Intravascular administration sets are accurate and in appropriate condition after 7 days of continuous use. An in-vitro study.

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ABSTRACT

Background. The ideal duration of intravascular administration set use is unknown. Studies have compared the infective implications of one to seven days of use. The Centers for Disease Control recommend at least three days usage. No previous study has evaluated the accuracy of volume delivery or integrity of administration sets after prolonged use.

Aim. To evaluate the accuracy and condition of intravascular administration sets used continuously for 7 days.

Design. Prospective, randomised, experimental study in the laboratory setting.

Methods. Four administration sets were randomly assigned to deliver 2 mL/h (IMED® syringe set 2280-0000), 20, 50 or 100 mL/h (IMED® infusion sets 2210-0500) of crystalloid solution continuously for 7 days through an IMED® Gemini® four channel infusion pump (PC4). At study commencement and daily for 7 days, a 4 hour volume measurement and an inspection for leaks/erosion of administration sets occurred for each administration set (total measurements = 32).

Results. Mean volume outputs over four hours were 7.84mL (2mL/h), 80.66 mL (20mL/h), 205.35 (50 mL/h) and 406.37 (100 mL/h). These differed significantly from the programmed volumes ($p = 0.00 – 0.01$). Usage duration did not influence performance ($F = 0.866$, $p = 0.55$). Accuracy of volume delivery differed significantly with pump speed ($F = 106.933$, $p < 0.001$) exhibiting increased volume to 50 mL/h then a reduction at 100 mL/h. Differences were within manufacturer specifications (+/- 5%) and were clinically acceptable. All administration sets remained in appropriate condition displaying no leakage or erosion.

Conclusion. There were small inaccuracies found between programmed and delivered volumes however there was no deterioration in performance over time. This suggests that inaccuracies were due to normal pump performance rather than the administration sets. Administration sets retain acceptable accuracy and condition after 7 days continuous use. Further research should assess the infective and other impacts of prolonged usage.

(Word count = 300)

BACKGROUND

Introduction

Intravascular administration sets are used for the administration of fluid, nutrition and medication, and also for the maintenance of intravascular pressure monitors (Raad & Darouiche *et al.* 1997). The administration set is minimally a length of tubing (often called a "giving set") connecting to the fluid reservoir (commonly a bag or syringe) at one end, and to the intravascular catheter at the other. Additionally, they may be enhanced by the incorporation of burettes or extension tubing, which should also be considered part of the administration set. Duration of administration set usage is determined by three factors. The first factor, commonly focussed on in the literature, is the potential for administration sets to provide a portal for infection. The second factor, also discussed in the literature, is the significant financial costs of administration sets and the nursing time required to configure them. The third factor seems to be the most basic, the actual physical capability of administration sets to continue performing acceptably over a prolonged period of time. The relationship between physical performance and duration of administration set use has not been addressed previously in the literature.

Historical Developments

Prior to 1970, administration sets were changed only when intravenous therapy was ceased or if the administration sets malfunctioned (Maki *et al.* 1976). In 1970 and 1971, an epidemic of catheter-related infection ensued in the United States secondary to manufacturer contaminated intravenous fluid. In 1971, in response, the Centers for Disease Control (CDC) recommended that 24 hour routine administration set changes be implemented. This practice became internationally accepted in developed countries and was not questioned for some years until

researchers began to publish studies advocating the prolongation of usage to 48 hours which allowed costs savings with no impact on infection (Band & Maki, 1979, Buxton *et al.*1979, Gorbea *et al.* 1984). In 1982, the CDC revised its guidelines to support the 48-hour administration set usage in most circumstances (CDC Working Group 1982). Researchers continued to examine the issue, evaluating 72, 96 and 120-hour usage (Josephson *et al.* 1985, Sitges-Serra *et al.* 1985, Jacobsen *et al.* 1986, Maki *et al.* 1987, Snydman *et al.* 1987, Robathan *et al.* 1995, Matlow *et al.* 1999). The CDC last revised its recommendations in 1996 to advocate the replacement of administration sets '72 hours or more after initiation of use' (Pearson *et al.* 1996 p.269). The actual duration of usage currently practiced by clinicians is unknown, with manufacturers advising replacement as per 'CDC guidelines or hospital policy' (ALARIS™ Medical Systems 1999 p.1). There have been two studies published giving some support to 168 hour administration set use (Chen *et al.* 2000, Raad & Hanna *et al.* 2001) and it is suspected some hospitals have implemented 168 hour or even longer intervals between changing administration sets, motivated by the reduction in material costs that this can achieve. Notably, all published works have focussed on infection control and financial endpoints, with none commenting on the physical condition or capability of administration sets after prolonged use.

