite™ (n=505)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cannula gauge</td>
<td>14 ga</td>
<td>95 (99%)</td>
<td>100 (99%)</td>
</tr>
<tr>
<td>Cannula site</td>
<td>Left</td>
<td>464 (92%)</td>
<td>464 (92%)</td>
</tr>
<tr>
<td>Degree of difficulty</td>
<td>Easy</td>
<td>440 (88%)</td>
<td>434 (86%)</td>
</tr>
<tr>
<td>Number of attempts</td>
<td>1</td>
<td>445 (88%)</td>
<td>435 (86%)</td>
</tr>
<tr>
<td>Anaeosthesist</td>
<td>1</td>
<td>92 (18%)</td>
<td>113 (22%)</td>
</tr>
<tr>
<td>Site of cannula</td>
<td>Antecubital</td>
<td>123 (24%)</td>
<td>101 (20%)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>TABLE 3</th>
<th>All Patients (n=1008)</th>
<th>Optiva™ (n=503)</th>
<th>Insite™ (n=505)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Non cannula-related</td>
<td>End of Trial</td>
<td>338 (65%)</td>
<td>319 (65%)</td>
</tr>
<tr>
<td>Ischaemic event</td>
<td>264 (53%)</td>
<td>264 (53%)</td>
<td>264 (53%)</td>
</tr>
</tbody>
</table>

FIGURE 1: The survival of the two types of cannula for the freedom from phlebitis at the cannula or cannula site. The Optiva™ survival line is shown as solid diamond joined by a continuous line. The survival curves have been extended beyond day 6 for clarity. The Insite™ is shown as a solid diamant joined by a dashed line. Although there is a higher mortality of the Optiva™ cannulae, this is not statistically significant.

<table>
<thead>
<tr>
<th>TABLE 4</th>
<th>All Patients (n=1008)</th>
<th>Optiva™ (n=503)</th>
<th>Insite™ (n=505)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Variable</td>
<td>Coef</td>
<td>Std.</td>
<td>Hazard Ratio</td>
</tr>
<tr>
<td>Eurofail</td>
<td>0.66</td>
<td>0.23</td>
<td>1.94</td>
</tr>
<tr>
<td>Site of cannula</td>
<td>Antecubital</td>
<td>1.05</td>
<td>0.12</td>
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<tr>
<td>Eurostasis</td>
<td>0.79</td>
<td>0.09</td>
<td>1.20</td>
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<tr>
<td>Nitis/acenter</td>
<td>0.51</td>
<td>0.05</td>
<td>1.00</td>
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</table>

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In both groups 47% of the cannulae were removed before the three days had expired. The commonest reason for removal was phlebitis (Optiva® 22% and Insyte® 25%); the difference is not significant (P=0.37 Fisher). A complete list is given in Table 3.

With both cannulae there was a progressive increase in phlebitis while the cannula remained in and some continued phlebitis in the three days after removal (Figure 1). However, although the Optiva® cannula had a slightly lower progressive incidence, this difference was not statistically significant. The adjusted survival for Optiva® after six days was estimated at 68.7% (95% CI 64.6-72.8) and for Insyte® was 67.2% (95% CI 63.1-71.3).

Only three factors were identified as influencing the incidence of phlebitis with the Con proportional hazards model. These were: the use of cannula, the site of the cannulation and the nurse observer identifying phlebitis (Table 4). The hazard ratio expresses the increased risk of the factor being present, e.g. cannulation on the forearm increased the risk of phlebitis 29% (confidence interval 0-43%, P=0.04).

The severity of phlebitis with each type of cannula was also assessed. At each grade the level of phlebitis was similar with both cannula (P=0.61 Chi square, Figure 2). In addition, the type of reaction was also similar (Figure 3). None of these reaction differences between cannulae was statistically significant (all categories P>0.01).

When the cannulae were removed, the shaft and tip of every cannula were examined. Evidence of damage was noted in 80 Optiva® cannulae and 120 Insyte® cannulae (Figure 4). Shaft kinking occurred to both types in about equal frequency (6.1% and 8.2% respectively). However, the incidence of tip damage or distortion with Insyte® was significantly greater than with Optiva® (P=0.001 Fisher).

DISCUSSION

The two cannulae groups are very well matched for the characteristics examined and gives grounds for confidence in the randomization. There was no statistically significant difference in phlebitis between the two cannulae three days after insertion and in the subsequent three days of observation. The incidence of phlebitis over the six days was 31% with the Optiva® cannula and 33% with the Insyte®. With 1008 patients and assuming an α=0.20, this trial has an estimated power of 87% to detect a real difference of 5%. As the difference in phlebitis score was 2% it is unlikely that a clinically significant difference in these two cannulae has been missed.

Although 22% of the Optiva® and 25% of the Insyte® were removed because phlebitis was identified, a further 15% of Optiva® and 12% of Insyte® cannulae were removed early for other reasons. The survival incidence at day 3 adjusted for the non-phlebitis removals is 75.3% (95% confidence intervals 71.5-79.1) for Optiva® and 73.1% (95% CI 69.5-77.0) for Insyte® respectively. At day 6 the survival (i.e. non-phlebitis rate) is 68.7% (95% confidence interval 64.6-72.8) for Optiva® and 67.2% (95% CI 63.1-71.3) for Insyte®. This shows that in both groups there was about 10% additional phlebitis over the three days after removal. The first day post-removal, however, has about 50% of the additional phlebitis and if the second day is included this will cover over 88% of the delayed phlebitis. Thus this pattern is faster than an exponential decay and can be reasonably extrapolated that over 90% of the additional change will be observed within the three days.

Figure 2: Comparison of the incidence and degree of phlebitis found in the Optiva® and Insyte® cannulae. Most cannulae showed no phlebitis but in those which did the grades of severity were equally distributed between the two types.

Figure 3: Comparison of the type and frequency of phlebitis found in the Optiva® and Insyte® cannulae. Most cannulae showed no phlebitis but in those which did the patterns of the phlebitis response were equally distributed between the two types.

Figure 4: Comparison of the type of cannula damage found with the Optiva® and Insyte® cannulae. Tip damage was more frequent with the Insyte® (P=0.001). However, this did not appear to affect the incidence of clinical phlebitis.
The Cox's proportional hazard model to identify the major factors in phlebitis in this study found three parameters of interest. The use of esmolol is identified as the most significant factor. This must remain in doubt as the number of patients receiving esmolol was very small. However esmolol is well known to provoke histamine release so that a phlebitic enhancement may be expected. The site of cannulae is of significance as the use of the mid forearm veins is common. Possibly in the cardiac scenario when patients are cold and vasoconstricted these veins are experiencing an unusually low flow as they tend to be superficial.

It appears that in spite of differences in appearance and needle profile, both the Optiva™ and the Fiaxyle™ cannulae have a similar risk of phlebitis in clinical use and similar survival expectations.

ACKNOWLEDGEMENT

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REFERENCES