Duration of Intravascular Administration Set Use and Infection Risk

Intravascular catheters break the skin, the body's natural defence barrier, putting the patient at risk of hospital acquired infection (Band & Maki 1979). This may lead to overwhelming costs not only for the patient, but also for the health system in terms of increased length of stay and treatment costs (Darouiche & Raad 1998). Pathogens may enter the patient at either the catheter skin site, or through any of the connections of the administration set. Intravenous fluid may harbour microorganisms, and upon connection to the administration set, these microorganisms may travel through the set and into the patient's vasculature. Alternately, the

administration set may be contaminated from the hands of clinicians or from the physical environment when the various interlocking sites of the system are connected or disconnected. Clinicians manipulate administration sets on multiple occasions; to initially set up the system, to accommodate changing treatment needs (such as adding a burette or extension tubing), to replace fluid bags and/or syringes. Many strategies are used by clinicians to minimise the risk of infection, one of these being the routine replacement of administration sets more frequently than the catheter itself is resited.

Duration of Intravascular Administration Set Use and Financial Costs

Due to the high volume of administration sets used in acute care settings, variation in duration of use has significant cost implications. The routine replacement of an administration set requires multiple possible variations of syringes, giving sets, burettes, extension and/or transducer tubing. Additionally required are new intravenous fluids (with or without medication additives), the dedicated time of one or more skilled nurses, large amounts of sterile products and the associated infection control drapes, gowns, gloves, disinfectants and so on. A single patient's administration set change may be up to $A300 in material costs alone for a complex intensive care patient. For an 18-bed unit such as the authors', decreasing routine administration set replacements from the current twice per week to a once per week policy would lead to savings of up to $A115,000 per year. It is not surprising, therefore, that hospitals have been eager to prolong administration set usage.

Duration of Intravascular Administration Set Use and Administration Set Performance

It is of utmost importance that administration sets are used in appropriate condition. An inaccurate administration set will not deliver prescribed treatment, perhaps leading to

subtherapeutic or over-dosage. Leakage of fluid from administration sets may pose an electrical or slippage hazard. Cytotoxic or biological fluids additionally may put the patient, visitors or staff at risk. It is likely that clinicians and researchers will continue to evaluate an increasingly prolonged duration of administration set usage. Although one could assume that administration set performance remained acceptable in the previously published infection-focussed studies, it is not necessarily safe to do so. The research projects were designed to detect changes in infection parameters (Band & Maki 1979, Buxton *et al.* 1979, Gorbea *et al.* 1984, Josephson *et al.* 1985, Sitges-Serra *et al.* 1985, Jacobsen *et al.* 1986, Maki *et al.* 1987, Snydman *et al.* 1987, Robathan *et al.* 1995, Matlow *et al.* 1999, Chen *et al.*2000), Raad & Hanna *et al.* 2001) and it is possible that any trends in physical performance may have been overlooked. Presumably manufacturers have tested their equipment, although to what time frame is unknown, as this data has not been published. Administration sets are a disposable item subjected to physical pressures from the mechanical pump and staff/patient actions. Intuitively, the physical wear and tear sustained during use must eventually reduce performance, although the time frame for this to occur is unknown. Infection control is obviously a major concern when determining the appropriate length of administration set usage. However, as studies continue to be published without any report of the physical performance of administration sets, it becomes more concerning whether these administration sets suffer loss of accuracy or physical integrity over time.

AIMS

The aims of this study were:

1. To test the accuracy of volume delivery of administration sets over 7 days of continuous use.

2. To test the physical condition of administration sets over 7 days of continuous use.

DESIGN

This study utilised a prospective, randomised, experimental design with repeated measures.

HYPOTHESES

There is no significant difference between the programmed and delivered volumes of administration sets over 7-days of continuous use.

There is no significant difference in the physical condition of administration sets used continuously over 1, 2, 3, 4, 5, 6 and 7 days.

METHOD

Setting

The study was undertaken in 1998 in the laboratory of the Department of Intensive Care, Royal Brisbane Hospital. The Royal Brisbane Hospital is an 800 bed, tertiary level, university affiliated hospital.

Sample and Equipment

Daily repeated measures were undertaken on four administration sets, which were the unit of measurement for the study (N=4). Three IMED® infusion (2210-0500) administration sets and one IMED® syringe (2280-0000) administration set were studied in the laboratory setting for 7 days of continuous use. Administration sets were infused through the commonly used IMED® Gemini® four channel infusion pumps (PC4, ALARIS™ Medical Systems, San

Diego, CA, USA). The same infusion pump channel was used for each administration set for the duration of the study.

Procedures and Data Collection

Administration sets were set up by a registered nurse as per clinical practice and manufacturer's instructions to deliver 2, 20, 50 or 100 mL/h of crystalloid solution. The syringe administration set was used at 2 mL/h. Infusion administrations sets were used for the other three pump settings. The pump speeds were selected to reflect clinically relevant rates and were randomly assigned to each administration set. The administration sets were run continuously through the pump at the assigned rate for 7 days. Immediately on commencing the experiment and at 24-hour intervals (each day) thereafter for 7-days, all eluent from the pump was collected for a precisely measured 4-hour period by a laboratory scientist (S.W.). The total period of the experiment was therefore 172 hours; 168 hours for the 7 day experiment plus the final four hour measuring period after day 7 had elapsed.

Eluent was collected in scientifically exact glass measuring cylinders. During collection, the measuring cylinders were covered with Parafilm® laboratory film to seal against any evaporation (American National Can, Greenwich, CT USA). The volume and tolerance of the cylinders, and the accuracy with which they could be read, for each pump speed is shown in Table 1.

Daily inspection of administration sets was undertaken by one of the investigators (C.R.) to assess for any deterioration in physical condition over time. Administration sets were examined visually and manually in a brightly lit room to assess for fluid leakage and for any signs of physical erosion.

(Insert Table 1)

Statistical Analysis

Descriptive statistics were calculated for all variables. Paired t-tests were performed to test for difference in programmed and delivered volumes for each of the administration sets. The administration set was the unit of measurement. Output volumes from all four administration sets were standardised to the 2 mL/h set to allow comparison between performances at differing speeds of volume delivery. A general linear model (ANOVA) +/- a Scheffe post hoc test to isolate difference was fitted to the standardised values to determine the effect of day of measurement and effect of volume delivery rate on the accuracy of volume delivery. As there was a null incidence of physical deterioration amongst the administration sets, further analysis was inappropriate for this variable.

Institutional Approval

Institutional Ethics Committee approval was not required as this was an *in vitro* study with no impact on patient care or confidentiality. The nursing and medical directors reviewed the research proposal prior to implementation and their consent for use of resources was obtained.

RESULTS

Accuracy of Volume Delivery

The mean output for the 2, 20, 50, and 100 mL/h administration sets over 4 hours was 7.84, 80.66, 205.35 and 406.37 mL respectively. This is in contrast to the respective programmed

outputs of 8 mL, 80 mL, 200 mL and 400 mL. The minimum, maximum and mean 4-hour volume outputs appear in Table 2.

(Insert Table 2)

To assess the accuracy of infusate volume delivered, t-tests were performed for each of the 4 administration sets to test for any difference between the mean 4 hour programmed and delivered volumes over the 7 day test period. For each of the 4 administration set speeds (2, 20, 50 and 100 mL/h), the test value was set at the mean programmed volume expected to have been delivered over the 4-hour test period for each respective administration set (8 mL, 80 mL, 200 mL and 400 mL). All four of the administration sets were found to output a significantly different mean volume when compared with the mean programmed volume at a 5% level of significance (p = 0.000 - 0.014). The results of this analysis appear in Table 3.

(Insert Table 3)

ANOVA was fitted to the standardised values to determine the effect of day of measurement on accuracy. Individual days of measurement did not significantly effect accuracy (F = 0.866, p = 0.55) for any of the administration sets. That is, once the administration set was set to a particular setting it stayed the same, on average, over time. If the administration set under-infused, it tended to under-infuse each day and vice-versa for over-infusers. Although there was variation each day, on average over time there was no change. Although the administration sets were not accurate, they were precise over time in their inaccuracy. Figure 1 displays the delivered volumes of the 4 administration set speeds standardised to 2 mL/h against each day of measurement. The nominal programmed volume output over the four hours was 8.0 mL for all four administration sets once standardised to 2 mL/h.

(Insert Figure 1)

ANOVA was also fitted to the standardised values to determine the effect of volume delivery rate on accuracy. Figure 2 displays the change in mean standardised delivered volumes against each programmed administration set rate (the nominal programmed volume output over the four hours was 8.0 mL for all four administration sets once standardised to 2 mL/h). The mean standardised values for administration set rates of 2 mL/h (7.84 mL), 20 mL/h (8.04 mL), 50 mL/h (8.21 mL) and 100 mL/h (8.12 mL) were significantly different from each other ($F = 106.933$, $p < 0.001$). A Scheffe post hoc test was applied to find out where the difference in performance occurred, and found that all 4 administration sets were significantly different from each other (when standardised) at a 5% level of significance. There was a trend to increasing output with administration set rates up to 50 mL/h with a reduction back at 100 mL/h.

(Insert Figure 2)

Administration Set Condition

There was no fluid leakage detected from any of the administration sets on any of the daily assessments. Similarly there was no evidence of erosion in the physical condition of the administration sets on any of the daily assessments. All administration sets remained in appropriate condition and, therefore, the planned statistical analysis was not undertaken for this variable.

DISCUSSION

This study has found administration set performance and condition to be indistinguishable after 7 days of continuous use, from that at commencement of use. Infection control issues

aside, this study provides support for prolonged use of intravascular administration sets of up to 7 days continuous use. Although the study found statistical differences between programmed and delivered volumes, discrepancies were not related to the duration of administration set usage. That is, there was no detectable deterioration over time in performance. The administration sets were not accurate, but they were no more or less accurate after 7-days of continuous use. The inaccuracies found did not seem to be a reflection on the performance of administration sets, but rather the 'normal' variation inherent in infusion pump performance. The manufacturer's specification for the infusion pump accuracy is +/- 5.0%. The difference detected in this study between programmed and delivered volumes ranged from -2.0 to + 2.7% and thus was well within the +/- 5.0% parameter. From a clinical perspective, the errors in volume delivery were small and should be interpreted as clinically acceptable error and of no risk to patients.

This study is the first to specifically address the appropriateness of using intravascular administration sets for extended periods of time from the perspectives of accuracy of volume delivery and administration set condition. The findings are significant because they complement results from previous works, which promote extended administration set usage as beneficial from financial and infection control perspectives. The results give support to clinicians who have chosen to implement findings from the few studies that have promoted >72 hour use.

This study should not be used as a basis for implementing 7 day administration set use in the clinical setting, as the study was not designed to evaluate the effect of 7 day use on catheter infection. There are only two *in vivo* studies to date evaluating the appropriateness of this time frame (Chen *et al.* 2000, Raad & Hanna *et al.* 2001). The study by Chen *et al.* has, to date, only been published in abstract form and although it recommends extended usage, there are concerns with generalisability because of its high reported catheter infection rate of 23%, as opposed to the more universally accepted rates of 3-7% quoted in the literature (Maki

1994). Raad & Hanna *et al.* have fully published their findings, and recommend extended usage in patients with a low risk of infection, however the study was small with only 26 patients receiving 7 day administration set changes.

Infusion rates chosen in the study were selected for their clinical relevance as rates commonly used in the adult patient population. It is possible that administration sets may perform differently at other rate settings, for example the miniscule volumes required in the treatment of neonatal patients (such as 0.1 mL/h).

It is possible that the same study with a larger sample size would have provided a different result. However although relatively few (four) administration sets were studied, the repeated measures design of four sets over 172 hours meant that the sample effectively consisted of 32 data points. Additionally the effect size of the experiment, with the finding of statistical significance in one variable (volume delivered) and the nil incidence of the other variable (set condition) suggests that a larger sample would not necessarily have yielded different data.

Each administration set was studied using the same infusion pump for the course of the study. This was done to control for any effect of the pumps on accuracy however it does leave open the question of whether inaccuracies detected were because of the inherent error of that particular pump or of all pumps at that setting. It was assumed for the purposes of this study that the regular servicing and testing regime endured by the infusion pumps rendered them identical to each other in performance.

Unfortunately one of the data points (the day 2) for volume output measurement of the 50 mL/h pump was missing due to the researcher error of not replacing the fluid bag before it ran through. This was treated on statistical analysis as missing data and it is doubtful that this would have significantly affected the results. The pump in question was continued and measured for an additional day after the conclusion of the study and whilst these results are

not reported, the reader may be interested to know that the results were comparable to those reported and included in analysis.

In the clinical setting, intravenous infusion fluids are pre-packaged in either glass bottles or plastic bags for large volume infusions (commonly intravenous fluid/electrolyte solutions) or plastic syringes for smaller volumes (commonly medication solutions). This study used infusion sets designed for both fluid bottles/bags as well as those for syringes, therefore, results should be seen as generalisable to both products.

The ideal time frame or even the absolute longest duration of administration set usage remains unknown with further randomised clinical trials evaluating the impact on infection rates required. The results of this current study provide a sound ethical platform upon which future *in vivo* studies can occur, as these findings show that administration sets remain accurate and in appropriate physical condition for at least 7 days under laboratory conditions. Further *in vitro* testing would not be inappropriate as patient variables may affect performance.

CONCLUSION

Volume delivery inaccuracies detected in this study seemed to be because of the inherent minor fluctuations of infusion pump performance rather than the administration sets. Inaccuracies were constant over the week of study; that is, they did not become worse the longer that the set was used. Inaccuracies found were small and clinically non-significant.

Intravascular administration sets are clinically accurate and maintain appropriate physical condition for 7 days of continuous usage in the laboratory setting. Future research could include replication of this study with a larger sample, different brands of intravenous fluid

pump or intravenous fluids, for example lipids, or additional pump speeds. Continued *in vivo*

experimentation of the relationship between prolonged administration set use and catheter

infection rates is also required.

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LIST OF TABLES AND FIGURES

TABLES

Table 1 Volume, tolerance and accuracy of measuring cylinders

Administration Set Rate (mL/h)	Cylinder Volume (mL)	Cylinder Tolerance (mL)	Reading Accuracy (mL)
2	10	+/- 0.075	+/- 0.01
20	100	+/- 0.75	+/- 0.1
50	250	+/- 2	+/- 0.2
100	500	+/- 3.75	+/- 0.5

Table 2 Descriptive Statistics

Administration Set Rate (mL/h)	N	Min	Max	Mean	SD	SE
2	8	7.80	7.95	7.84	.05	.01
20	8	80.0	82.0	80.66	.57	.20
50	7	204.0	207.0	205.35	.93	.35
100	8	401.0	409.0	406.37	2.38	.84

Table 3 Administration Set Rate

Administration Set Rate (mL/h)	t	df	Sig	Mean difference
2	-9.025	7	.000	-.1600
20	3.268	7	.014	.6688
50	15.178	6	.000	5.3571
100	7.555	7	.000	6.3750

FIGURES

Figure 1 Standardised four hour delivered volumes by day of measurement
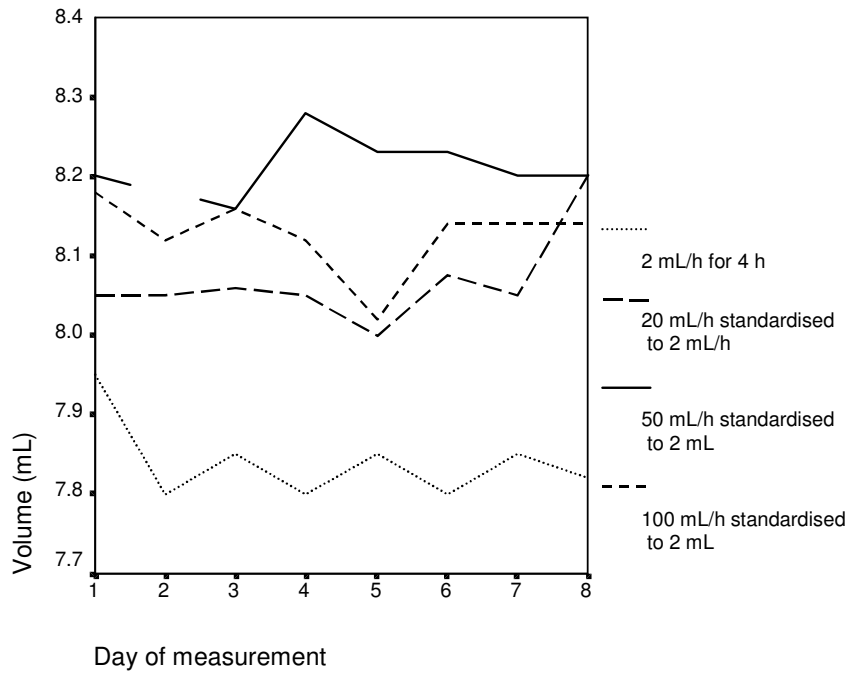

Day of measurement

Figure 2 Mean standardised delivered volumes by programmed administration set rate